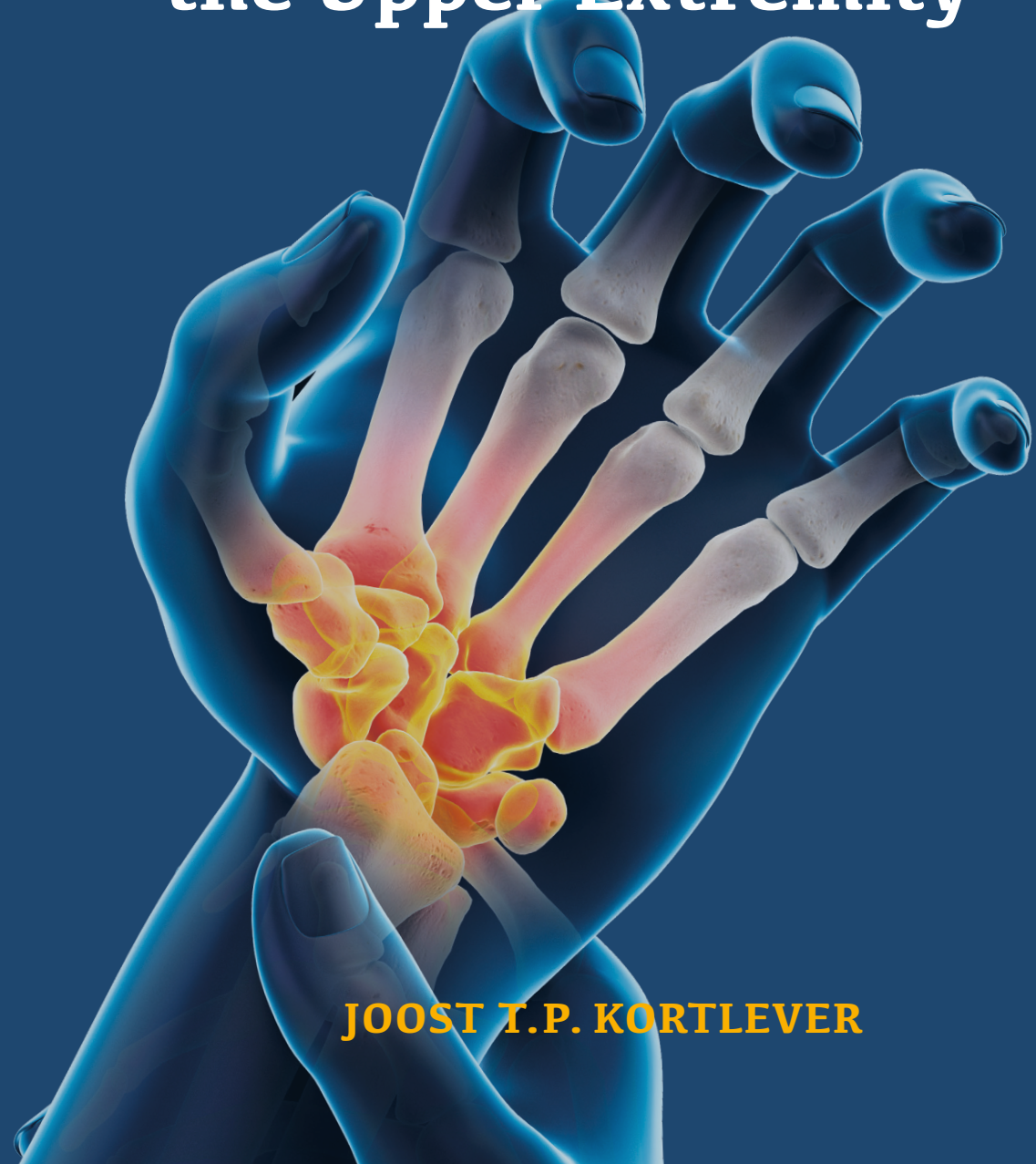
Common Idiopathic Mononeuropathies of the Upper Extremity



JOOST T.P. KORTLEVER

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The research fellowship was financially supported by:
A stipend from the Department of Surgery and Perioperative Care of the Dell Medical School at The University of Texas at Austin
Generous donations to the HornRaiser platform from The University of Texas at Austin

Printing of this thesis was financially supported by:
University Medical Center Utrecht
Stichting Orthoresearch Sint Maartenskliniek
Nederlandse Orthopaedische Vereniging
ChipSoft

ISBN 978-94-6483-702-5
DOI https://doi.org/10.33540/2093

Provided by thesis specialist Ridderprint, ridderprint.nl
Printing: Ridderprint
Layout and design: Bart Roelofs, persoonlijkproefschrift.nl

Common Idiopathic Mononeuropathies of the Upper Extremity

Veelvoorkomende Idiopathische Mononeuropathieën van de Bovenste Extremiteit
(met een samenvatting in het Nederlands)

Proefschrift

ter verkrijging van de graad van doctor aan de
Universiteit Utrecht
op gezag van de
rector magnificus, prof. dr. H.R.B.M. Kummeling,
ingevolge het besluit van het college voor promoties
in het openbaar te verdedigen op

donderdag 23 mei 2024 des middags te 2.15 uur

door

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geboren op 31 januari 1990
te Nieuwegein

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Chapter 1

General Introduction

Pathophysiology of Nerve Compression

The purpose of (peripheral) nerves is to transmit impulses.[1-3] Different nerves have different functions. Autonomic nerve fibers control vasomotor and pilomotor function and are part of the autonomic (i.e. self-regulating) nervous system.[1] The somatic (i.e. voluntary) nervous system consists of motor (efferent), sensory (afferent), and motor-sensory (mixed) nerve fibers.[1-4] Motor nerve fibers carry signals away from the spinal cord to effector organs (e.g. muscles) and sensory nerve fibers carry signals from highly specialized sensory organs located in the skin and deeper tissues towards the spinal cord.[1-4] Nerves lie embedded in protective tissues, but they can be affected by either injury[4,5] or (long-standing) compression.[1-4,6] This thesis focusses on idiopathic (i.e. a condition related to unknown cause) compression neuropathies of the upper extremity.

The most common idiopathic peripheral mononeuropathies are ascribed largely to mechanical compression (a tight anatomical space), as with idiopathic median neuropathy at the carpal tunnel (MNCT), although traction is also suggested as a possible factor with idiopathic ulnar neuropathy at the elbow (UNE).[1,2,4,6-9] The neural changes that occur depend on the duration and force of the compression.[1-4,6,9] Short term nerve compression causes local ischemia that results in a focal conduction block, which is reversible as long as the duration of compression is brief.[1-3,6,7,9,10] An ongoing pressure on a nerve leads to predictable histopathologic changes; a breakdown of the blood-nerve barrier, endoneural edema, and increased endoneural pressure; followed by localized and diffuse nerve fiber demyelination; and finally, axonal degeneration.[1-3,5,6,9,10] There is evidence that some systemic conditions (e.g. diabetes mellitus) can depress overall peripheral nerve function, which in turn might make nerves more susceptible to compression.[1,3,6] However, most mononeuropathies of the upper extremity are idiopathic and structural, and they are likely mostly genetically mediated.[6,11]

Common Mononeuropathies of the Upper Extremity

Common objectively verifiable compression mononeuropathies of the upper extremity include idiopathic MNCT, idiopathic UNE, and cervical radiculopathy.[1,2,6,12-17] Less common objectively verifiable mononeuropathies include radial sensory neuropathy (Wartenberg syndrome), anterior interosseous neuropathy (AIN), posterior interosseous neuropathy (PIN), and ulnar neuropathy at the Guyon canal.[1,2,6,15-20] Radial sensory neuropathy (the superficial radial nerve travels between the brachioradialis and extensor carpi radialis longus tendon) and AIN (tight fascia or tight arc of the flexor digitorum superficialis origin) may not be related to compression, while PIN and ulnar neuropathy at the Guyon canal are often related to mass effect from a benign tumor such as a ganglion cyst.[15-17,19,20]

Idiopathic MNCT and UNE are, by far, the most common idiopathic peripheral mononeuropathies of the upper extremity.[1,2,6,7,12-14,21-32] The symptoms and signs of these conditions are referred to as carpal and cubital tunnel syndrome (CTS and CubTS, respectively) and mainly consist of paresthesia and, when advanced, loss of sensibility and strength, and muscle atrophy.[1,2,6,7,12,16,17,26,28-30,33-36] As nerve compression and the resulting neuropathy progresses from mild to severe, symptoms will typically go from occasional intermittent paresthesia to constant loss of sensibility.[6,29,30,33,36] Pain is often described as a symptom.[8,12,26,31,32,34,36-39] But pain without paresthesia is not characteristic of neuropathy.[30,40] Confusion arises when people describe intense paresthesia as pain. This sensation is more accurately described as painful paresthesia, intense paresthesia, or dysesthesia. Idiopathic MNCT and UNE are the main focus of this thesis and are described more in the following sections.

Median Neuropathy at the Carpal Tunnel

Idiopathic MNCT is the most common mononeuropathy of the upper extremity.[1,2,7,10,12,21-23,28,30-32,36,39,41] It is characterized by compression-related neuropathy of the median nerve at the carpal tunnel, which is formed at the roof by the transverse carpal ligament (i.e. flexor retinaculum).[1,2,6,16,17,41] The ligament attaches to some of the carpal bones; the pisiform, triquetrum, and hamate on the ulnar side and to the scaphoid and trapezium on the radial side.[1,2,6,16,17,41,42] The base of the tunnel is formed by the volar radiocarpal ligaments covering the carpal bones.[1,6] Besides the median nerve, the carpal tunnel contains nine tendons (the flexor policis longus, four flexor digitorum superficialis, and four flexor digitorum profundus tendons).[1,2,6,17,41,42] In the forearm, the median nerve gives off two major branches; the anterior interosseous nerve (supplies the deep muscles in the anterior forearm) and the palmar cutaneous nerve (provides sensation to the thenar skin).[1,6,16,17,41] At or just beyond the distal edge of the transverse carpal ligament the median nerve divides into the recurrent motor nerve at the radiopalmar side (innervation of thenar musculature) and into the palmar digital branch (innervation of radial two lumbricals, palmar surface and fingertips of the first three and a half fingers.[1,2,6,16,17,41,42]

The umbrella term for the symptoms and signs characteristic of idiopathic MNCT is CTS.[28,33,39,41,43] The hallmark symptom is nocturnal and intermittent paresthesia progressing to loss of sensibility in the distribution of the median nerve (i.e. radio-palmar hand, first 3 fingers, and radial half of the ring finger).[1,2,6,8,12,30,34,36–39,41,43] Provocation of paresthesia by prolonged pressure or tapping over the median nerve at or just proximal to the carpal tunnel (Durkan's test or Tinel sign, respectively) or with prolonged wrist flexion (Phalen maneuver) can be present on physical examination.[1,2,6,7,16,30,33,34,36,38,39] When there

is advanced neuropathy, people can have loss of sensibility, loss of palmar abduction strength, and loss of thenar muscle mass.[1,2,6,7,12,30,33,39] Some discrete pathologies that can cause MNCT are synovitis or synovial thickening of the digital flexor tendons (e.g. related to rheumatoid arthritis, diabetes, or pregnancy) and trauma (acute median nerve compression from bleeding, swelling, and deformity related to perilunate dislocation and/or a fracture of the distal radius).[1–3,6,41] Associations with anatomical variations such as hypertrophic lumbrical muscles are not verified experimentally and remain speculative.

Ulnar Neuropathy at the Elbow

Idiopathic UNE is the second most common mononeuropathy of the upper extremity following idiopathic MNCT.[2,6,13,14,24–27,29,30,35] Given that people often have advanced neuropathy at the time of diagnosis, it is possible that idiopathic UNE may be accommodated and undiagnosed in a lifetime, and may be much more common.[30] Idiopathic UNE is characterized by compression of the ulnar nerve at or near the cubital tunnel.[1,2,6,15,16,26,35] The cubital tunnel is formed at the roof by the Osborne ligament; a thickened area of the aponeurosis between the two heads (humeral and ulnar) of the flexor carpi ulnaris muscle; spanning from the medial epicondyle to the olecranon, which act as the sides of the tunnel.[1,2,6,16,17] The base is formed by the medial (i.e. ulnar) collateral ligament and elbow joint capsule.[1,6,17]

The umbrella term for the symptoms and signs of idiopathic UNE is CubTS and consists of nocturnal and intermittent paresthesia progressing to loss of sensibility in the distribution of the ulnar nerve (i.e. ulnar-dorsal hand, ulnar half of the ring finger, and small finger).[1,2,6,26,29,30,35] Paresthesia in the small and ring finger can be provoked or worsened with sustained elbow flexion or pressure over the cubital tunnel.[1,2,6,29,30] Advanced neuropathy can present as loss of sensibility, loss of hand dexterity, and weakness and atrophy of the first dorsal interosseous muscle.[1,2,6,26,29,30,35] As with MNCT, some discrete pathologies that can cause UNE are local synovitis or synovial thickening and trauma.[2,6,26] (Repeated) subluxation of the ulnar nerve over the medial epicondyle (with local inflammation and irritation) and cubitus valgus are also described as causes for compression, but these are open to debate.[1,2,6] However, as with MNCT[6,41], most UNE is idiopathic.[6,26]

Comfort and Capability

The intensity of compression neuropathy symptoms varies substantially. Patient-reported outcome measurements (PROMs) and patient-reported experience measures (PREMs) are used, both in the office and in research, to quantify the subjective aspects of health and the experience of care. PROMs quantify capability (perceived ability to perform or

engage in activities), symptom intensity, and quality of life (overall sense of health and wellbeing).[6,21,28,38,43–53] PREMs quantify a patient's experience while receiving care.[38] There are many self-report questionnaires available to compare treatment strategies.

PROMs can address general health or musculoskeletal health, and they can be extremity-specific, region-specific, or condition-specific.[28,38,43–47,49–53] There is mounting evidence that PROMs of varying specificity are notably correlated.[28,44,45,49–53] There does not seem to be a single 'best' PROM or PREM and research is underway to continue to optimize methods of quantifying the subjective aspects of health and care.

Workup

There is no consensus reference standard for the diagnosis of idiopathic MNCT and UNE. Surgeons may use diagnostic tools, strategies, scales, or prediction rules (i.e. tools based on the history and physical examination) to estimate the probability of neuropathy.[6,33,39,54,55]

For people with a clinical diagnosis of CTS or CubTS, electrodiagnostic testing (EDx) could be used as a diagnostic adjunct to objectively verify neuropathy (or to adjust diagnostic probabilities depending on a person's opinion regarding the reference standard), measure its severity, or to establish a preoperative baseline.[1,2,6,7,10,12–14,21–23,25–36,39,41,43,56–61] Nerve conduction studies (NCS) and electromyography (EMG) are two broadly used EDx to evaluate the electrophysiological health of nerves. Nerve conduction studies measure motor, sensory, and mixed nerves' wave amplitude, duration, latency, and conduction velocity by placing surface electrodes over the muscle and applying an electrical stimulus proximal to the electrode and recording action potentials distally.[1,2,6,10,13,14,23,25–28,57,62] Electromyography is performed by inserting a needle electrode in a muscle belly to record abnormalities in muscle membrane depolarization at rest, with needle insertion, and with voluntary muscle contraction.[1,2,6,10,13,14,23,25,28,57,62] There is imprecision in the results of EDx due to variations in how the test is performed and interpreted.[2,6,10,13,25–29,35,56] This imprecision may be more notable at relatively mild degrees of neuropathy.[26,35,57,61]

Routine radiographic imaging is not recommended.[2] Ultrasonography can – among others – detect and measure enlargement of the median or ulnar nerve proximal to their respective 'tunnels' in MNCT and UNE.[17,35,63–67] Dynamic ultrasonography can be used to show decreased mobility patterns of the median nerve during finger and wrist motion in patients with MNCT.[63-67] Though, as with EDx, the role of ultrasound and its diagnostic accuracy is open to debate.[17,60,67,68]

Grading the (EDx) severity of peripheral mononeuropathies is variable and somewhat subjective.[2,7,10,28,30,56] In general, gradients of severity are reported as; mild (evidence of sensory conduction slowing, but normal sensory amplitudes and normal motor respons-

es), moderate (evidence of sensory axonal loss and/or motor conduction slowing), or severe (evidence of motor axonal loss).[2,7,10,12,28,30–32,34,56]

A survey-based study including 108 surgeons found that clinical severity grading is based on palmar abduction weakness, longer duration of symptom episodes, nocturnal numbness in spite of splint immobilization, constant numbness, positive Tinel and Phalen test results, and older age.[33] Patient comfort and capability does not seem to influence the severity grading.[28,33]

Treatment

The natural history of idiopathic MNCT and UNE is not completely understood but seems to be slow progression to irreversible nerve damage. Surgery seems to be the only treatment that can alter this natural history (disease-modifying treatment). All other treatments may be for alleviation of symptoms alone (palliative). Splints can help people sleep by limiting positioning that elicits paresthesia.[1,2,6–8,12,21,31,32,37,41,69] Non-steroidal anti-inflammatory drugs (NSAIDs), optimizing the management of systemic conditions (e.g. diabetes mellitus), and oral steroids are all suggested as palliative treatment options.[1,2,6,7,12,21,31,32,37,41,43] Some may think corticosteroid injections can be disease modifying, however, there is limited supporting experimental data demonstrating they are better than simulated treatment and they seem palliative or give temporary symptom relieve at best.[1,2,6,7,12,31,32,37,41,43,69] Another practice open to debate is the use of symptom palliation after corticosteroid injections to determine who to offer surgery.

An important area of debate is the offer of surgery to patients who have symptoms thought to be consistent with idiopathic MNCT or UNE (i.e. CTS or CubTS), but no or very mild neuropathy on EDx.[7,33] To understand the root of this debate, it is important to distinguish between pathophysiology from illness (discomfort and incapability).[21,33,34] On the one hand there are physicians who believe patients can benefit from surgery when there is little or no measurable neuropathy but have notable symptoms and incapability. They might offer surgery in an attempt to alleviate these symptoms with less regard for objective verification of pathophysiology. This approach seems problematic given that the intensity of the comfort and incapability corresponds with mindset factors rather than the severity of pathophysiology.[33] A focus on symptoms seems to risk misdiagnosis and undertreatment or mistreatment of unhelpful thinking and feelings of worry or despair. A recent study suggests that most surgeons are not influenced by symptom intensity and magnitude of incapability when reviewing hypothetical cases of patients with signs and symptoms that could relate to MNCT, suggesting that this perspective may be over-represented in academic discourse.[33] From the perspective of physicians who focus their

treatment strategies on pathophysiology rather than symptoms, symptoms and signs are used to assess the probability of pathophysiology that can benefit from treatment, and disproportionate symptoms and incapability indicate likely unhelpful thoughts and feelings of distress. [33] These physicians believe that mild or unmeasurably mild neuropathy is typically accommodated and best treated nonoperatively.

While some people accommodate loss of median nerve function, most patients with idiopathic MNCT or UNE choose surgery to relieve symptoms and maintain sensibility. Surgery is indicated in patients who have symptoms typical of idiopathic MNCT or UNE progressing from moderate to severe including consistent night paresthesia in spite of brace wear or prolonged paresthesia.[7,29] Surgery is also offered to people with severe neuropathy although recovery of nerve function occurs over a period of 2-3 years and is often incomplete.[2,6,30]

Carpal tunnel release (CTR) can be done using an open or endoscopic approach based on surgeon and patient preference with the goal of a complete release of the transverse carpal ligament under direct visualization of the median nerve.[1,2,6,7] For release of the cubital tunnel (CubTR), there is no single procedure universally accepted although simple in situ release is now commonplace.[2,6,29,70] In general, CubTR involves decompression with or without ulnar nerve transposition.[1,2,6,29,70,71]

Depending on the preoperative neuropathy severity, loss of sensibility, atrophy, and weakness of palmar abduction can persist for months to years or can even be permanent.[2,6,30,72] It is debated if idiopathic MNCT and UNE can return or worsen after surgical release without another pathology such as rheumatoid arthritis being present. It is not clear that incomplete surgical release can be reliably diagnosed[6,7] and people often misinterpret persistent symptoms as recurrent symptoms. Because most apparent recurrences may be a misinterpretation of persistent symptoms, caution is warranted. If progressive neuropathy is documented objectively after a complete surgical release, surgeons should look for another discrete pathology such as rheumatoid arthritis[6,7], or possible compression more proximally (e.g. AIN).[15,16]

Outline of Chapters

Part I – Patient-Reported Outcome Measures

There are numerous PROMs that quantify comfort and capability (i.e. subjective aspects of health). For patients with an upper extremity nerve-related diagnosis, it has yet to be determined if one measure outperforms another in terms of correlation with pathology,

responsiveness, or recovery. As a first step, **Chapter 2** compares a relatively new PROM developed to quantify capability in patients with either idiopathic or traumatic peripheral nerve problems of the upper extremity (Impact of Hand Nerve Disorders; I-HaND) to other upper extremity musculoskeletal PROMs (Patient-Reported Outcomes Measurement Information System Physical Function Upper Extremity; PROMIS-PF-UE and the short form of Disabilities of the Arm, Shoulder and Hand; QuickDASH), pain intensity, and quality of life in patients with any upper extremity nerve-related diagnosis. **Chapter 3** focuses on patients with either CTS and/or CubTS and compares the upper extremity nerve-related I-HaND to condition-specific PROMs (Boston Carpal Tunnel Syndrome Questionnaire; BCTQ and Patient-Rated Ulnar Nerve Evaluation; PRUNE) and an upper extremity-specific PROM (PROMIS PF-UE). Comparisons are done using correlation testing, instrument properties (items needed to complete, completion time, and floor and ceiling effect), and finally by testing demographic and mental health factors independently associated with each outcome.

Part II – Electrodiagnosis

While idiopathic MNCT and UNE are the most common peripheral mononeuropathies of the upper extremity, there is no reference standard for their diagnosis. Electrodiagnostic tests are seen as the gold standard to determine nerve pathophysiology. Though, EDx results can be equivocal, especially in patients with no to mild pathology. **Chapter 4** retrospectively reviewed a large sample of EDx results of patients with a clinical diagnosis of CTS and analyzed EDx measurements around the borderline of threshold values with respect to concordance between the clinical diagnosis and final EDx results. **Chapter 5** aims to determine if symptoms and signs of patients with a clinical diagnosis of CubTS are due to measurable UNE, another neuropathy, or whether there is no measurable neuropathology. Both chapters identify biopsychosocial factors independently associated with electrodiagnosis of idiopathic MNCT and UNE, respectively.

Part III – Shared Decision-Making

Debate exists for various conditions about which diagnostic and treatment steps to take. For instance, in patients with CTS, the role of EDx, corticosteroid injections, and surgery (CTR) in case of mild median neuropathy are all debated. Diagnostic and treatment choices are best based on the strategy consistent with both best evidence and what matters most to a patient (their values), a process often referred to as shared decision-making (SDM). **Chapter 6** assesses patient preferences regarding SDM using a general SDM scale and a scale divided in preoperative, operative, and postoperative aspects of treat-

ment for patients with clinical CTS. **Chapter 7** uses a hypothetical scenario of mild CTS – in both patients with clinical CTS and in patients with another diagnosis – and highlights patient attitudes towards health care costs and tests whether patients are equally likely to choose surgery when provided with total societal cost information versus those who do not receive this information. We studied this in more detail in **Chapter 8**, where we employed qualitative content analysis to evaluate patients' rationale for their treatment choice, identifying themes such as financial obligations and risk-benefit profiles of treatment.

Part IV – Treatment

The evidence suggests that the natural history of idiopathic MNCT and UNE is progressive, resulting in permanent nerve damage. Surgery may be the only pathophysiology-altering treatment with nonoperative treatments like splinting and corticosteroid injections perhaps palliative (symptom alleviating) at best. **Chapter 9** calculates the rate of corticosteroid injections given at new patient visits for patients with a new clinical diagnosis of CTS or CubTS, including potential reduction in costs by omitting these injections, and determines which patient factors are associated with receiving a corticosteroid injection.

Since there are often various treatment choices for a certain condition, health choices should be based on patients' values. Decision aids can help inform patients and correct misconceptions so they can choose the treatment option consistent with their values. **Chapter 10** is a randomized controlled trial (RCT) where patients either reviewed or did not review a decision aid about their condition, including patients with clinical CTS. Differences in treatment choice and decision regret are tested longitudinally between these two groups.

This thesis is concluded by a general discussion including conclusions and future perspectives for idiopathic mononeuropathies of the upper extremity (**Chapter 11**) and summary (**Chapters 12 & 13**).

Primary Study Questions

Part I – Patient-Reported Outcome Measures

What questionnaire – comparing nerve-specific, condition-specific, and upper extremity-specific PROMs – is most useful for measurement of comfort and capability in patients with idiopathic mononeuropathy of the upper extremity?

What factors are independently associated with comfort and capability in patients with idiopathic mononeuropathy of the upper extremity?

Part II – Electrodiagnosis

What is the concordance between the clinical diagnosis of carpal tunnel syndrome and the electrodiagnostic test results indicating idiopathic median neuropathy at the carpal tunnel, especially discriminating between no and mild neuropathology?

What is the percentage of patients with a clinical diagnosis of cubital tunnel syndrome that have electrodiagnostic test results consistent with idiopathic ulnar neuropathy at the elbow, other neuropathology, and no detectable neuropathology?

What factors are independently associated with an electrodiagnosis of idiopathic median neuropathy at the carpal tunnel or ulnar neuropathy at the elbow?

Part III – Shared Decision-Making

What do patients with a clinical diagnosis of idiopathic carpal tunnel syndrome and/or electrodiagnostically confirmed median neuropathy at the carpal tunnel prefer regarding shared decision-making for various aspects of the treatment plan?

Does exposure to societal cost information alter the probability of choosing the more expensive treatment option (i.e. carpal tunnel release over splinting), comparing patients with a clinical diagnosis to patients with a hypothetical diagnosis of mild carpal tunnel syndrome?

What factors are independently associated with the treatment decision-making process in patients with idiopathic median neuropathy at the carpal tunnel?

Primary Study Questions. *Continued.*

Part IV – Treatment

What is the rate of radiographs ordered and corticosteroid injections given at a new patient visit for patients with a new diagnosis of clinical carpal tunnel syndrome or cubital tunnel syndrome?

Is there a difference in decision regret, treatment choice, and satisfaction with the visit between patients who reviewed a decision aid and those who did not?

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Part I Patient-Reported Outcome Measures

Chapter 2

Correlation of the I-HaND Scale with Other Musculoskeletal Patient-Reported Outcome Measurement Scores

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Journal of Hand and Microsurgery
2021 Aug;15(3):175-180

Abstract

Background

Experiments can determine if nerve-specific patient-reported outcome measures (PROMs) can outperform regional or condition-specific PROMs. We compared a nerve-specific PROM of the upper extremity, the Impact of Hand Nerve Disorders (I-HaND) scale, to other validated measures quantifying activity intolerance and sought to assess interquestionnaire correlations and factors independently associated with activity intolerance and pain intensity.

Methods

One hundred and thirty patients with any upper extremity nerve-related condition completed measures of demographics, psychological limitations, quality of life, activity intolerance, and pain intensity. To quantify activity intolerance, we used the I-HaND, Patient-Reported Outcomes Measurement Information System Physical Function Upper Extremity, and Disabilities of the Arm, Shoulder and Hand short form.

Results

Strong interquestionnaire correlations were found between the activity intolerance measures (*r* between 0.70 and 0.91). Multivariable analysis revealed that greater activity intolerance and greater pain intensity correlated most with greater symptoms of depression on all scales, with symptoms of depression accounting for 53 to 84% of the variability in the PROMs.

Conclusion

There is no clear advantage of the nerve-specific I-HaND over shorter, regional PROMs, perhaps because they are all so closely tied to mental health. Unless an advantage relating to responsiveness to treatment is demonstrated, we support using a brief arm-specific PROM for all upper extremity conditions.

Introduction

Nerve-specific patient-reported outcome measures (PROMs) were developed on the assumption that they would discern small improvements in symptoms and activity tolerance after treatment of peripheral nerve lesions better (i.e., they would be more responsive) than regional PROMs (e.g., Michigan Hand Outcome Questionnaire,[1] Disabilities of the Arm, Shoulder and Hand [DASH/QuickDASH],[2,3] or Patient-Reported Outcomes Measurement Information System [PROMIS] Physical Function Upper Extremity [PF-UE][4]). Experiments can determine if nerve-specific PROMs can outperform regional or condition-specific PROMs (e.g., the Boston Carpal Tunnel Questionnaire[5]) in terms of correlation with pathology, responsiveness to treatment, or recovery.

The Impact of Hand Nerve Disorders (I-HaND) scale is a PROM developed to quantify symptom intensity and activity intolerance for both idiopathic/compression and traumatic peripheral nerve disorders of the upper extremity.[6] The originators' preliminary validation study including 82 patients with an upper extremity nerve problem confirmed content and construct validity, high internal consistency (α 0.98), and showed that it can detect change over a 3-month period.[6]

To further evaluate the use of I-HaND, we completed a prospective study and compared the scale to other validated measures of upper extremity-specific activity intolerance. Specifically, in this study we assessed interquestionnaire correlations between the I-HaND and other upper extremity musculoskeletal PROMs (PROMIS PF-UE and QuickDASH), pain intensity, and quality of life (using EuroQol's 5-domain and 3-level [EQ-5D-3L] health state index score and their single question health score using a 0 to 100 Visual Analogue Scale [VAS]). Furthermore, we assessed factors (patient, clinical, and psychological) independently associated with activity tolerance and pain intensity.

Materials and methods

Study design

After institutional review board approval, we prospectively enrolled 140 adult patients over an 8-month period. We included all English-speaking, new or return patients with any upper extremity nerve condition (i.e., idiopathic/com- pression or traumatic nerve laceration) whom presented themselves to one of four participating orthopaedic offices in a large urban area. We excluded patients for which the primary diagnosis was not nerve-related (e.g., carpal tunnel syndrome [CTS] associated with fracture of the distal radius). After being diagnosed by the surgeon, patients were asked to participate in this

study by research assistants who were not involved with patient care. They then completed a set of questionnaires on a tablet in a private room. Completion of the surveys implied informed consent.

These data set are from a multistudy longitudinal cohort. This study makes use of cross-sectional data at enrollment of people with any nerve problem to address correlation among various PROMs. Patients from this study that have CTS or cubital tunnel syndrome (CubTS) will be included in another cross-sectional study examining correlation with various nerve specific PROMs.

Measures

After the visit, the treating surgeon entered the cause for the condition (idiopathic/compression or traumatic), the diagnosis, laterality, if electrodiagnostic studies were present, severity (based on electrodiagnostic study results, or if not present, per surgeon assessment), and finally if there was CTS or CubTS-related atrophy or static numbness. Patients were then asked to complete a set of questionnaires in the following order: demographics (including age, sex, marital status, level of education, insurance, type of visit [nonoperative or postoperative], and perceived symptom duration), the Pain Self-Efficacy Questionnaire short form (PSEQ-2), Tampa Scale for Kinesiophobia short form (TSK-4), Patient Health Questionnaire short form (PHQ-2), EQ-5D-3L index and VAS measures, I-HaND, PROMIS PF-UE 7-item short form, QuickDASH, and pain intensity. The survey took 10 to 15 minutes to complete.

The two-item PSEQ measures ability to achieve goals and stick to one's routine in spite of pain.[7] The items are scored on a 7-point ordinal scale (scores 0–6), the final score is the sum of both items, and higher scores indicate greater self-efficacy.[7]

The four-item TSK measures fear of painful movement.[8] The items are scored on a 4-point Likert scale and the final score is the sum of all items (score 4–16), with higher scores indicating more fear of movement.[8]

To screen for symptoms of depression we used the PHQ-2.[9] This is a two-item tool inquiring about the presence of depressed mood and anhedonia in the past 2 weeks. It uses a subset of the earlier created PHQ-9, which used nine items to screen for depression and depression severity.[10] The two items of the short form are scored on a 4-point Likert scale, with a total score being the sum of both items (score 0–6) and with higher scores indicating more symptoms of depression. A PHQ-2 score of 3 or more is set as the ideal cutoff point for screening purposes.[9]

Quality of life was assessed using the EQ-5D-3L, a standardized and non-disease-specific instrument to describe various health states.[11] It consists of five domains

(mobility, self-care, activities, pain/discomfort, and anxiety/depression) all rated on three levels (0 "no problems," 1 "some problems," and 2 "extreme problems").[11] The five final digits indicate a health state.[12] When validated, this health state can then be transformed into a country specific index score, like for the United States.[13,14] The index is ranged from –0.33 to 1.0, with a higher score indicating a better quality of life. The second part of the EQ-5D-3L is a self-perceived overall health score using a VAS with a score from 0 to 100 and a higher score indicating better overall health.[12]

The first measurement we used to assess physical limitations was the I-HaND, a measure for both traumatic and compression upper extremity nerve conditions.[6] It consists of 32 items, each scored on a 5-point Likert scale. The average raw score of all answered items is transformed into a score from 0 to 100, with a higher score indicating more physical limitations.[6]

We then used the PROMIS PF-UE 7-item short form.[4] The regular PROMIS PF-UE was recently updated from a 15- to a 46-item computerized adaptive test (CAT) and a subset of 7 items showed a good fit to use as a short form.[4] Each item is scored on a 5-point Likert scale and the raw sum is then transformed into a T-score ranging from 16.3 to 58.2, with a higher score indicating less physical limitations.[4,15]

The original DASH, which provides an outcome score for patients with upper extremity conditions,[3] was abbreviated into an 11-item measure with congruent findings as the full scale.[2] Similar to the I-HaND, the QuickDASH's average raw score is transformed into a 0 to 100 score, with a higher score indicating more physical limitations.[2]

Finally, a single question measure of pain intensity was asked using an 11-point ordinal scale, with 0 being "no pain at all" and 10 the "worst pain possible."

Study population

After enrollments were completed, 2 (1.4%) patients were excluded because of a diagnosis that was determined to be non-nerve related (1 sprained wrist and 1 scaphoid fracture) and 8 were left out of the final analysis because they stopped filling out the survey at a very early stage with no usable information. The remaining 130 patients analyzed had a mean age of 54 ± 15 years old and most were women (n = 79; 61%; Table 1). There was a relatively even spread in perceived symptom duration which we analyzed as brief (≤ 3 months), moderate (3 months to ≤ 1 year), and prolonged (> 1 year). Most patients had CTS (n = 106; 82%), 7 (5.4%) had a trauma-related nerve problem, and 8 (6.2%) had both CTS and CubTS at presentation (Table 2). Diagnoses for a traumatic condition were: 5 digital nerve lacerations, 1 ulnar nerve laceration, and 1 blunt trauma to the ulnar nerve.

Table 1. Patient Characteristics

Variable	n = 130
Age, y	54 ± 15 (23-81)
Men	51 (39)
Marital status	
Married/unmarried couple	82 (63)
Other	48 (37)
Level of education	
High school or less	48 (37)
2-year college	25 (19)
4-year college	36 (28)
Post-college graduate degree	21 (16)
Insurance	
Private	91 (70)
Other	39 (30)
Visit	
Nonoperative visit	105 (81)
Postoperative visit	25 (19)
Symptom duration	
≤3 months	34 (26)
3 months to ≤1 year	43 (33)
>1 year	53 (41)
PSEQ-2 *(n = 4 missing)*	10 (7-12)
TSK-4 *(n = 4 missing)*	9 (6-11)
PHQ-2 *(n = 4 missing)*	0 (0-2)
EQ-5D-3L index *(n = 3 missing)*	0.80 (0.69-0.83)
EQ-5D-3L VAS *(n = 3 missing)*	72 ± 17 (9-100)
I-HaND	37 ± 20 (0-94)
PROMIS PF-UE-7 *(n = 1 missing)*	41 ± 10 (19-58)
QuickDASH-11 *(n = 2 missing)*	38 ± 23 (0-98)
Pain intensity *(n = 2 missing)*	4.5 ± 2.7 (0-10)

Continuous variables as mean ± SD (range) or as median (IQR; interquartile range); Discrete variables as number (percentage); PSEQ-2: Pain Self-Efficacy Questionnaire short form; TSK-4: Tampa Scale for Kinesiophobia short form; PHQ-2: Patient Health Questionnaire short form; EQ-5D-3L: EuroQol's 5-domains and 3-level questionnaire; I-HaND: Impact of Hand Nerve Disorders; PROMIS PF-UE-7: Patient-Reported Outcomes Measurement Information System Upper Extremity questionnaire short form; QuickDASH: Disabilities of the Arm, Shoulder and Hand short form.

Table 2. Clinical Characteristics

Variable	n = 130
Cause	
Idiopathic/compression	123 (95)
Traumatic	7 (5.4)
Diagnoses[a]	
Carpal tunnel syndrome	106 (82)
Cubital tunnel syndrome	24 (18)
Traumatic nerve problem	7 (5.4)
Possible parsonage turner	1 (0.77)
Carpal tunnel syndrome; n = 106	
Bilateral	67 (63)
Electrodiagnostic studies present	59 (56)
Severity	
Mild	17 (16)
Moderate	62 (58)
Severe	27 (25)
Related atrophy	11 (10)
Related static numbness	73 (69)
Cubital tunnel syndrome; n = 24	
Bilateral	8 (33)
Electrodiagnostic studies present	11 (46)
Severity	
Mild	6 (25)
Moderate	10 (42)
Severe	8 (33)
Related atrophy	8 (33)
Related static numbness	22 (92)

Discrete variables as number (percentage); [a]Multiple diagnoses possible per patient.

Statistical analysis

The distributions of continuous variables were assessed using histogram plots. Continuous variables are presented as mean with standard deviation or as median (interquartile range) and discrete data as proportions. We used Pearson's and Spearman's correlation tests for the relationships between continuous variables (e.g., correlation between age and PROM scores) with Bonferroni corrections where appropriate, one-way analysis of

variance tests for differences in mean scores among categorical variables (e.g., difference in PROM scores between patients with either mild, moderate, or severe symptoms/pathology), and Student's *t* tests to assess differences in mean scores among dichotomous variables (e.g., difference in PROM scores between men and women). Missing data was believed to be missing at random and was present for some of the dependent outcomes for 1 to 4 patients only and therefore a complete-case analysis was used for our bivariate and multivariable statistics. We created four multivariable linear regression models to assess factors independently associated with each of the dependent variables (i.e., I-HaND, PROMIS PF-UE-7, QuickDASH, and pain intensity). We included all variables with $P < 0.10$ on bivariate analysis in the final models (Appendix 1). The regression coefficient (β) indicates the change in the value of a dependent variable corresponding to the unit change in the independent variable. We interpreted correlation effects as negligible for a correlation of 0.0 to 0.10, weak for 0.10 to 0.39, moderate for 0.40 to 0.69, strong for 0.70 to 0.89, and very strong for 0.90 to 1.0.[16] Adjusted R-squared (R^2) values indicate the amount of variability explained in the dependent variable that the model accounts for. Semipartial R^2 expresses the specific variability of a given independent variable. We considered $P < 0.05$ significant.

Since multivariable analysis yields more participants than correlation testing, we powered on our secondary hypothesis. An a priori power calculation indicated that a sample of 129 subjects would provide 80% statistical power, with α set at 0.05, for a regression with five predictors if one of the predictor variables would account for 5% or more of the variability in disability, and our complete model would account for 20% of the overall variability. We aimed to enroll 140 patients to account for 5 to 10% incomplete or incorrect data.

Results

Interquestionnaire correlations

The I-HaND had a strong, inverse correlation (r –0.70; $P < 0.001$) with PROMIS PF-UE-7 and a very strong correlation with QuickDASH (r 0.91; $P < 0.001$; Table 3). Moderate correlations were found between the I-HaND and pain intensity, EQ-5D-3L index, and EQ 5D-3L VAS (Table 3).

Table 3. Interquestionnaire Correlations*

Variable	I-HaND	PROMIS PF-UE-7	QuickDASH-11	Pain intensity	EQ-5D-3L index	EQ-5D-3L VAS
I-HaND (*r*)	-					
PROMIS PF-UE-7 (*r*)	-0.70; ***P* <0.001**	-				
QuickDASH-11 (*r*)	0.91; ***P* <0.001**	-0.76; ***P* <0.001**	-			
Pain intensity (*r*)	0.68; ***P* <0.001**	-0.49; ***P* <0.001**	0.70; ***P* <0.001**	-		
EQ-5D-3L index (*ρ*)	-0.64; ***P* <0.001**	0.60; ***P* <0.001**	-0.73; ***P* <0.001**	-0.58; ***P* <0.001**	-	
EQ-5D-3L VAS (*r*)	-0.40; ***P* <0.001**	0.36; ***P* <0.001**	-0.40; ***P* <0.001**	-0.41; ***P* <0.001**	0.44; ***P* <0.001**	-

*Bold indicates statistically significant difference; Multiple comparisons using Bonferroni corrections; Pearson and Spearman correlation indicated by *r* and *ρ*; I-HaND: Impact of Hand Nerve Disorders; PROMIS PF-UE-7: Patient-Reported Outcomes Measurement Information System Upper Extremity questionnaire short form; QuickDASH: Disabilities of the Arm, Shoulder and Hand short form; EQ-5D-3L: EuroQol's 5-domains and 3-level questionnaire.

Factors Associated with I-HaND, PROMIS PF-UE-7, QuickDASH, and Pain Intensity

After controlling for confounding variables (i.e., age, sex, type of visit, mental health, and idiopathic vs. traumatic nerve problem) using multivariable analysis greater activity intolerance (on all PROMs) and greater pain intensity correlated with greater symptoms of depression on all scales (Table 4). The PHQ-2 accounted for the greatest amount of variability in each model.

Additionally, men had less and patients with a traumatic nerve problem had more physical limitations looking at PROMIS PF-UE-7 (regression coefficient [β] 4.2; 95% confidence interval [CI] 0.75–7.6; P = 0.02; β –8.2; 95% CI –16 to –0.87; P = 0.03, respectively; Table 4). Patients presenting at their postoperative visit independently experienced less pain than patients at their first or preoperative visit (β –1.5; 95% CI –2.6 to –0.38; P = 0.01).

Discussion

In this study we compared a nerve-specific PROM, the I-HaND, to other upper extremity-specific musculoskeletal PROMs, and measures of pain intensity and quality of life. We found strong interquestionnaire correlations and similar patient and psychosocial influences that accounted for the variability in scores, indicating that the I-HaND provides no clear advantage over region-specific PROMs.

This study has some limitations. First, the I-HaND was created to assess activity intolerance in patients with either idiopathic/compression neuropathy or a traumatic nerve condition.[6] The vast majority of our subjects had a compression neuropathy – and most of them had CTS – which limited the diversity of our cohort. However, our distribution was typical of hand surgery practice and therefore a good setting for testing the relative performance of the measure. Second, not every patient was sent for electrodiagnostic testing so the diagnoses were based on symptoms and signs. When no electrodiagnostic studies were present, the surgeon also indicated the severity of either CTS or CubTS. In addition to this, static numbness in CTS or CubTS is an indication for severe and possible permanent pathology.[17,18] Not all patients with static numbness were categorized severe (e.g., of the 79 patients with CTS and static numbness, 3 were rated mild, 44 moderate, and 26 severe). This might be a result of variations in surgeon interpretation of this as a symptom and others investigating it as a sign. It is also possible that some surgeons rated “severe” based on symptom intensity and activity intolerance rather than neuropathology.

Table 4. Multivariable Regression Analyses of Factors Associated with Patient-Reported Outcome Scores*

Dependent variable	Retained variable	Regression coefficient [β] (95% Confidence interval)	Standard error	*P* value	Semipartial R^2	Adjusted R^2
I-HaND	Men	-4.9 (-11 to 1.4)	3.2	0.13		0.25
	Postoperative visit	-6.0 (-14 to 1.9)	4.0	0.13		
	PHQ-2	6.1 (4.1 to 8.1)	1.0	**<0.001**	0.21	
PROMIS PF-UE-7	Men	4.2 (0.75 to 7.6)	1.7	**0.02**	0.04	0.15
	PHQ-2	-1.9 (-3.0 to -0.84)	0.55	**0.001**	0.08	
	Traumatic nerve problem	-8.2 (-16 to -0.87)	3.7	**0.03**	0.03	
QuickDASH-11	Men	-6.4 (-14 to 0.92)	3.8	0.09		0.23
	PHQ-2	6.6 (4.3 to 9.0)	1.2	**<0.001**	0.19	
	Traumatic nerve problem	15 (-1.2 to 30)	8.0	0.07		
Pain intensity	Age, y	0.002 (-0.03 to 0.03)	0.02	0.92		0.19
	Postoperative visit	-1.5 (-2.6 to -0.38)	0.57	**0.01**	0.05	
	PHQ-2	0.62 (0.33 to 0.91)	0.15	**<0.001**	0.12	
	Traumatic nerve problem	1.6 (-0.39 to 3.6)	1.0	0.11		

*Bold indicates statistically significant difference; Only the semipartial R^2 of significant variables displayed; All variance inflation factors <10 (highest 1.2); PHQ-2: Patient Health Questionnaire short form; I-HaND: Impact of Hand Nerve Disorders; PROMIS PF-UE-7: Patient-Reported Outcomes Measurement Information System Upper Extremity questionnaire short form; QuickDASH: Disabilities of the Arm, Shoulder and Hand short form.

In other words, people with well-adapted static numbness might not be rated as severe. Third, most of the evidence using PROMIS scales use a CAT, for logistical reasons we used the short form. The PROMIS PF-UE-7 is comparable to the CAT version[4] and therefore interpretations using the CAT are reasonable. Finally, we assessed three measures of psychological limitations (PSEQ-2, TSK-4, and PHQ-2) but we only used PHQ-2 in the multivariable models, because of signs of collinearity. A priori, all three tools measure related aspects of mental health and in bivariate analysis they had strong interquestionnaire correlations. We chose to use PHQ-2 over the others, because PSEQ-2 uses general questions more characteristic of a PROM and TSK-4 measures fear of movement very specifically, making the PHQ-2 the most inclusive psychological measure. The strong interquestionnaire correlations between arm-specific and nerve-specific PROMs suggest there may be limited advantage to disease or tissue-specific PROMs. The originators of the I-HaND completed a longitudinal validation study, including 82 patients in the United Kingdom with a range of hand nerve disorders and found a strong (*r* 0.87) correlation with QuickDASH.[6] These remarkably strong correlations alone argue against any benefit for a nerve-specific PROM.

The observation that symptoms of depression influence all measures of activity intolerance and pain intensity suggests that the strong correlation between PROMs could reflect the relative influence of mental and social health compared with pathophysiology on symptom intensity and activity intolerance. A study of 1,299 hand and upper extremity patients found that patients with more symptoms of anxiety and pain interference – along with a retired or unemployed work status – had more activity intolerance on PROMIS PF CAT, PROMIS PF UE CAT, and QuickDASH (adjusted R^2 between 0.45 and 0.61).[19] A systematic review of 41 studies found that psychological and social factors are the factors most consistently associated with activity intolerance after upper extremity injury in adults.[20] The main contributing factors were symptoms of depression, anxiety, and cognitive biases about pain such as catastrophic thinking. Measures of pathology and impairment such as range of motion and injury severity contributed relatively little to the variation in PROMs.[20]

We confirmed that the 32-item, nerve-specific, I-HaND has strong correlations with shorter regional PROMs. Unless a clear advantage can be demonstrated in terms of responsiveness to treatment, we support the principle of using a brief arm-specific PROM for all arm conditions. There are benefits to the simplicity, brevity, familiarity, and consistency with no apparent limitations compared with disease or tissue-specific PROMs.

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Appendix 1. Bivariate Analyses of Factors Associated with Patient-Reported Outcome Scores*

Variable; n = 130	I-HaND	*P* value	PROMIS PF-UE-7	*P* value	QuickDASH-11	*P* value	Pain intensity	*P* value
Age, y (*r*)	-0.10	0.25	0.02	0.82	-0.11	0.22	-0.16	0.08
Sex								
Women	40 ± 19	0.09	39 ± 9.8	**0.02**	41 ± 24	0.07	4.7 ± 2.9	0.31
Men	34 ± 20		43 ± 11		33 ± 21		4.2 ± 2.4	
Marital status								
Married/unmarried couple	38 ± 20	0.72	41 ± 10	0.60	39 ± 23	0.52	4.6 ± 2.6	0.59
Other	36 ± 20		40 ± 10		36 ± 23		4.3 ± 2.9	
Level of education								
High school or less	39 ± 20	0.79	40 ± 10	0.88	39 ± 23	0.92	4.7 ± 3.0	0.59
2-year college	36 ± 17		42 ± 10		35 ± 20		4.8 ± 2.6	
4-year college	38 ± 21		41 ± 9.9		38 ± 23		4.1 ± 2.6	
Post-college graduate degree	34 ± 22		40 ± 12		39 ± 27		4.1 ± 2.6	
Insurance								
Private	37 ± 19	0.86	41 ± 9.8	1.0	37 ± 22	0.78	4.5 ± 2.4	0.91
Other	37 ± 22		41 ± 12		39 ± 27		4.4 ± 3.4	
Visit								
Nonoperative visit	39 ± 20	0.10	41 ± 10	0.77	39 ± 23	0.17	4.8 ± 2.7	**0.003**
Postoperative visit	31 ± 21		40 ± 11		32 ± 24		3.0 ± 2.6	

Appendix 1. *Continued.*

Variable; n = 130	I-HaND	*P* value	PROMIS PF-UE-7	*P* value	QuickDASH-11	*P* value	Pain intensity	*P* value
Symptom duration								
≤3 months	39 ± 24		39 ± 11		42 ± 26		4.9 ± 2.3	
3 months to ≤1 year	35 ± 19	0.63	40 ± 8.8	0.52	33 ± 22	0.25	4.0 ± 2.8	0.37
>1 year	38 ± 18		42 ± 11		39 ± 22		4.5 ± 2.9	
PSEQ-2 (*ρ*)	-0.47	**<0.001**	0.47	**<0.001**	-0.56	**<0.001**	-0.49	**<0.001**
TSK-4 (*ρ*)	0.42	**<0.001**	-0.28	**0.002**	0.40	**<0.001**	0.35	**<0.001**
PHQ-2 (*ρ*)	0.43	**<0.001**	-0.32	**<0.001**	0.44	**<0.001**	0.33	**<0.001**
Diagnoses								
No carpal tunnel syndrome	36 ± 22	0.71	40 ± 12	0.91	40 ± 25	0.58	4.8 ± 2.2	0.57
Carpal tunnel syndrome	38 ± 20		41 ± 10		37 ± 23		4.4 ± 2.8	
No cubital tunnel syndrome	38 ± 19	0.67	40 ± 10	0.62	38 ± 23	0.99	4.4 ± 2.8	0.68
Cubital tunnel syndrome	36 ± 23		42 ± 11		38 ± 25		4.7 ± 2.6	
No traumatic nerve problem	37 ± 20	0.24	41 ± 10	**0.02**	37 ± 23	**0.04**	4.4 ± 2.7	0.07
Traumatic nerve problem	46 ± 27		32 ± 7.2		56 ± 22		6.3 ± 1.7	
Carpal tunnel syndrome; n = 106								
Unilateral	39 ± 23	0.58	39 ± 11	0.30	40 ± 26	0.43	4.5 ± 2.8	0.74
Bilateral	37 ± 18		41 ± 9.5		36 ± 21		4.3 ± 2.9	

Appendix 1. *Continued.*

Variable; n = 130	I-HaND	*P* value	PROMIS PF-UE-7	*P* value	QuickDASH-11	*P* value	Pain intensity	*P* value
Electrodiagnostic studies not present	37 ± 18	0.82	41 ± 10	0.46	37 ± 22	0.91	4.7 ± 2.7	0.37
Electrodiagnostic studies present	38 ± 21		40 ± 10		38 ± 24		4.2 ± 2.9	
Severity								
Mild	40 ± 24		40 ± 13		39 ± 28		4.9 ± 2.5	
Moderate	37 ± 17	0.89	40 ± 8.8	0.91	38 ± 21	0.82	4.6 ± 2.6	0.17
Severe	37 ± 22		41 ± 11		35 ± 25		3.5 ± 3.5	
Cubital tunnel syndrome; n = 24								
Unilateral	32 ± 22	0.26	42 ± 11	0.97	35 ± 25	0.40	4.2 ± 2.4	0.21
Bilateral	43 ± 24		41 ± 13		44 ± 25		5.6 ± 2.8	
Electrodiagnostic studies not present	31 ± 15	0.25	46 ± 10	**0.03**	31 ± 24	0.16	4.5 ± 2.2	0.68
Electrodiagnostic studies present	41 ± 29		36 ± 11		46 ± 25		4.9 ± 3.0	
Severity								
Mild	34 ± 18		43 ± 11		31 ± 22		5.0 ± 3.2	
Moderate	28 ± 17	0.20	43 ± 9.5	0.72	33 ± 20	0.32	4.2 ± 1.9	0.77
Severe	47 ± 29		39 ± 14		49 ± 32		5.0 ± 3.1	

*Bold indicates statistically significant difference; Pearson and Spearman correlation indicated by *r* and *ρ*; Continuous variables as mean ± SD, unless otherwise indicated; PSEQ-2: Pain Self-Efficacy Questionnaire short form; TSK-4: Tampa Scale for Kinesiophobia short form; PHQ-2: Patient Health Questionnaire short form; I-HaND: Impact of Hand Nerve Disorders; PROMIS PF-UE-7: Patient-Reported Outcomes Measurement Information System Upper Extremity questionnaire short form; QuickDASH: Disabilities of the Arm, Shoulder and Hand short form.

Chapter 3

A Comparison of Nerve-Specific, Condition-Specific, and Upper Extremity-Specific Patient-Reported Outcome Measures in Patients with Carpal and Cubital Tunnel Syndrome

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The Journal of Hand Surgery American Volume
2022 Aug;47(8):791.e1-.e10

Abstract

Purpose

Arm-, region-, tissue-, and condition-specific patient-reported outcome measures (PROMs) are available to address idiopathic mononeuropathy. This study compared PROMs with varying specificities in patients with idiopathic neuropathy of the upper extremity with respect to correlations with each another, sources of variation in scores, and floor and ceiling effects.

Methods

One hundred fifty patients (130 with carpal tunnel syndrome, 30 with cubital tunnel syndrome, and 10 with both conditions) completed a nerve-specific PROM (Impact of Hand Nerve Disorders), a condition-specific PROM (Boston Carpal Tunnel Syndrome Questionnaire and/or Patient-Rated Ulnar Nerve Evaluation), and an upper extremity-specific PROM (Patient-Reported Outcomes Measurement Information System Physical Function Upper Extremity 7). We also gathered demographic and condition-related data (side, electrodiagnostic studies present, muscle atrophy, static loss of sensibility), and patients completed questionnaires measuring self-efficacy, kinesiophobia, and symptoms of depression. Correlation of the PROMs with each another and factors accounting for their variation were assessed, as well as the number of items to complete, time to complete, and floor and ceiling effects.

Results

Pearson correlations between PROMs were moderate to strong (0.56-0.90). Self-reported symptoms of depression were best able to account for the variations in symptom intensity and activity intolerance on all PROMs (adjusted R^2 between 0.09 and 0.31). The Impact of Hand Nerve Disorders is a long questionnaire and took the most time to complete. All instruments had comparable floor effects; Patient-Reported Outcomes Measurement Information System Physical Function Upper Extremity had a ceiling of effect of 16%.

Conclusions

This study adds to the evidence that specific and general PROMs correlate with each another, perhaps in part through their correlation with mental health. Based on this line of evidence and pending testing of potentially greater responsiveness in specific settings, we prefer to use a single simple, brief, and general PROM to quantify symptom intensity and activity intolerance for both routine patient care and research.

Introduction

Patient-reported outcome measures (PROMs) are used to quantify subjective aspects of health, such as symptom intensity and capability. Measures of the severity of pathology (disease activity) include electrodiagnostic studies, measures of sensibility, and assessments of strength of palmar abduction and atrophy of the thenar eminence. Musculoskeletal PROMs can be general (eg, Patient-Reported Outcomes Measurement Information System Physical Function [PROMIS PF][1]), extremity-specific (eg, PROMIS PF Upper Extremity [UE][2]), region-specific (eg, Michigan Hand Outcome Questionnaire[3]), or condition-specific (eg, Boston Carpal Tunnel Syndrome Questionnaire [BCTQ][4] and Patient-Rated Ulnar Nerve Evaluation [PRUNE][5]). The Impact of Hand Nerve Disorders [I-HaND] scale is a tissue (nerve)-specific and upper limb-specific PROM.[6] It is designed for use with any upper extremity nerve problem. The most common nerve diseases treated by hand specialists are carpal tunnel syndrome (CTS) and cubital tunnel syndrome (CubTS). There is an established line of evidence documenting that PROMs of varying specificity are correlated.[2,6–8] We designed an experiment to further this line of evidence by testing the relatively new I-HaND among patients with CTS and/or CubTS.

In this cross-sectional study, we compared the nerve-specific I-HaND to condition-specific PROMs for CTS and CubTS (the BCTQ and PRUNE, respectively) and an upper extremity-specific PROM (the PROMIS PF-UE-7). We tested the following hypotheses: (1) the I-HaND does not correlate with the BCTQ, PRUNE, or PROMIS PF-UE-7 in patients diagnosed with CTS and/or CubTS; and (2) there are no biopsychosocial factors (demographical, condition-related, and psychological factors) independently associated with I-HaND, BCTQ, PRUNE, or PROMIS PF-UE-7 scores. Finally, we assessed instrument properties such as items needed to complete, completion time, and floor and ceiling effects (ie, the percentage of patients scoring at the lowest or highest possible score, respectively).

Materials and methods

Study design

This study was performed at The Dell Medical School – The University of Texas. After approval by the Office of Research Support and Compliance, we prospectively invited people to complete questionnaires. The inclusion criteria were all new, established, or postoperative adult patients who spoke English, had a diagnosis of idiopathic CTS and/

or CubTS, and presented to 1 of 3 participating orthopedic surgeons in an urban location in the United States. Patients were diagnosed based on the specialist's interpretation of symptoms and signs alone or with additional electrodiagnostic testing. We excluded patients with nonidiopathic CTS or CubTS (eg, following trauma). Research assistants not involved with patient care explained the study to patients in a private room. Completion of the survey implied informed consent.

This is partly a secondary use of the initial cross-sectional data. We created 3 different studies using 1 continuous enrollment cohort – 2 cross-sectional and 1 longitudinal study – with a total of around 200 patients. For the first study, we used the initial 140 patients and looked at the I-HaND, upper extremity-specific PROMs, pain intensity, and quality of life in both compression neuropathy and traumatic nerve lesion patients. For this study, we included patient numbers 41 to 195, because there were no patients with CubTS in the initial 40 patients and the objective was to include at least 15% to 20% of patients having CubTS in a consecutively enrolled cohort.

Measures

The treating surgeon recorded the diagnosis, laterality, presence of electrodiagnostic study results, and signs of advanced neuropathy: the presence of atrophy (thenar atrophy for CTS and first dorsal interosseous atrophy for CubTS) or static numbness.[9] Next, patients were asked to complete a set of questionnaires on a tablet, starting with demographics asking about age, sex, partnered status, level of education, insurance, type of visit (new or established patient visit or postoperative visit), and perceived symptom duration. This was followed by short forms for psychological screening, including the Pain Self-Efficacy Questionnaire (PSEQ-2), Tampa Scale for Kinesiophobia (TSK-4), and Patient Health Questionnaire (PHQ-2). Activity intolerance was quantified using the BCTQ among the 150 people diagnosed with CTS and the PRUNE among the 30 people diagnosed with CubTS. All subjects completed the I-HaND and the PROMIS PF-UE-7.

A 7-point ordinal scale (scores 0-6) is used for both items of the PSEQ-2 to quantify an individual's ability to achieve goals in spite of pain.[10] Greater self-efficacy is indicated by a higher summed score of both items combined (final scores 0-12).[10]

A 4-point Likert scale (scores 1-4) is used for the 4 items of the TSK-4 to quantify an individual's fear of painful movement: that is, kinesiophobia.[11] More fear of movement is indicated by a higher summed score of all items combined (final scores 4-16).[11]

A 4-point Likert scale (scores 0-3) is used for both items of the PHQ-2 to measure symptoms of depression in the past 2 weeks.[12] Having more symptoms of depression is indicated by a higher summed score of both items combined (final scores 0-6).[12]

The I-HaND uses a 5-point Likert scale (scores 1-5) and a total of 32 items to quantify activity intolerance in patients with either traumatic or compressive upper extremity neuropathology.[6] More activity intolerance is indicated by a higher raw score of all items combined, which is then scaled into a final score of 0 to 100.[6]

The BCTQ uses a 5-point Likert scale (scores 1-5) and a total of 19 items to quantify symptom intensity and activity intolerance in patients with CTS.[4] The first 11 items quantify symptom intensity and the remaining 8 quantify the functional status.[4] Greater severity of CTS is indicated by a higher mean score of all (subscale) items combined (final scores 1-5).[4]

The PRUNE uses an 11-point ordinal scale (scores 0-10) and a total of 20 items to quantify the symptom intensity and activity intolerance in patients with CubTS.[5] The first 10 items quantify symptom intensity and the other 10 quantify difficulties in performing certain activities.[5] Greater severity of CubTS is indicated by a higher mean score of all (subscale) items combined (final scores 0-10).[5]

Because some collaborators did not have access to PROMIS computerized adaptive test (CAT) versions, we used the PROMIS PF-UE-7. This measure is comparable to its CAT version and uses a 5-point Likert scale (scores 1-5) for each of 7 items to quantify upper extremity-specific activity intolerance.[2] Less activity intolerance is indicated by a higher raw score of all items combined, which is then transformed into a final *T*-score between 16.3 and 58.2.[2,13] The final score is comparable to CAT-based PROMIS measures, with a *T*-score mean of 50 with an SD of 10 in a general population.[2]

Study sample

We prospectively invited 159 people to complete questionnaires, and 4 patients declined participation. After enrollment, 5 people (3.2%) were excluded from the analysis: 2 stopped completing the questionnaires at an early stage and 3 were incorrectly enrolled and did not have CTS or CubTS (2 had cervical radiculopathy and 1 had De Quervain tenosynovitis). Of the 150 patients, 130 had CTS, 30 had CubTS, and 10 had both (Table 1). The mean age was 55 ± 14 years and the majority of the patients (n = 114; 76%) had symptoms for 3 months or more when they filled out the questionnaires (Table 2).

Table 1. Clinical Characteristics

Variable	n = 150[1]
Carpal tunnel syndrome	n = 130
Bilateral	81 (62)
Electrodiagnostic studies present	74 (57)
Cubital tunnel syndrome[2]	n = 30
Bilateral	9 (31)
Electrodiagnostic studies present	14 (48)

Discrete variables as number (percentage); [1]10 patients had both carpal and cubital tunnel syndrome; [2]Clinical characteristics for 1 patient missing.

Table 2. Patient Characteristics

Variable	n = 150
Age, y	55 ± 14 (24-81)
Men	55 (37)
Partnered status	
Married/unmarried couple	99 (66)
Other	51 (34)
Level of education	
High school or less	56 (37)
2-year college	32 (21)
4-year college	40 (27)
Post-college graduate degree	22 (15)
Insurance	
Private	101 (67)
Other	49 (33)
Visit	
New or established patient visit	113 (75)
Postoperative visit	37 (25)
Symptom duration	
≤3 months	36 (24)
3 months to ≤1 year	48 (32)
>1 year	66 (44)
PSEQ-2 *(n = 6 missing)*	10 (7.5-12)
TSK-4 *(n = 6 missing)*	9 (6-11)
PHQ-2 *(n = 6 missing)*	0 (0-1)
I-HaND	36 ± 19 (0-94)

Table 2. *Continued.*

Variable	n = 150
BCTQ *(n = 3 missing)*	2.6 ± 0.86 (1-5)
BCTQ symptoms subscale	2.7 ± 0.92 (1-5)
BCTQ function subscale	2.3 ± 0.96 (1-5)
PRUNE	4.3 ± 2.2 (0.85-9.7)
PRUNE symptoms subscale	4.8 ± 2.2 (1.7-10)
PRUNE function subscale	3.8 ± 2.7 (0-9.3)
PROMIS PF-UE-7 *(n = 2 missing)*	41 ± 10 (16-58)

Continuous variables as mean ± standard deviation (range) or as median (interquartile range); Discrete variables as number (percentage); PSEQ-2: Pain Self-Efficacy Questionnaire short form; TSK-4: Tampa Scale for Kinesiophobia short form; PHQ-2: Patient Health Questionnaire short form; I-HaND: Impact of Hand Nerve Disorders; BCTQ: Boston Carpal Tunnel Syndrome Questionnaire; PRUNE: Patient Rated Ulnar Nerve Evaluation; PROMIS PF-UE-7: Patient-Reported Outcomes Measurement Information System Upper Extremity questionnaire short form.

Statistical analysis

Histogram plots were used to assess the distributions of continuous variables. We presented continuous variables as means ± SDs or as medians (interquartile ranges), where appropriate, and presented discrete data as proportions. Pearson and Spearman tests were used to assess correlations between continuous variables (eg, between the I-HaND and BCTQ). For differences in mean scores among dichotomous variables, we used Student *t* tests (eg, I-HaND score difference between patients presenting at a first/preoperative or postoperative visit). For differences between mean scores among categorical variables, we used a 1-way analysis of variance (eg, I-HaND score differences among patients with different levels of education). Not all surveys were completely filled out, but all instruments started were completed in full. Six (4%) patients did not complete the psychological measures, 2 (1.3%) did not complete the PROMIS PF-UE-7, and 3 (2%) patients with CTS did not complete the BCTQ. We believe the missing data were completely at random and for multivariable statistics we opted to use a complete case analysis. Data were determined to be missing completely at random because there was no clear pattern (eg, there were no missing data based on the order of questionnaires) and there were no associations of the missing data with other variables. Correlation effects were interpreted as negligible for a correlation of 0.0 to 0.10, weak for 0.10 to 0.39, moderate for 0.40 to 0.69, strong for 0.70 to 0.89, and strong for 0.90 to 1.0.[14] Four multivariable linear regression models were created to identify independent predictors of the studied PROMs (the

I-HaND, BCTQ, PRUNE, and PROMIS PF-UE-7). All variables available were tested in a bivariate analysis and those with a *P* value < .10 (Appendix 1) were included in the multivariable models. We anticipated collinearity of the psychological measures. We chose to use the PHQ-2 in multivariable analyses because of the demonstrated importance of symptoms of depression to overall health.[15] The change in a PROM score by a 1-unit increase in the predictor variable is indicated by the regression coefficient (ß). The amount of variability explained in the dependent variable is indicated by the adjusted R squared (R^2), with the specific contribution of a predictor variable indicated by the semipartial R^2. We manually calculated the number of patients who rated every question using either the minimum score (floor effect) or the maximum score (ceiling effect) per instrument. The time taken to complete each instrument was automatically recorded electronically when completing the surveys and the mean completion time was assessed for each instrument separately. Significance was set at a *P* value < .05.

We powered on our multivariable analysis, and an a priori sample size estimate showed that we would need 136 patients. This was based on an alpha of 0.05, 80% power, and a linear regression model with 5 predictors that would explain 15% of the variability in activity intolerance, with 1 of the predictors explaining at least a third in that model. Since we included both patients with CTS and CubTS – and generally there are more patients presenting with CTS – we enrolled 10% more so we would have enough data for both the BCTQ and PRUNE.

Ethical committee approval

This study received approval from the Institutional Review Board of the University of Texas at Austin. This study was performed in accordance with the ethical standards in the 1964 Declaration of Helsinki and in accordance with relevant regulations of the US Health Insurance Portability and Accountability Act.

Results

Interquestionnaire correlations

The nerve, disease, and upper extremity PROMs were all strongly correlated, with Pearson correlations of 0.88 between the I-HaND and BCTQ, 0.87 between the I-HaND and PRUNE, and -0.76 between the I-HaND and PROMIS PF-UE-7 (all *P* values < .05; Table 3).

The symptom subscales of the BCTQ and PRUNE correlated the least with the I-HaND and PROMIS PF-UE-7. The lowest moderate correlation was found between the PRUNE symptom subscale and the PROMIS PF-UE-7 (*r*, -0.41; *P* < .05; Table 3).

Table 3. Interquestionnaire Correlations*

Variable	I-HaND	BCTQ	BCTQ symptoms subscale	BCTQ function subscale	PRUNE	PRUNE symptoms subscale	PRUNE function subscale	PROMIS PF-UE-7
I-HaND (*r*)	-							
BCTQ (*r*)	0.88; ***P* <.05**	-						
BCTQ symptoms subscale (*r*)	0.78; ***P* <.05**	0.94; ***P* <.05**	-					
BCTQ function subscale (*r*)	0.87; ***P* <.05**	0.90; ***P* <.05**	0.70; ***P* <.05**	-				
PRUNE (*r*)	0.87; ***P* <.05**	0.90; ***P* <.05**	0.87; ***P* <.05**	0.93; ***P* <.05**	-			
PRUNE symptoms subscale (*r*)	0.75; ***P* <.05**	0.85; ***P* <.05**	0.85; ***P* <.05**	0.84; ***P* <.05**	0.89; ***P* <.05**	-		
PRUNE function subscale (*r*)	0.83; ***P* <.05**	0.90; ***P* <.05**	0.85; ***P* <.05**	0.95; ***P* <.05**	0.93; ***P* <.05**	0.66; ***P* <.05**	-	
PROMIS PF-UE-7 (*r*)	-0.76; ***P* <.05**	-0.72; ***P* <.05**	-0.56; ***P* <.05**	-0.80; ***P* <.05**	-0.58; ***P* <.05**	-0.41; ***P* <.05**	-0.63; ***P* <.05**	-

*Bold indicates statistically significant; Pearson correlation indicated by *r*; I-HaND: Impact of Hand Nerve Disorders; BCTQ: Boston Carpal Tunnel Syndrome Questionnaire; PRUNE: Patient Rated Ulnar Nerve Evaluation; PROMIS PF-UE-7: Patient-Reported Outcomes Measurement Information System Upper Extremity questionnaire short form.

Factors associated with the I-HaND, BCTQ, PRUNE, and PROMIS PF-UE-7

In a multivariable analysis, lower capability (PROM scores) was associated with greater symptoms of depression (higher PHQ-2 scores) for all PROMs (adjusted R^2 between 0.09 and 0.31; Table 4).

Instrument properties

The number of items to complete (32 vs 7 items, respectively) and consequently the time needed to complete was highest for the I-HaND and lowest for the PROMIS PF-UE-7 (251 vs 50 seconds, respectively; Table 5). All instruments had comparable floor effects; the PROMIS PF-UE-7 had a ceiling of 16% (Table 5).

Discussion

We compared nerve-, condition-, and upper extremity-specific PROMs in patients with idiopathic CTS or CubTS and found moderate to strong correlations between all measures. We also found that variation in symptoms of depression accounted for the variation in PROM scores better than other factors, like patient demographics or symptom duration.

We address some limitations: First, there were only 30 patients with CubTS. Correlation tests and multivariable analysis results might differ when a larger CubTS sample is studied. Second, in 41% of patients the diagnosis of CTS and/or CubTS was made based on symptoms and signs rather than electrodiagnostic testing, introducing some subjectivity. This study did not look at correlations between physical examinations or diagnostic tests and PROMs. We accepted the specialist's diagnosis as a reflection of daily practice, and we feel there are advantages to this approach since the symptoms and signs of CTS and CubTS are shown to have good diagnostic performance characteristics.[16,17] Constant numbness is a hallmark finding of advanced disease.[18,19] After reviewing the data, the authors found that some surgeons interpreted "constant numbness" as a symptom reported by the patient, while others thought of it as an objective sign (static loss of sensibility). Interestingly, neither indicator for advanced neuropathy – the presence of thenar atrophy or static loss of sensibility – correlated with PROMs in patients with CTS. For patients with CubTS, we did find associations of first dorsal interosseous atrophy with the PROMs tested, though with the limited number of patients, we did not test this in our multivariable model. Third, we used the short form of the PROMIS PF-UE instead of its CAT version because some collaborators did not have access to the CAT version. The upper extremity short form for PROMIS is comparable to its CAT version,

Table 4. Multivariable Regression Analyses of Factors Associated With Patient-Reported Outcome Scores*

Dependent variable	Retained variable	Regression coefficient [β] (95% Confidence interval)	Standard error	*P* value	Semipartial R^2	Adjusted R^2
I-HaND	Postoperative visit	-5.7 (-12 to 0.96)	3.4	0.09		0.18
	PHQ-2	5.9 (3.7 to 8.2)	1.1	**<.05**	0.16	
BCTQ	Postoperative visit	-0.43 (-0.76 to -0.10)	0.17	**<.05**	0.05	0.19
	PHQ-2	0.25 (0.14 to 0.36)	0.06	**<.05**	0.13	
PRUNE	PHQ-2	0.82 (0.36 to 1.3)	0.22	**<.05**	0.31	0.31
PROMIS PF-UE-7	PHQ-2	-2.5 (-3.8 to -1.2)	0.66	**<.05**	0.09	0.09

*Bold indicates statistically significant; Only the semipartial R^2 of significant variables displayed; All variance inflation factors <10 (highest 1.02); PHQ-2: Patient Health Questionnaire short form; I-HaND: Impact of Hand Nerve Disorders; BCTQ: Boston Carpal Tunnel Syndrome Questionnaire; PRUNE: Patient Rated Ulnar Nerve Evaluation; PROMIS PF-UE-7: Patient-Reported Outcomes Measurement Information System Upper Extremity questionnaire short form.

Table 5. Instrument Properties

Questionnaire	Number of items	Item completion rate (%)	Mean score	Score range	Possible range	Floor effect	Ceiling effect	Mean time to complete (seconds)
I-HaND	32	100	36 ± 19	0-94	0-100	1 (0.67)	0 (0)	251
BCTQ	19	100	2.6 ± 0.86	1-5	1-5	2 (1.6)	1 (0.80)	131
PRUNE	20	100	4.3 ± 2.2	0.85-9.7	0-10	1 (3.3)	1 (3.3)	128
PROMIS PF-UE-7	7	100	41 ± 10	16-58	16-58	2 (1.4)	24 (16)	50

Continuous variables as mean ± SD; Discrete variables as number (percentage); I-HaND: Impact of Hand Nerve Disorders; BCTQ: Boston Carpal Tunnel Syndrome Questionnaire; PRUNE: Patient Rated Ulnar Nerve Evaluation; PROMIS PF-UE-7: Patient-Reported Outcomes Measurement Information System Upper Extremity questionnaire short form.

although it is more prone to ceiling and floor effects.[2] Fourth, we used only 1 of the 3 psychological measures in our multivariable analyses. A combination of psychological factors may explain more variability in activity intolerance; however, this is more difficult to test due to collinearity between the measures. Fifth, it could be argued that CTS and CubTS should be evaluated separately; however, we believe including people with a typical mix of diagnoses at various points in care can be seen as a strength, especially since we tested a new PROM intended for use with nerve pathology in general, and we are extending a line of evidence establishing the relative interchangeability of PROMs of varied specificity. Sixth, we did not test responsiveness in this study, and it might prove better for more specific PROMs. Finally, for logistical reasons, we were not able to randomize the order of the instruments. Some questions look alike and overlap with those in the next instrument; therefore, survey fatigue was possible. However, the mean time taken to complete all instruments was less than 10 minutes.

Similar to the developmental study of the I-HaND, where a strong Pearson correlation of 0.87 was found with the Quick Disabilities of the Arm, Shoulder, and Hand questionnaire (QuickDASH),[6] we also found strong interquestionnaire correlations using both condition- and upper extremity-specific PROMs. Of the 4 instruments tested, the BCTQ and PROMIS are the most studied. Our correlations are consistent with the evidence to date.[20,21] In a separate, as yet unpublished experiment, we also found similar strong correlations of the I-HaND with upper extremity-specific PROMs (the PROMIS PF-UE-7 and QuickDASH) and pain intensity. This suggests the use of more specific PROMs may have few advantages over more general PROMs. Interestingly, we found the lowest – but still moderate – correlations between the PROMIS PF-UE-7 and the BCTQ and PRUNE symptom intensity subscales. One potential explanation is that the PROMIS PF-UE-7 had notable ceiling effects that would have been avoided if we were able to use the CAT version. These ceiling effects limit the spread in the scores, which might have reduced the correlations. Another explanation might be that 5 out of 11 questions for the BCTQ symptom intensity subscale and 6 out of 10 for the PRUNE symptom intensity subscale are related to pain and the remaining questions ask about other symptoms, like numbness, tingling, or weakness.[4,5] The numbness can be described or experienced as pain, but pain without concurrent numbness is not a symptom of either CTS or CubTS. Diagnostic scales for CTS, such as the CTS-6, do not include symptoms of pain.[16] Questions about weakness may measure pain more than they measure true weakness. It is our impression that people with muscle weakness usually describe issues with dexterity, not strength.

This study adds to the evidence that psychosocial factors have more influence on activity intolerance than pathophysiology, as symptoms of depression (as measured by

the PHQ-2) were not only highly correlated with all PROMs, but depression was also the factor best able to account for the variability in the PROM scores. Factors such as symptoms of depression, anxiety, and catastrophic thinking are most consistently associated with activity intolerance.[22] For instance, studies of patients with CTS using the BCTQ identify mental health as a preoperative correlate of symptom intensity, and improvements in mental health are associated with improvements in symptom intensity.[23–25] A longitudinal study of 60 patients with CTS undergoing carpal tunnel release found more improvement on the BCTQ symptom intensity subscale if their symptoms of depression and pain anxiety also improved.[23]

The finding that the shortest instrument tested (the PROMIS PF-UE-7) had a comparable floor effect to the other instruments but a greater ceiling effect is expected and might not have occurred if all sites could use the computer adaptive test. The length of a PROM tries to balance efficiency with limited floor and ceiling effects. One of the advantages of a CAT is that it can limit flooring and ceiling effects while remaining brief.[21,26,27]

This study confirmed that specific and general PROMs correlate strongly in patients with idiopathic CTS or CubTS. It also confirmed that mental health accounts for variation in PROMs and might be the reason that less specific and more specific PROMs correlate: they might be similarly influenced by factors other than pathology. Based on this line of evidence, pending testing of potentially greater responsiveness in specific settings, we prefer to use a single simple, brief, and general PROM to quantify symptom intensity and activity intolerance for both routine patient care and research.

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Appendix 1. Bivariate Analyses of Factors Associated With Patient-Reported Outcome Scores*

Variable; n = 150	I-HaND n = 150	*P* value	BCTQ n = 130	*P* value	PRUNE n = 30	*P* value	PROMIS PF-UE-7 n = 148	*P* value
Age, y(*r*)	-0.09	0.25	-0.07	0.42	-0.29	0.12	-0.02	0.84
Sex								
Women	36 ± 18	0.66	2.6 ± 0.88	0.87	5.0 ± 2.2	0.14	40 ± 10	0.17
Men	35 ± 20		2.5 ± 0.85		3.8 ± 2.2		43 ± 11	
Partnered status								
Married/unmarried couple	36 ± 19	0.53	2.6 ± 0.84	0.29	4.6 ± 2.2	0.50	41 ± 10	0.43
Other	34 ± 19		2.4 ± 0.91		4.0 ± 2.3		40 ± 11	
Level of education								
High school or less	37 ± 19	0.19	2.7 ± 0.93	0.13	3.7 ± 1.9	0.76	39 ± 9.8	0.43
2-year college	36 ± 17		2.5 ± 0.81		4.7 ± 1.8		41 ± 10	
4-year college	37 ± 21		2.6 ± 0.86		4.8 ± 3.6		41 ± 11	
Post-college graduate degree	28 ± 17		2.1 ± 0.62		4.5 ± 2.5		44 ± 12	
Insurance								
Private	36 ± 18	0.60	2.5 ± 0.79	0.59	4.4 ± 2.1	0.61	41 ± 9.4	0.63
Other	34 ± 20		2.6 ± 1.0		4.0 ± 2.6		40 ± 12	
Visit								
New or established patient visit	37 ± 18	0.06	2.7 ± 0.77	**<.05**	4.5 ± 2.3	0.46	41 ± 9.9	0.50
Postoperative visit	30 ± 22		2.2 ± 1.0		3.8 ± 2.0		40 ± 12	
Symptom duration								

Appendix 1. *Continued.*

Variable; n = 150	I-HaND n = 150	*P* value	BCTQ n = 130	*P* value	PRUNE n = 30	*P* value	PROMIS PF-UE-7 n = 148	*P* value
≤3 months	34 ± 22		2.5 ± 1.0		4.3 ± 2.3		40 ± 11	
3 months to ≤1 year	34 ± 16	0.51	2.4 ± 0.74	0.28	3.2 ± 2.7	0.50	41 ± 9.1	0.87
>1 year	38 ± 19		2.7 ± 0.87		4.7 ± 2.0		41 ± 11	
PSEQ-2 (*ρ*)	-0.40	**<.05**	-0.37	**<.05**	-0.39	**<.05**	0.39	**<.05**
TSK-4 (*ρ*)	0.44	**<.05**	0.45	**<.05**	0.53	**<.05**	-0.30	**<.05**
PHQ-2 (*ρ*)	0.37	**<.05**	0.35	**<.05**	0.54	**<.05**	-0.32	**<.05**
Diagnoses								
No carpal tunnel syndrome	35 ± 20	0.82	-	-	4.0 ± 1.9	0.31	42 ± 11	0.56
Carpal tunnel syndrome	36 ± 19		-		4.9 ± 2.9		41 ± 10	
No cubital tunnel syndrome	35 ± 18	0.81	2.6 ± 0.85	0.81	-	-	41 ± 10	0.71
Cubital tunnel syndrome	36 ± 22		2.6 ± 1.1		-		40 ± 11	
Carpal tunnel syndrome; n = 130								
Unilateral	35 ± 21	0.86	2.5 ± 0.98	0.58	5.9 ± 3.2	0.28	39 ± 11	0.18
Bilateral	36 ± 17		2.6 ± 0.79		3.9 ± 2.4		42 ± 9.6	
Electrodiagnostic studies not present	34 ± 17	0.33	2.6 ± 0.81	0.75	2.8 ± 1.2	0.13	43 ± 9.8	0.06
Electrodiagnostic studies present	37 ± 20		2.5 ± 0.91		5.8 ± 2.9		39 ± 11	

Appendix 1. *Continued.*

Variable; n = 150	I-HaND n = 150	*P* value	BCTQ n = 130	*P* value	PRUNE n = 30	*P* value	PROMIS PF-UE-7 n = 148	*P* value
Related atrophy not present	36 ± 18	0.54	2.6 ± 0.83	0.73	-	-	41 ± 10	0.73
Related atrophy present	33 ± 24		2.5 ± 1.1		-		40 ± 13	
Related static numbness not present	34 ± 21	0.48	2.5 ± 0.90	0.79	-	-	43 ± 11	0.14
Related static numbness present	36 ± 18		2.6 ± 0.85		-		40 ± 9.9	
Cubital tunnel syndrome; n = 30								
Unilateral	33 ± 22	0.24	2.4 ± 1.1	0.68	3.9 ± 2.1	0.15	40 ± 10	0.86
Bilateral	44 ± 22		2.8 ± 1.3		5.2 ± 2.5		41 ± 12	
Electrodiagnostic studies not present	34 ± 17	0.51	2.1 ± 0.24	0.34	3.9 ± 1.9	0.28	44 ± 11	0.06
Electrodiagnostic studies present	40 ± 26		3.0 ± 1.4		4.8 ± 2.6		37 ± 9.7	
Related atrophy not present	31 ± 18	**<.05**	-	-	3.8 ± 1.9	**<.05**	43 ± 10	0.10
Related atrophy present	50 ± 25		-		5.6 ± 2.7		36 ± 10	
Related static numbness not present	26 ± 4.3	0.38	-	-	2.9 ± 0.86	0.26	49 ± 8.3	0.17
Related static numbness present	38 ± 23		-		4.5 ± 2.3		40 ± 11	

*Bold indicates statistically significant difference; Pearson and Spearman correlation indicated by *r* and *ρ*; Continuous variables as mean ± SD, unless otherwise indicated; PSEQ-2: Pain Self-Efficacy Questionnaire short form; TSK-4: Tampa Scale for Kinesiophobia short form; PHQ-2: Patient Health Questionnaire short form; I-HaND: Impact of Hand Nerve Disorders; BCTQ: Boston Carpal Tunnel Syndrome Questionnaire; PRUNE: Patient Rated Ulnar Nerve Evaluation; PROMIS PF-UE-7: Patient-Reported Outcomes Measurement Information System Upper Extremity questionnaire short form.

Part II Electrodiagnosis

Chapter 4

Borderline Nerve Conduction Velocities for Median Neuropathy at the Carpal Tunnel

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The Journal of Hand Surgery American Volume
2020 May;45(5):379-388.e1
Editor's choice

Abstract

Purpose

Patient knowledge of the frequency with which electrodiagnostic testing (EDx) for suspected median neuropathy at the carpal tunnel addresses nuance in the distinction between normal and abnormal neurophysiology might help them make an informed decision about whether or not to have this test. We reviewed a large set of consecutive EDx for possible carpal tunnel syndrome (CTS) and associated medical records to determine (1) the percentage of EDx measurements within 10% of threshold values; (2) discordance between clinician and EDx diagnosis of CTS using diagnostic performance characteristics; and (3) demographic and disease characteristics independently associated with EDx diagnosis of median neuropathy at the carpal tunnel.

Methods

We retrospectively reviewed nerve conduction study (NCS) results of 537 consecutive patients evaluated for possible idiopathic median neuropathy at the carpal tunnel. We measured the number of patients within 10% of 3 NCS diagnostic thresholds; the diagnostic performance characteristics comparing clinician and EDx diagnosis; and patient and disease characteristics associated with EDx diagnosis of CTS.

Results

The 3 NCS parameters were within 10% of the threshold for diagnosis of median neuropathy at the carpal tunnel in 2.6% to 33% of patients. Overall, 76% of EDx results were interpreted as median neuropathy at the carpal tunnel, 19% as normal, and 5% as another diagnosis (eg, cervical radiculopathy). Patients with normal EDx were significantly younger, more likely not to report paresthesias/numbness, more likely to have prior normal EDx, and less likely to have had a previous contralateral carpal tunnel release.

Conclusions

This data set reflecting management strategies for suspected CTS at a large institution confirms inherent diagnostic uncertainty, relatively strong concordance between clinician and EDx diagnosis, and the importance of focusing on paresthesia rather than pain. These findings support the use of clinical prediction rules and may help inform a patient's decision regarding whether or not to have EDx.

Introduction

Idiopathic median neuropathy at the carpal tunnel manifests as symptoms of nocturnal and intermittent paresthesias progressing to loss of sensibility in the median nerve distribution (carpal tunnel syndrome [CTS]). The physical examination findings include signs such as provocation of paresthesia with tapping or pressure over the median nerve at the carpal tunnel and paresthesias with prolonged wrist flexion. There is eventual progression to static loss of discriminant sensibility, palmar abduction strength, and thenar muscle mass.[1–15]

The American Association of Electrodiagnostic Medicine (AAEM) reports pooled sensitivities of 63% to 85% and specificities of 97% or greater for nerve conduction studies (NCSs) based on a review of 278 articles of which 22 were included in an analysis.[16] Given that there is no consensus reference standard for diagnosis of idiopathic median neuropathy among people diagnosed with clinical CTS[12,17], these may be over- or underestimates.[18]

Electrodiagnostic tests (EDx) are sometimes ordered to establish a preoperative baseline in case a patient is dissatisfied with the result of surgery and sometimes in scenarios in which the probability of CTS is low with the rationale of not missing the opportunity to treat this correctable problem. Diagnostic tests can be misleading in this second, low-prevalence scenario. Another potentially low-prevalence scenario is when nonspecialists order EDx because specialists insist on EDx prior to referral. In circumstances with limited access to specialists, nonspecialists may use the tests to help triage people and gain earlier access to a specialist. Clinical prediction rules such as the CTS-6[7] can be used to estimate the probability of median neuropathy. Clinical prediction rules improve the diagnostic performance characteristics of EDx. They also make EDx optional given that clinical prediction rules are infrequently discordant with EDx, especially with a higher pretest probability.[1,19]

It might help patients considering EDx for suspected median neuropathy at the carpal tunnel to know the prevalence of nuance in the distinction between normal and abnormal neurophysiology and the characteristics associated with this scenario. We reviewed the use of EDx for possible CTS in daily practice at a large institution to (1) determine the percentage of EDx measurements within 10% of threshold values; (2) assess discordance between clinical diagnosis of CTS and normal EDx results using diagnostic performance characteristics; and (3) identify demographic and disease characteristics independently associated with EDx diagnosis of median neuropathy at the carpal tunnel.

Materials and Methods

Study design

This retrospective study was approved by our institutional review board. All electronic medical records of patients who underwent EDx tests over a 4-year period were manually reviewed by research assistants not involved in patient care to establish whether the patient fulfilled the predefined eligibility criteria. We included a consecutive series of 565 eligible patients who were aged 18 years or older and sent by various specialist and nonspecialists clinicians for EDx to confirm or rule out median neuropathy based on their personal criteria for when this might be worthwhile. This is a representation of how EDx is used in clinical practice in one region and not a reflection of standardized diagnostic criteria or a clinical prediction rule. Only 1 hand per patient was analyzed. In people with bilateral symptoms, the less electrodiagnostically abnormal side was used because the main aim of the study was to assess electro- diagnostic results near the threshold values. We excluded patients who were pregnant at the time of the NCS and patients who previously underwent ipsilateral carpal tunnel release (CTR).

A total of 565 patients underwent 568 EDx to look for median neuropathy at the carpal tunnel. Thirty-one tests were excluded in 28 patients (3 had 2 tests within the study period, 1 was pregnant at the time of the test, 20 had a previous ipsilateral CTR, for 2 there was not enough information in the medical records around the time of the test, and 5 NCSs were misplaced or incomplete), leaving 537 patients for analysis of which 82% (441) were tested bilaterally. Specialists (orthopedic surgeons, plastic surgeons, neurosurgeons, or neurologists) referred 404 patients (75%) for EDx, and nonspecialists referred 133 patients (25%).

All patients underwent NCSs in an outpatient setting using a TECA Synergy N2 EMG (Oxford Instruments Medical, Surrey, England). In line with most other studies and the American Association of Electrodiagnostic Medicine (AAEM) standards and guidelines[16,20], the following electrodiagnostic criteria for median neuropathy were used: (1) difference in median-ulnar mixed nerve palmar latencies (palm to wrist stimulation over 8 cm distance) of 0.4 ms or greater; (2) difference in median nerve distal motor latency (DML) between sides of 1.0 ms or greater; and (3) difference between median and ulnar nerve DML of the same side of 1.8 ms or greater. Other criteria for CTS that are used by 1 of the authors (M.Z.) are (1) median nerve distal sensory latency (DSL) of 3.6 ms or greater; (2) median nerve DML of 4.4 ms or greater; and (3) median nerve motor amplitude of 5 mV or less (Table 1). In case of abnormality, another nerve in the same limb was tested. In case of normal results, median nerve conductions were tested over a

shorter (7-8 cm instead of over 8 cm) distance or a comparison of the median conduction across the wrist was made with radial or ulnar sensory conductions in the same limb. There are no strict criteria to interpret results and interpretation of the different tests as median neuropathy or not and its severity (mild, moderate, or severe) is according to the testing physician's judgment. The EDx result was classified as median neuropathy at the carpal tunnel, normal EDx, or other neuropathy (eg, cubital tunnel syndrome [CubTS] or cervical radiculopathy; Table 2).

Table 1. Overview of 10% Lower and Upper Margins of Cut-Off Values

Variables	Cut-Off Values (± 10%)
Median DSL	3.6 (3.25-3.95)[1]
Median DML	4.4 (3.95-4.85)[1]
Difference in median-ulnar mixed nerve palmar latency	0.4 (0.35-0.45)[1]
Median motor amplitude	5.0 (4.5-5.5)
Difference in median DML between sides	1.0 (0.90-1.10)
Difference in median and ulnar DML same side	1.8 (1.60-2.00)[1]

[1]Values were rounded to the nearest 0.05 multiple. DSL = Distal Sensory Latency; DML = Distal Motor Latency.

The following data were obtained from medical records at the time point prior to NCSs: age, sex, paresthesias/numbness, diagnosis of median neuropathy on a previous NCS, previous contralateral CTR, myelopathy, cerebrovascular accident, systemic inflammatory disease that could involve the upper extremities (eg, rheumatoid arthritis), diabetes mellitus, hypothyroidism, and diagnosed major depression (not taking bipolar disease into account; Table 2). Paresthesias/numbness was divided into the following categories: (1) no; (2) ipsilateral; (3) contralateral; and (4) bilateral. For findings of previous NCSs for median neuropathy, we used the same categories and added (5) unknown result; and (6) no previous NCSs. Diabetes mellitus was divided into (1) no; (2) type 1; and (3) type 2. We also recorded the final clinical diagnosis: CTS or not.

The mean age of patients diagnosed with median neuropathy on EDx (n = 407) was 57 ± 15 years and 266 (65%) were women; the mean age of patients diagnosed with normal EDx (n = 103) was 48 ± 13 years and 74 (72%) were women; and the mean age of patients with another electrodiagnostically confirmed neuropathy (n = 27) was 58 ± 17 years and 11 (41%) were women (Table 2). We displayed the number of patients for all NCS criteria per diagnostic group (Table 3).

Table 2. Patient and Clinical Characteristics per Diagnostic Group*

Variables n = 537	Median neuropathy n = 407	No median neuropathy n = 103	Other Diagnosis n = 27	*P* value
Age (y)	57 ± 15 (22-93)	48 ± 13 (19-76)	58 ± 17 (31-89)	**< 0.05**
Sex				
Men	141 (35)	29 (28)	16 (59)	**< 0.05**
Women	266 (65)	74 (72)	11 (41)	
Paresthesias/numbness				
No	8 (2.0)	14 (14)	1 (3.7)	**< 0.05**
Ipsilateral	146 (36)	44 (43)	18 (67)	
Contralateral	4 (1.0)	1 (1.0)	0 (0)	
Bilateral	249 (61)	44 (43)	8 (30)	
Previous EDx				
No	337 (83)	93 (90)	24 (89)	**< 0.05**
No median neuropathy	4 (1.0)	7 (6.8)	3 (11)	
Ipsilateral median neuropathy	7 (1.7)	1 (1.0)	0 (0)	
Contralateral median neuropathy	10 (2.5)	1 (1.0)	0 (0)	
Bilateral median neuropathy	42 (10)	1 (1.0)	0 (0)	
Unknown results	7 (1.7)	0 (0)	0 (0)	
Previous CTR				
No	366 (90)	102 (99)	27 (100)	**< 0.05**
Contralateral	41 (10)	1 (1.0)	0 (0)	

Table 2. *Continued.*

Variables n = 537	Median neuropathy n = 407	No median neuropathy n = 103	Other Diagnosis n = 27	*P* value
Contralateral median neuropathy				
No	72 (18)	64 (62)	18 (67)	
Yes	287 (71)	0 (0)	1 (3.7)	**< 0.05**
Not tested	48 (12)	39 (38)	8 (30)	
Nonlocalizing median neuropathy				
No	400 (98)	103 (100)	25 (93)	
Ipsilateral	0 (0)	0 (0)	2 (7.4)	**< 0.05**
Contralateral	7 (1.7)	0 (0)	0 (0)	
Median neuropathy proximal to flexor carpi radialis branch				
No	407 (100)	103 (100)	26 (96)	**< 0.05**
Ipsilateral	0 (0)	0 (0)	1 (3.7)	
Median neuropathy distal to anterior interosseous branch				
No	407 (100)	103 (100)	26 (96)	**< 0.05**
Ipsilateral	0 (0)	0 (0)	1 (3.7)	
Nonlocalizing ulnar neuropathy				
No	361 (89)	102 (99)	23 (85)	
Ipsilateral	7 (1.7)	0 (0)	1 (3.7)	**< 0.05**
Contralateral	5 (1.2)	1 (1.0)	1 (3.7)	
Bilateral	34 (8.4)	0 (0)	2 (7.4)	

Table 2. *Continued.*

Variables n = 537	Median neuropathy n = 407	No median neuropathy n = 103	Other Diagnosis n = 27	*P* value
CubTS				
No	375 (92)	103 (100)	20 (74)	**< 0.05**
Ipsilateral	13 (3.2)	0 (0)	4 (15)	
Contralateral	9 (2.2)	0 (0)	0 (0)	
Bilateral	10 (2.5)	0 (0)	3 (11)	
Cervical radiculopathy				
No	383 (94)	102 (99)	10 (37)	**< 0.05**
Ipsilateral	14 (3.4)	0 (0)	13 (48)	
Contralateral	3 (0.7)	1 (1.0)	0 (0)	
Bilateral	7 (1.7)	0 (0)	4 (15)	
Polyneuropathy				
No	391 (96)	103 (100)	22 (81)	**< 0.05**
Yes	16 (3.9)	0 (0)	5 (19)	
Myelopathy				
No	402 (99)	102 (99)	26 (96)	0.52
Yes	5 (1.2)	1 (1.0)	1 (3.7)	
Cerebrovascular accident				
No	393 (97)	98 (95)	24 (89)	0.14
Yes	14 (3.4)	5 (4.9)	3 (11)	

Table 2. *Continued.*

Variables n = 537	Median neuropathy n = 407	No median neuropathy n = 103	Other Diagnosis n = 27	*P* value
Systemic inflammatory disease				
No	393 (97)	95 (92)	26 (96)	0.15
Yes	14 (3.4)	8 (7.8)	1 (3.7)	
Diabetes mellitus				
No	348 (86)	94 (91)	21 (78)	
Type 1	2 (0.5)	0 (0)	0 (0)	0.34
Type 2	57 (14)	9 (8.7)	6 (22)	
Hypothyroidism				
No	353 (87)	95 (92)	25 (93)	0.23
Yes	54 (13)	8 (7.8)	2 (7.4)	
Depression				
No	252 (62)	59 (57)	19 (70)	0.43
Yes	155 (38)	44 (43)	8 (30)	

*Bold indicates statistically significant difference; Continuous variables as mean ± standard deviation (range); Discrete variables as number (percentage); EDx = Electrodiagnostic test; CTR = Carpal Tunnel Release.

Table 3. Number of Patients per EDx Criterium per Diagnostic Group*

Variables n = 537	Median neuropathy n = 407	No median neuropathy n = 103	Other Diagnosis n = 27	*P* value
Median DSL ≥ 3.6 (n = 537)				
No	68 (17)	101 (98)	24 (89)	**< 0.05**
Yes	339 (83)	2 (1.9)	3 (11)	
Median DML ≥ 4.4 (n = 536)				
No	148 (37)	103 (100)	23 (85)	**< 0.05**
Yes	258 (64)	0 (0)	4 (15)	
Difference in median-ulnar mixed nerve palmar latency ≥ 0.4 (n = 431)				
No	8 (2.6)	97 (97)	22 (92)	**< 0.05**
Yes	299 (97)	3 (3.0)	2 (8.3)	
Median motor amplitude ≤ 5.0 (n = 536)				
No	320 (79)	101 (98)	23 (85)	**< 0.05**
Yes	86 (21)	2 (1.9)	4 (15)	
Difference in median DML between sides ≥ 1.0 (n = 403)				
No	268 (79)	47 (100)	15 (88)	**< 0.05**
Yes	71 (21)	0 (0)	2 (12)	
Difference in median and ulnar DML same side ≥ 1.8 (n = 529)				
No	146 (36)	98 (99)	24 (89)	**< 0.05**
Yes	257 (64)	1 (1.0)	3 (11)	

*Bold indicates statistically significant difference; Discrete variables as number (percentage). EDx = Electrodiagnostic test; DSL = Distal Sensory Latency; DML = Distal Motor Latency.

Statistical analysis

Continuous variables are presented as mean ± SD and discrete data as proportions. We used Student *t* tests to assess differences between continuous variables and Pearson's chi-square tests for discrete variables (or Fisher exact tests if the cell frequency < 5). Differences between proportions are reported with 95% confidence intervals (95% CIs).

Among the subset of patients diagnosed with median neuropathy at the carpal tunnel or normal electrophysiology on EDx, we calculated the number of patients within 10% of each threshold category (below or above 10% of the cutoff value) for each patient with median neuropathy and for each patient with a normal NCS (eg, 0.35-0.45 ms difference in median ulnar mixed nerve palmar latency).

We used diagnostic performance characteristics to measure discordance between clinical diagnosis and EDx.

We created a backward stepwise multivariable logistic regression model to assess factors independently associated with EDx of median neuropathy at the carpal tunnel. Variables with *P* less than .10 on bivariate analysis (Appendix A) were included in the final model. We considered *P* less than .05 significant.

We used all data available of all eligible patients who underwent NCSs for clinical CTS in our given timeline. A post hoc power analysis based on a binomial test demonstrated that a sample size of 510 patients with a normal distribution of the median DSL, which had a mean value of 4.9 and SD of 1.9, yielded greater than 99% statistical power to detect patients within 10% of the DSL cutoff value.

Results

The percentage of final measurements within 10% of the cutoff values for each of the 6 different NCS criteria ranged from 2.6% for the difference in median DML between sides to 33% for the median DSL (Table 4). Two (8.3%) of 24 patients diagnosed as EDx normal had an above-threshold median DSL within 10% of the cutoff (Fig. 1). Fifty-five (38%) of 144 patients with EDx of median neuropathy at the carpal tunnel had a below-threshold median DSL within 10% of the cutoff.

Seventy-six percent of EDx results (n = 407) were interpreted as median neuropathy, 19% (n = 103) as normal, and only 5% (n = 27) as another peripheral neuropathy (2 had nonlocalizing median neuropathy; 1 had a median neuropathy proximal to the flexor carpi radialis branch; 1 had a median neuropathy distal to the anterior interosseous branch; 4 had nonlocalizing ulnar neuropathy; 7 had CubTS; 17 had cervical radiculopathy; and

Table 4. Number of Patients Within 10% of the Threshold of EDx criteria per Diagnostic Group

	Median neuropathy n = 407	No median neuropathy n = 103	Overall n = 510
Variables n = 510	Frequency	Frequency	Frequency
Median DSL ≥ 3.6 (n = 510)	144 (35)	22 (21)	166 (33)
Median DML ≥ 4.4 (n = 509)	142 (35)	3 (2.9)	145 (29)
Difference in median-ulnar mixed nerve palmar latency ≥ 0.4 (n = 407)	37 (12)	10 (10)	47 (12)
Median motor amplitude ≤ 5.0 (n = 509)	33 (8.1)	2 (1.9)	35 (6.9)
Difference in median DML between sides ≥ 1.0 (n = 386)	10 (2.9)	0 (0)	10 (2.6)
Difference in median and ulnar DML same side ≥ 1.8 (n = 502)	67 (17)	0 (0)	67 (13)

EDx = Electrodiagnostic test; DSL = Distal Sensory Latency; DML = Distal Motor Latency.

5 had polyneuropathy; Table 2). These distributions were similar for specialists (78%; 17% and 5%, respectively) and nonspecialists (70%; 24% and 6%). Using diagnostic performance characteristics to quantify discordance between the final clinical diagnosis and EDx, the sensitivity among the different NCS criteria was highest for the difference in median-ulnar mixed nerve palmar latency (97%; Table 5). Specificity was between 95% and 97% for all measurements.

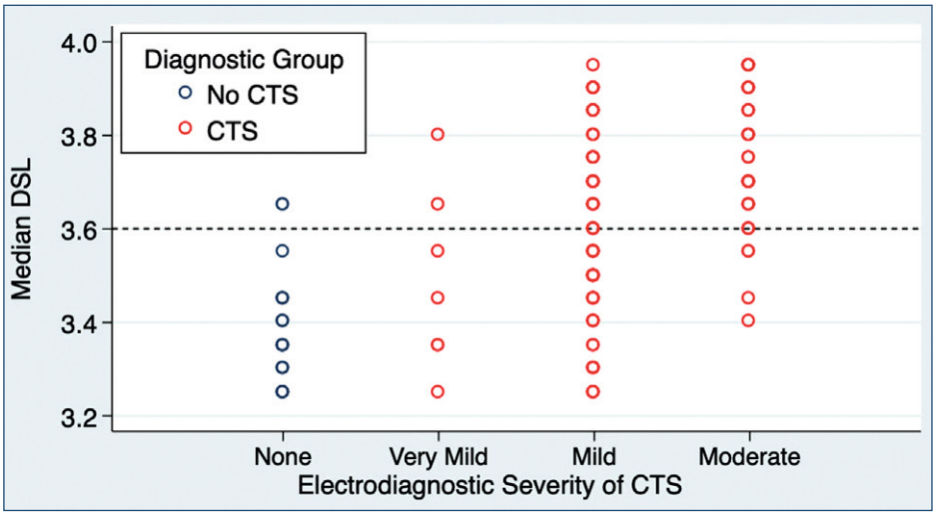

Figure 1. The median DSL among the 10% threshold is shown in comparison with the electrodiagnosis as assessed by the electrodiagnostician. The horizontal dotted line represents the threshold for abnormal median DSL of 3.6 ms. The individual circles may contain multiple measurements.

Accounting for potential interaction of variables using multivariable logistic regression analysis, older age (odds ratio [OR], 1.01; 95% CI, 1.0-1.1; $P < .05$), ipsilateral paresthesias/numbness (OR, 5.5; 95% CI, 2.2-14; $P < .05$), bilateral paresthesias/numbness (OR, 12; 95% CI, 4.9-32; $P < .05$), and previous contralateral CTR (OR, 12; 95% CI, 1.4-106; $P < .05$) were independently associated with increased likelihood of EDx of median neuropathy at the carpal tunnel (Table 6). A previous EDx interpreted as normal was independently associated with decreased likelihood of EDx diagnosis of median neuropathy at the carpal tunnel (OR, 0.16; 95% CI, 0.04-0.62; $P < .05$).

Table 5. Sensitivity and Specificity of the Different EDx Criteria.

Variables n = 537	Sensitivity[1]	Specificity[1]
Median DSL ≥ 3.6 (n = 537)	83%	96%
Median DML ≥ 4.4 (n = 536)	64%	97%
Difference in median-ulnar mixed nerve palmar latency ≥ 0.4 (n = 431)	97%	96%
Median motor amplitude ≤ 5.0 (n = 536)	21%	95%
Difference in median DML between sides ≥ 1.0 (n = 403)	21%	97%
Difference in median and ulnar DML same side ≥ 1.8 (n = 529)	64%	97%

[1]Values were rounded to the nearest integer. EDx = Electrodiagnostic test; DSL = Distal Sensory Latency; DML = Distal Motor Latency.

Table 6. Multivariable Logistic Regression Analysis of Factors Associated With Electrodiagnostic Median Neuropathy*

Retained variables	Odds Ratio	95% CI	*P* value
Age	1.01	1.0 to 1.1	**< 0.05**
Paresthesias/numbness			
Ipsilateral paresthesias/numbness	5.5	2.2 to 14	**< 0.05**
Bilateral paresthesias/numbness	12	4.9 to 32	**< 0.05**
Previous EDx			
Previous EDx ruled out median neuropathy	0.16	0.04 to 0.62	**< 0.05**
Previous EDx confirmed bilateral median neuropathy	7.4	0.99 to 56	0.05
Previous CTR			
Contralateral	12	1.4 to 106	**< 0.05**

*Bold indicates statistically significant difference; CI = Confidence Interval; EDx = Electrodiagnostic test; CTR = Carpal Tunnel Release.

Discussion

There is nuance in the distinction between normal and abnormal neurophysiology that limits the degree to which objective testing can be used to help determine the most effective strategies for diagnosis and treatment of median neuropathy at the carpal tunnel. This study used data from the care of patients in a single large hospital to measure the

prevalence of NCS values within 10% of accepted thresholds (a measure of the magnitude of the nuance situation); discordance between clinical and EDx diagnosis; and factors associated with normal EDx.

We acknowledge some study limitations. First, this is a retrospective study of usual clinical care with no standardization and limited data on physical examination and no measure of the pretest confidence of the physicians in the diagnosis (low physician confidence in the diagnosis of median neuropathy is highly predictive of normal NCS results[3]). Second, we used diagnostic performance characteristics to quantify the discordance between single electrodiagnostic parameter thresholds on the testing physician's overall interpretation (including EDx results), which might be confusing to readers expecting comparison with a reference standard. The use of clinical diagnosis has several limitations, one being that the EDx results were used to determine the final diagnosis. There is no consensus reference standard for the diagnosis of median neuropathy, so this examination of how EDx are used in standard practice has some value. Third, patients with CTS that were sent for EDx in this urban institution may not be representative of the population sent for testing in other hospitals or practice settings, which might limit generalizability. Fourth, the spectrum of measured pathophysiology may be specific to our testing paradigm (spectrum bias) with about a quarter of patients referred by nonspecialists, perhaps including some patients that were not experiencing numbness, although there were minimal differences in the tests ordered by specialists and nonspecialists. Fifth, the 95% CI for a previous contralateral CTR in our multivariable logistic regression model was substantial. This is likely because only 51 members of the cohort (9.5%) had had a previous CTR, of which only 1 patient fell in the no median neuropathy group in our data. However, sensitivity analysis without this variable did not change the model. Finally, some might wonder whether electrodiagnostic findings other than median neuropathy would have influence on the results. None of the patients without median neuropathy had CubTS and 23 patients had CubTS on the same side as the median neuropathy. In case of concomitant median neuropathy and CubTS, the median-ulnar comparisons could indeed be altered. If an electrodiagnostician finds motor or sensory nerve conduction slowing or less amplitude, she or he will test for possible CubTS (or Guyon neuropathy[21]) as well. In addition, the diagnosis of CubTS is made by some test criteria starting from the axilla to around and just below the elbow. There is only 1 criterion for CubTS that compares NCSs from above to below the elbow versus below the elbow to the wrist.[22] Therefore, we think that the other electrodiagnostic findings had little or no impact on the interpretation of the study results.

We found that up to a third of patients were within 10% of some of the threshold values for the diagnosis of median neuropathy, particularly the median DSL. Within these thresholds for the median DSL, 55 (38%) were false negatives based on clinical diagnosis (Figure 1). Sensory conduction studies are generally more sensitive than their motor counterparts.[23–25] The relationship between the median DSL and the severity of median neuropathy showed a large proportion of median DSL within the normal range among people diagnosed with median neuropathy (Figure 2). This is one reason that electrodiagnosis is based on side-to-side and ipsilateral ulnar- or radial-to-median comparisons in combination with absolute latencies.[4,11,14,26] In our cohort, neither the comparison of the median DML with the contralateral median DML nor the ipsilateral ulnar DML were within 10% of the thresholds in patients with normal NCSs. The median-ulnar mixed nerve palmar sensory latency difference was more sensitive for the detection of (mild) median neuropathy. Using comparisons also helps control for factors such as age, sex, body mass index, skin thickness, hand size, limb temperature, and comorbidities (eg, diabetes mellitus).[4,16,23,27,28] The AAEM, the American Academy of Neurology (AAN), and the American Academy of Physical Medicine and Rehabilitation (AAPMR) have done 2 systematic reviews of electrodiagnostic studies in CTS in 1993[11,20] and 2002[16,28] and have made and endorsed practice recommendations based on the findings[11,16,20,28], although no definitive thresholds are recommended. The current recommendations are (1) (standard) median sensory NCSs or mixed nerve NCSs across the wrist and a comparison with the ipsilateral ulnar or radial NCS in the forearm, across the wrist, or in the digital segments; (2) (guideline) median motor NCS from the thenar muscle and a comparison with another ipsilateral motor nerve NCS.[11,16,20,28] Supplementary NCSs like the residual latency (the time difference between the calculated expected and the observed conduction time) may, in mild cases of median neuropathy in which conventional NCS shows abnormalities only in sensory studies, better demonstrate the effect on the median nerve motor fibers and may raise the sensitivity of NCSs for the diagnosis of CTS[29], but this is still best described as an investigational option.[11,16,20,28]

We found that 76% of NCSs were interpreted as median neuropathy. In addition, 19% of people in whom the diagnosis of CTS was considered had no measurable median neuropathy. This is consistent with multiple prior studies that report up to 10% to 40% of patients with CTS having normal NCS testing.[4,5,9–11,30–32] This should not be interpreted as insensitivity of the test because we have no way of determining whether these patients have very mild median neuropathy. Five percent of our cohort had another electrodiagnostic diagnosis emphasizing that diagnosis based solely on symptoms or signs carries a small risk of misdiagnosis.[2,4–6,10,12,33] Specificities were over 95% for all

measurements indicating a low, but notable rate of false positives. The systematic reviews of the AAEM, AAN, and AAPMR report similar (pooled) sensitivities and specificities for the sensory and motor median nerve latencies.[16,28] Decision-making is affected by the fact that patients with median neuropathy are at risk for permanent nerve damage if the disease progresses, which some evidence following people over time and looking at the prevalence and severity of bilateral CTS suggests that it will do.[34,35] Consequently, patients with moderate disease sometimes consider surgery—even if they have few or no symptoms—in order to preserve nerve function. On the opposite end of the spectrum, patients with substantial symptoms and slight or no changes in NCSs can choose to safely put surgery off and manage the problem with night orthoses.[4]

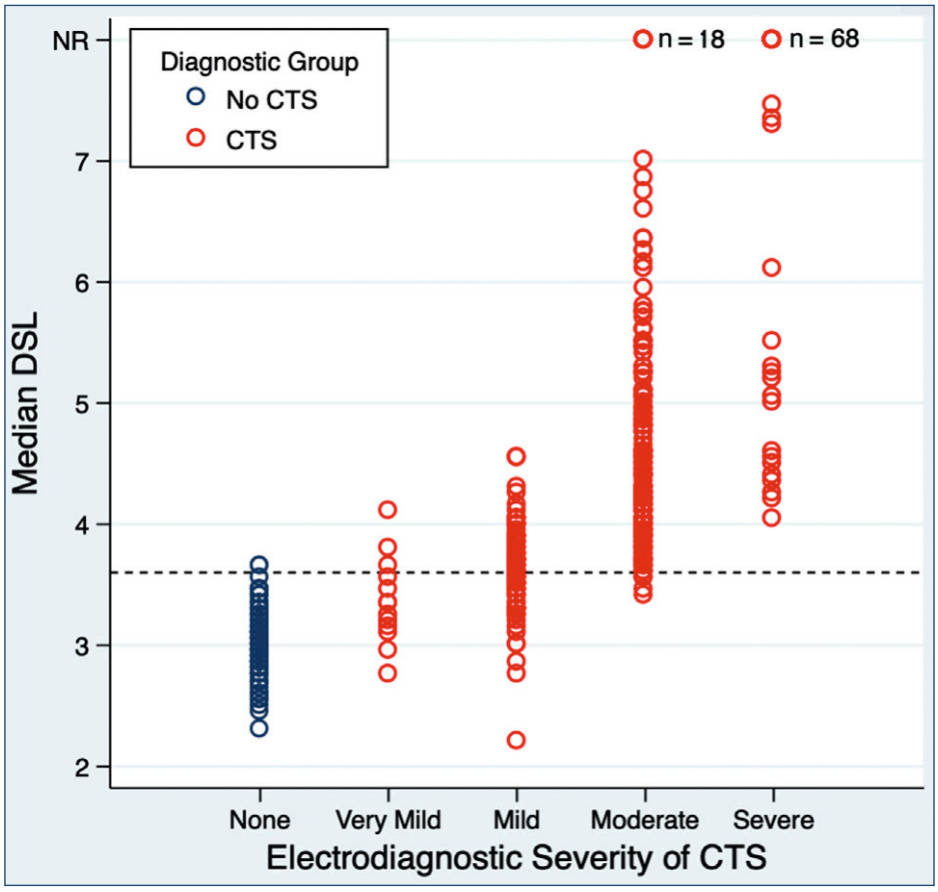

Figure 2. All values for the median DSL are shown in comparison with the electrodiagnostic severity of median neuropathy as measured by the electrodiagnostician; The horizontal dotted line represents the threshold for abnormal median DSL of 3.6 ms. The number of patients with a nonrecordable (NR) DSL is shown as n = X.

Older patients and patients with (ipsilateral and/or bilateral) paresthesias and numbness had an increased likelihood of electrodiagnosis of median neuropathy. Previous studies also found that patients with electrodiagnostically confirmed median neuropathy are significantly older[1,3,5,9] and report more sensory symptoms and paresthesias.[9] We had no information about the numbness being constant or intermittent or whether it was perceived as painful. The relationship between symptom severity and slower nerve conduction is inconsistent.[1,2,4–6,8–11,13,15,30–33] Most of the studies that found an association were limited to surgically treated patients and they used different NCS measures than recommended by the AAEM.[16]

There is an inherent imprecision in the electrodiagnostic distinction between mild and no median neuropathy (as documented in this and other studies) and no consensus reference standard for the diagnosis of idiopathic median neuropathy at the carpal tunnel, which emphasizes the impossibility of diagnostic certainty and leaves patients and surgeons with a conundrum. The daily practice of at a large institution documented herein and a clinical prediction rule such as the CTS-6[7] seems to have comparable levels of uncertainty and imprecision. Given the diagnostic uncertainty created by an absence of a reference standard, patients and surgeons can decide whether they are going to base treatment decisions on probabilities assigned on the basis of objective measures of neurophysiology or on symptoms and signs alone. Future studies can address the outcomes of the 2 treatment strategies in terms of median nerve function, patient-reported outcomes, and decision conflict and decision regret when various information is provided to patients.

Acknowledgments

We would like to thank M. van Suchtelen, M.A.M. Mulders, and C.E.S. Hoogstins, for their help in pilot work, study design, and data collection.

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Appendix A. Bivariate Analysis of Factors Associated With Electrodiagnostic Median Neuropathy*

Variables n = 510	Median neuropathy n = 407	No median neuropathy n = 103	*P* value
Age (y)	57 ± 15 (22-93)	48 ± 13 (19-76)	**< 0.05**
Sex			
Men	141 (35)	29 (28)	0.21
Women	266 (65)	74 (72)	
Paresthesias/numbness			
No	8 (2.0)	14 (14)	**< 0.05**
Ipsilateral	146 (36)	44 (43)	
Contralateral	4 (1.0)	1 (1.0)	
Bilateral	249 (61)	44 (43)	
Previous EDx			
No	337 (83)	93 (90)	**< 0.05**
No median neuropathy	4 (1.0)	7 (6.8)	
Ipsilateral median neuropathy	7 (1.7)	1 (1.0)	
Contralateral median neuropathy	10 (2.5)	1 (1.0)	
Bilateral median neuropathy	42 (10)	1 (1.0)	
Unknown results	7 (1.7)	0 (0)	
Previous CTR			
No	366 (90)	102 (99)	**< 0.05**
Contralateral	41 (10)	1 (1.0)	

Appendix A. *Continued.*

Variables n = 510	Median neuropathy n = 407	No median neuropathy n = 103	*P* value
Myelopathy			
No	402 (99)	102 (99)	0.99
Yes	5 (1.2)	1 (1.0)	
Cerebrovascular accident			
No	393 (97)	98 (95)	0.50
Yes	14 (3.4)	5 (4.9)	
Systemic inflammatory disease			
No	393 (97)	95 (92)	0.05
Yes	14 (3.4)	8 (7.8)	
Diabetes mellitus			
No	348 (86)	94 (91)	
Type 1	2 (0.5)	0 (0)	0.27
Type 2	57 (14)	9 (8.7)	
Hypothyroidism			
No	353 (87)	95 (92)	0.13
Yes	54 (13)	8 (7.8)	
Depression			
No	252 (62)	59 (57)	0.39
Yes	155 (38)	44 (43)	

*Bold indicates statistically significant difference; Continuous variables as mean ± SD (range); Discrete variables as number (percentage); EDx = Electrodiagnostic test; CTR = Carpal Tunnel Release.

Chapter 5

Electrodiagnostic Test Results in People with a Working Diagnosis of Cubital Tunnel Syndrome

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Journal of Orthopaedics
2023 Jan;36:114-119

Abstract

Background

Electrodiagnostic tests (EDx) can determine when symptoms and signs suggestive of idiopathic ulnar neuropathy at the elbow (cubital tunnel syndrome; CubTS) is due to measurable ulnar neuropathy at the elbow (UNE), cervical radiculopathy, or median neuropathy at the carpal tunnel, and when there is no measurable neuropathology associated with the symptoms. The role of EDx in management of CubTS is debated.

Questions

(1) What is the percentage of patients with CubTS (both including and excluding patients with a previous electrodiagnosis of idiopathic UNE) that have EDx results consistent with idiopathic UNE, other neuropathology, and no detectable neuropathology; (2) What factors (e.g. age and gender) are independently associated with electrodiagnosis of UNE.

Methods

We retrospectively reviewed all medical records of 133 patients with a working diagnosis of CubTS sent for EDx over a 5-year period in one large urban medical center. We recorded data on patient demographics, comorbidities, non-specialist or specialist referring physician, and EDx results.

Results

Among 133 patients, 61% (n = 81) of EDx identified idiopathic UNE, 14% (n = 18) identified other neuropathology, and for 26% (n = 34) there was no measurable neuropathology. Among the 14 patients with a previous ipsilateral or contralateral electrodiagnosis of UNE, all 14 had electrodiagnosis of UNE. Older age and men were independently associated with an increased likelihood of UNE.

Conclusions

The observation that people diagnosed with CubTS often do not have UNE, particularly if they are relatively young, suggests that the diagnosis of CubTS may benefit from a more stringent clinical prediction rule.

Introduction

It is important to distinguish symptoms and signs suggestive of a pathophysiology and objectively verifiable pathophysiology. For instance, the diagnosis of cubital tunnel syndrome (CubTS) may not always correspond with idiopathic ulnar neuropathy at the elbow/cubital tunnel (UNE). UNE is the second most common peripheral mononeuropathy of the upper extremity after idiopathic median neuropathy at the carpal tunnel (MNCT).[1–4] The symptoms and signs suggestive of UNE (paresthesia in the small and ring finger, worse with sustained elbow flexion or pressure over the cubital tunnel, progressing to loss of sensibility, loss of dexterity, and weakness and atrophy of the first dorsal interosseous muscle) are referred to as CubTS. The estimated annual incidence of diagnosed CubTS is up to 1 in 3000.[2,3,5] Given initial diagnosis of CubTS (at least with strict diagnostic criteria) tends to be associated with advanced UNE with weakness, loss of sensibility, and atrophy,[1,6,7] it is possible that UNE is often undiagnosed and may be much more common.[4,5] A population-based study of 1001 metropolitan United States residents identified a prevalence of CubTS between 1.8% (strict criteria) and 5.9% (inclusive criteria) using a survey of hand and upper extremity nerve compression symptoms and hand diagrams for numbness.[8] In a study of 102 patients with end-stage renal disease receiving hemodialysis at one unit, 90 were eligible and were screened for signs and symptoms of CubTS.[9] Among the 73 patients (81%) with at least 1 symptom or sign of CubTS, 37 (51%) had UNE on electrodiagnostic testing (EDx).[9] What is not clear is the degree to which this very high prevalence of UNE is related to renal insufficiency (or perhaps diabetes) or if this is a manifestation of the relatively older age of these patients.

Similar to MNCT, to date, there is no consensus reference standard for the diagnosis of UNE. Some clinicians believe that UNE meriting operative treatment may not be detectable on EDx,[10] while others consider this – at worst – very mild UNE and are concerned about potential misdiagnosis, and would not offer surgery.[7]

A study of patients referred for EDx with a working diagnosis of CubTS applied by both specialists and non-specialists in one medical center represents the spectrum of application of this diagnosis. The corresponding range of EDx test results can help determine when symptoms and signs suggestive of idiopathic UNE (CubTS) are due to measurable UNE, cervical radiculopathy, or MNCT, and when there is no measurable neuropathology to account for the symptoms. If there is a notable lack of correspondence between what clinicians guess is the cause of the symptoms and the electrophysiological evidence regarding what might be causing the symptoms, it would indicate a need for more stringent criteria for applying the diagnosis of CubTS. For instance, perhaps some people apply the diagnosis based on pain rather than paresthesia. Or perhaps provocative tests are

not adequately accounted for. An understanding of the current percentages of accurate diagnosis, inaccurate diagnosis, and absence of measurable pathology might aid in more accurate diagnosis based on symptoms and signs (e.g. clinical prediction rules), more selective use of EDx, and more appropriate utilization of operative treatment. Identification of factors such as age, gender, and contralateral prior UNE independently associated with electrodiagnosis of UNE might further inform construction of a better clinical prediction rule.

Materials and methods

Study design

This retrospective study was approved by our institutional review board. The only inclusion criterion was referral to the EDx testing center with a working diagnosis of CubTS. We excluded patients who were pregnant at the time of the EDx, had a known injury of the ulnar nerve of the affected arm, had polyneuropathy, or who previously underwent ipsilateral cubital tunnel release (CubTR). All electronic medical records of patients who underwent EDx tests over a 5-year period were manually reviewed – by research assistants not involved in patient care – to establish whether the patient fulfilled the predefined eligibility criteria. After application of inclusion and exclusion criteria, we had a consecutive series of 180 eligible patients with a working diagnosis of CubTS who were sent to an EDx unit in an academic institution in a large urban area to confirm or rule out UNE.

Outcome measures

The following data was derived from medical records at the time point prior to EDx: age, sex, symptomatic side, diagnosis of UNE or MNCT on previous EDx (Tables 1 and 2), diabetes mellitus, thyroid disease, and chronic inflammatory disease like ulcerative colitis or Crohn's disease (Appendices 1 and 2). Previous electrodiagnosis of UNE or MNCT was divided into the following categories: (1) no (not done or not electrodiagnostically confirmed); (2) ipsilateral; (3) contralateral to the symptomatic side; and (4) bilateral. Thyroid disease was divided into: (1) hypothyroidism; and (2) hyperthyroidism. We recorded if the referring physician was a specialist that treats CubTS (an orthopaedic surgeon, a plastic surgeon, a neurosurgeon, or a neurologist) or not (other specialty or non-specialist). Initial treatment given by the referring physician after EDx was also assessed and divided into: (1) unknown; (2) nonoperative; and (3) operative (Appendices 1 and 2).

The primary outcomes were electrodiagnosis of UNE, other neuropathology (e.g. MNCT, cervical radiculopathy, or brachial plexopathy), and no neuropathology.

Table 1. Patient and Clinical Characteristics Per Diagnostic Group for the Total Cohort*

Variable	Total cohort n = 133			
	No UNE n = 34 (26)	UNE n = 81 (61)	*P* value	Other neuropathology n = 18 (14)
Age, y	43 ± 13 (17-74)	53 ± 13 (16-83)	**<.001**	57 ± 12 (40-86)
Sex				
Women	21 (62)	30 (37)	**0.02**	9 (50)
Men	13 (38)	51 (63)		9 (50)
Symptomatic side				
Unilateral	28 (82)	69 (85)	0.78	12 (67)
Bilateral	6 (18)	12 (15)		6 (33)
Previous UNE[1]				
No	33 (100)	66 (83)		18 (100)
Ipsilateral	0 (0)	3 (3.8)	0.10	0 (0)
Contralateral	0 (0)	7 (8.8)		0 (0)
Bilateral	0 (0)	4 (5.0)		0 (0)
Previous MNCT[1]				
No	32 (97)	73 (91)		16 (89)
Ipsilateral	1 (3.0)	3 (3.8)	0.87	2 (11)
Contralateral	0 (0)	1 (1.3)		0 (0)
Bilateral	0 (0)	3 (3.8)		0 (0)

*Bold indicates statistically significant difference; Continuous variables as mean ± SD (range); Discrete variables as number (percentage); UNE: Ulnar neuropathy at the elbow; MNCT: median neuropathy at the carpal tunnel; [1]Data for 1 patient missing for the “No UNE” and the “UNE” groups.

Table 2. Patient and Clinical Characteristics Per Diagnostic Group Looking At the Cohorts With and Without a Previous UNE Diagnosis*

Variable	Without previous UNE n = 117				With previous UNE n = 14		
	No UNE n = 33 (28)	UNE n = 66 (56)	*P* value	Other neuropathology n = 18 (15)	No UNE n = 0	UNE n = 14 (100)	Other neuropathology n = 0
Age, y	44 ± 13 (17-74)	53 ± 13 (16-83)	**0.002**	57 ± 12 (40-86)	-	55 ± 14 (28-77)	-
Sex							
Women	20 (61)	24 (36)	**0.03**	9 (50)	0 (0)	5 (36)	0 (0)
Men	13 (39)	42 (64)		9 (50)	0 (0)	9 (64)	0 (0)
Symptomatic side							
Unilateral	27 (82)	57 (86)	0.56	12 (67)	0 (0)	11 (79)	0 (0)
Bilateral	6 (18)	9 (14)		6 (33)	0 (0)	3 (21)	0 (0)
Previous UNE							
No	-	-	-	-	-	0 (0)	-
Ipsilateral	-	-		-	-	3 (21)	-
Contralateral	-	-		-	-	7 (50)	-
Bilateral	-	-		-	-	4 (29)	-
Previous MNCT							
No	32 (97)	64 (97)	1.00	16 (89)	0 (0)	9 (64)	0 (0)
Ipsilateral	1 (3.0)	1 (1.5)		2 (11)	0 (0)	2 (14)	0 (0)
Contralateral	0 (0)	0 (0)		0 (0)	0 (0)	1 (7.1)	0 (0)
Bilateral	0 (0)	1 (1.5)		0 (0)	0 (0)	2 (14)	0 (0)

*Bold indicates statistically significant difference; Continuous variables as mean ± SD (range); Discrete variables as number (percentage); UNE: Ulnar neuropathy at the elbow; MNCT: median neuropathy at the carpal tunnel.

Electrodiagnostic testing

In our hospital system, in line with AANEM guidelines,[4,11] skin temperatures were monitored, the elbow was flexed between 70 and 90◦, and the following electrodiagnostic criteria for UNE were used: (1) above elbow to below elbow (AE to BE) nerve conduction velocity (NCV) of <50 m/s (m/s); (2) AE to BE NCV of >10 m/s slower than BE to wrist NCV; (3) >20% decrease of compound motor action potential (CMAP) from BE to AE; and (4) change of CMAP waveforms between AE and BE. We then calculated the number of patients for all EDx criteria per diagnostic group (Table 3). According to AANEM guidelines, a diagnosis of UNE was made when at least two out of four criteria were met.[4,11]

Study population

Within our timeline, a total of 180 patients were referred to the EDx unit for assessment of possible UNE. Forty-seven (26%) tests were excluded (25 had an ipsilateral trauma or lesion of the ulnar nerve; 21 had an ipsilateral previous decompression or transposition of the ulnar nerve; and 1 had polyneuropathy), leaving 133 patients for analysis. Fifty-six percent were referred by a specialist and the remaining 44% were referrals from other physicians from within or out of the hospital health care system. Fourteen patients had previous electrodiagnosis of UNE including 3 ipsilateral, 7 contralateral, and 4 bilateral.

Calculation

The distributions of continuous variables and assumptions concerning normality were assessed using histogram plots and Shapiro-Wilk tests to determine the appropriateness of the statistical tests. Continuous variables are presented as mean ± standard deviation and discrete data as proportions. We used Pearson correlation tests for the relationships between continuous variables, one-way analysis of variance tests to assess mean differences between categorical variables, Student's *t*-tests to assess differences between continuous variables, and Fisher's exact tests for discrete variables.

For further analysis, only the diagnostic groups (1) with UNE and (2) without UNE were used, omitting the group with another neuropathology.

We created a multivariable logistic regression model to assess factors independently associated with electrodiagnostically confirmed UNE (Table 4). We included all variables with $P < 0.10$ on bivariate analysis in the final model (Table 1). An odds ratio demonstrates the odds of having electrodiagnosis of UNE in one group as compared with another (for categorical variables) or a per-unit increase for continuous variables. The C statistic is a measure of model fit and is the area under the receiver operating characteristics curve. We considered $P < 0.05$ significant.

Table 3. Number of Patients Per Electrodiagnostic Criterion Per Diagnostic Group*

Variable	No UNE n = 34	UNE[1] n = 79	*P* value	Other neuropathology n = 18	*P* value
AANEM #1: AE to BE NCV <50m/s					
No	32 (94)	30 (38)	**<.001**	12 (71)	**<.001**
Yes	2 (5.9)	49 (62)		5 (29)	
AANEM #2: AE to BE NCV >10m/s slower than BE to wrist					
No	31 (91)	38 (48)	**<.001**	17 (100)	**<.001**
Yes	3 (8.8)	41 (52)		0 (0)	
AANEM #3: BE to AE CMAP decrease waveforms >20%					
No	33 (97)	64 (81)	**0.04**	16 (94)	**0.04**
Yes	1 (2.9)	15 (19)		1 (5.9)	
AANEM #4: Change of CMAP waveforms between AE to BE	*Not assessed*				

*Bold indicates statistically significant difference; Discrete variables as number (percentage); UNE: Ulnar neuropathy at the elbow; AANEM: American Association of Neuromuscular & Electrodiagnostic Medicine; AE: Above elbow; BE: Below elbow; NCV: Nerve conduction velocity; CMAP: Compound motor action potential; m/s: meter per second; [1]Data for 2 patients missing.

We did not perform an a priori power analysis since we included all eligible patients in our given timeline.

Results

Electrodiagnosis of UNE, other neuropathology, and no neuropathology

For the entire cohort of patients referred for EDx with a working diagnosis if CubTS, 61% of EDx results (n = 81) were interpreted as UNE, 26% (n = 34) as no neuropathology, and 14% (n = 18) as another diagnosis (9 had MNCT; 6 had cervical radiculopathy; 2 had peripheral neuropathy; and 1 had brachial plexopathy; Table 1). Patients with UNE were, on average, 10 years older (53 vs. 43 years old) and more likely to be men (63% vs. 38%), compared with the non-UNE group (Table 1).

Among the 14 patients with a previous electrodiagnosis of UNE (21% [n = 3] ipsilateral, 50% (n = 7) contralateral, and 29% (n = 4) bilateral), all had electrodiagnosis of UNE (Table 2).

In the group without a previous UNE electrodiagnosis, 56% of EDx results (n = 66) were interpreted as UNE, 28% (n = 33) as normal, and 15% (n = 18) as another diagnosis (Table 2).

Factors associated with electrodiagnosis of UNE

Among the subgroup of people without a prior electrodiagnosis of UNE, older age (odds ratio [OR] 1.1; 95% confidence interval [CI] 1.0 to 1.1; *P* = 0.003) and men (OR 2.5; 95% CI 1.0 to 6.2; *P* = 0.04; C statistic full model = 0.72) were independently associated with an increased likelihood of electrodiagnosis of UNE (Table 4). Interpreting the model, a 1-year increase in age increases the chance of having an electrodiagnosis of UNE by 1.1 times and men were 2.5 times more likely to have UNE than women.

Table 4. Multivariable Logistic Regression Analysis of Factors Associated With UNE*

Retained variable	Odds ratio	95% confidence interval	Standard error	*P* value	C statistic[1]
Age in years	1.1	1.0 to 1.1	0.02	**0.003**	
Men	2.5	1.0 to 6.2	1.2	**0.04**	0.72
Previous UNE[2]	*Omitted from model: perfect prediction*				

*Bold indicates statistically significant difference; UNE: ulnar neuropathy at the elbow; [1]The C statistic is a measure of model fit and is the area under the receiver operating characteristics curve; [2]Either ipsilateral, contralateral, bilateral.

Discussion

Idiopathic UNE is the second most common peripheral mononeuropathy of the upper extremity.[1–4] We assessed discrepancies between the number of patients with a working diagnosis of CubTS sent for EDx and those with objectively verifiable pathophysiology (UNE). We found that 100% of patients with ipsilateral or contralateral UNE in the past had confirmed UNE, but among people with no prior diagnosis, just over half had UNE, nearly a third had normal tests, and 14% had another neuropathology and this was true for both specialists and non-specialists.

This study has some limitations. First, this is a retrospective study with no systematic collection of data on symptoms or examinations, and no protocol utilizing diagnostic scores, clinical prediction rules, or clinician pretest confidence in the diagnosis. For instance, we did not have data available for the presence of osteoarthritis or deformity of the elbow, which could aid in diagnosing CubTS and make clinicians more confident that EDx would be positive for UNE. On the other hand, we consider it a good representation of daily practice because it represents all the EDx performed at a large institution from multiple specialist and non-specialist referring physicians. The exact numbers might change in different settings, but the observation that a clinical diagnosis is often not supported by EDx results is unlikely to change. A more structured study would be able to better distinguish people sent for confirmation and people sent to exclude idiopathic UNE as a cause of the symptoms. Second, patients with suspected UNE that were sent for EDx in this large urban institution may not be representative of the population sent for testing in other areas, hospitals or practice settings, which might limit generalizability. Third, this sample represents all ordered tests by many different health care providers. However, 56% (n = 75) were referred by a specialist. The working diagnoses of CubTS, as currently made based on symptoms and signs, might be suboptimal for a substantial number of patients. We feel that this testing paradigm is representative of the typical paradigm in the United States. Finally – and maybe most importantly, there is no consensus reference standard for the diagnosis of UNE. The American Academy of Orthopaedic Surgeons has a clinical practice guideline for CTS, but not for CubTS.[12] The American Association of Electrodiagnostic Medicine (AAEM) published practice guidelines with standards and recommendations for additional EDx studies for patients diagnosed with UNE in 1999[4,11] and many electrodiagnosticians use these standards.[2,13–17] Based on a critical review of 13 out of 398 studies, the AANEM report sensitivities ranging from 37% to 86% and specificities of 95% or greater for the various nerve conduction measures, i.e. latencies and amplitudes.[4] The lack of a reference standard for UNE and the broad

range in sensitivities for EDx highlight room for improvement in electrodiagnosis of UNE. Therefore, the actual percentage of patients with UNE in this cohort might be higher or lower. Some may wonder about the absence of thoracic outlet syndrome. But thoracic outlet syndrome is variably diagnosed (in our hands it is rare and typically associated with other pathophysiology such as clavicle malunion, an anomalous rib, or subclavian vein thrombosis), typically diagnosed based on pain rather than paresthesia, and nearly always diagnosed in the absence of electrodiagnostic abnormality, which is a primary reason we do not find the diagnosis useful (not objectively verifiable and potentially socially constructed). No one in the cohort was diagnosed with thoracic outlet syndrome by the independent group of neurologists and physical medicine physicians that staff the electrodiagnostic lab, further supporting the relatively limited utility of the diagnosis in our opinion.

The observation that fewer than two out of three patients with a provisional diagnosis of CubTS received an electrodiagnosis of UNE and 14% had a different nerve problem (e.g. cervical radiculopathy) suggest the potential benefits of a more stringent set of symptoms and signs (clinical prediction rule) for CubTS. Another prior similar review of 283 patients found 58% had an electrodiagnosis of UNE, 35% had no measurable neuropathology, and 6.7% were uncertain.[14] In a study of 350 worker compensation patients who had surgery for CubTS, 34% of EDx results were not consistent with AANEM guidelines, which raises the concern that overvaluing imprecise syndromes might increase the potential for unnecessary or unhelpful surgery.[17]

The finding that older age and men were more likely to develop UNE, is generally consistent with other studies[2,3,5,6,14,16,17] and also supports the concept that this is an inherent, slowly progressive disease. The observation that UNE detected before did not resolve, combined with the fact that everyone tested who had known ulnar neuropathy on the other side had it on the newly tested contralateral side, is consistent with the concept that idiopathic mononeuropathy at the cubital tunnel is a structural, slowly progressive disease.

Conclusions

The high rate (39%) of patients with a working diagnosis of clinical CubTS that had no measurable neuropathology, with no difference between specialists and non-specialist referring physician, suggests a potential role for improved diagnostic criteria (clinical prediction rule). A test has better diagnostic performance characteristics when the pre-test likelihood of diagnosis is higher. Ordering a test because one is confused and uncertain

often has more potential for harm than benefit. Therefore, ordering a test to confirm a likely diagnosis is preferred. If we can agree that mild UNE is best treated nonoperatively,[13] then an improved clinical prediction rule with a higher probability of moderate to severe UNE could limit the role of EDx, and reduce the potential for unhelpful or unnecessary surgery. Said differently, there seems to be a need for comfort with less specific diagnoses in the absence of characteristic symptoms and signs. Applying a specific diagnosis such as CubTS might be associated with less appropriate and potentially harmful treatment strategies than a less specific diagnosis such as nonspecific arm pain or nonspecific paresthesia.

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Appendix 1. Additional Patient and Clinical Characteristics Per Diagnostic Group for the Total Cohort*

Variable	Total cohort n = 133			
	No UNE n = 34 (26)	UNE n = 81 (61)	*P* value	Other neuropathology n = 18 (14)
Diabetes Mellitus[1]				
No	31 (94)	70 (88)	0.50	16 (89)
Yes	2 (6.1)	10 (13)		2 (11)
Thyroid disease[1]				
No	29 (88)	76 (95)		17 (94)
Hypothyroidism	3 (9.1)	2 (2.5)	0.26	1 (5.6)
Hyperthyroidism	1 (3.0)	2 (2.5)		0 (0)
Chronic inflammatory disease[1]				
No	25 (76)	61 (76)	1.00	16 (89)
Yes	8 (24)	19 (24)		2 (11)
Treatment given				
Unknown	15 (44)	9 (11)		7 (39)
Nonoperative	19 (56)	42 (52)	**<.001**	11 (61)
Operative	0 (0)	30 (37)		0 (0)

*Bold indicates statistically significant difference; Discrete variables as number (percentage); UNE: Ulnar neuropathy at the elbow; [1]Data for 1 patient missing for the “No UNE” and the “UNE” groups.

Appendix 2. Additional Patient and Clinical Characteristics Per Diagnostic Group Looking at the Cohorts With and Without a Previous UNE Diagnosis*

Variable	Without previous UNE n = 117				With previous UNE n = 14		
	No UNE n = 33 (28)	UNE n = 66 (56)	*P* value	Other neuropathology n = 18 (15)	No UNE n = 0	UNE n = 14 (100)	Other neuropathology n = 0
Diabetes Mellitus							
No	31 (94)	59 (89)	0.71	16 (89)	0 (0)	11 (79)	0 (0)
Yes	2 (6.1)	7 (11)		2 (11)	0 (0)	3 (21)	0 (0)
Thyroid disease							
No	29 (88)	62 (94)		17 (94)	0 (0)	14 (100)	0 (0)
Hypothyroidism	3 (9.1)	2 (3.0)	0.43	1 (5.6)	0 (0)	0 (0)	0 (0)
Hyperthyroidism	1 (3.0)	2 (3.0)		0 (0)	0 (0)	0 (0)	0 (0)
Chronic inflammatory disease							
No	25 (76)	51 (77)	1.00	16 (89)	0 (0)	10 (71)	0 (0)
Yes	8 (24)	15 (23)		2 (11)	0 (0)	4 (29)	0 (0)
Treatment given							
Unknown	14 (42)	8 (12)		7 (39)	0 (0)	1 (7.1)	0 (0)
Nonoperative	19 (58)	34 (52)	**<.001**	11 (61)	0 (0)	7 (50)	0 (0)
Operative	0 (0)	24 (36)		0 (0)	0 (0)	6 (43)	0 (0)

*Bold indicates statistically significant difference; Discrete variables as number (percentage); UNE: Ulnar neuropathy at the elbow.

Part III Shared Decision-Making

Chapter 6

Patient Perspectives on Decision Making for Carpal Tunnel Syndrome

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The Journal of Hand Surgery American Volume
2019 Nov;44(11):940-946.e4
Editor's choice

Abstract

Purpose

Interventions that improve a patient's understanding of the problem and their options might reduce surgeon-to-surgeon variation, activate healthier patient behaviors and mindset, and optimize stewardship of resources while improving quality of care. Patients with carpal tunnel syndrome (CTS) have more uncertainty about which course of action to take (so-called decision conflict) than hand surgeons. We studied patient preferences regarding shared decision making (SDM) for different parts of the treatment for CTS. We assessed the following hypotheses: (1) Younger age does not correlate with a preference for greater involvement in decisions; (2) Demographic and socioeconomic factors are not independently associated with (A) preferences for decision making (separated into preoperative, operative, postoperative, and the full SDM scale) and (B) the Control Preference Scale; (3) the SDM scale does not correlate with the Control Preference Scale.

Methods

We prospectively invited 113 new and postoperative patients with CTS to participate in the study. We recorded their demographics and they completed the SDM scale and the Control Preference Scale.

Results

The full SDM scale and all subsets showed a patient preference toward sharing the decisions for treatment with the surgeon with a moderate tendency toward patients wanting more surgeon involvement in decision making. On multivariable analysis, having commercial insurance compared with Medicare was independently associated with a preference for less surgeon involvement (ie, higher SDM scores) in decision making (regression coefficient, 0.60; 95% confidence interval, 0.03-1.2).

Conclusions

Patients with CTS generally prefer to share decisions with their surgeon with a tendency for more surgeon involvement especially in the operative and postoperative period.

Clinical relevance

Decision aids and preference elicitation tools used to ensure diagnostic and treatment decisions for CTS that are aligned with patient preferences are needed. Future studies might address the routine use of these tools on patient outcomes.

Introduction

Evidence-based practice combines patient preferences with the best available scientific evidence and clinical expertise.[1] Patient-centered care embodies physicians' interest in an individual's preferences based on their values and attempts to verify patient understanding of their illnesses.[1–3] Over the years, decision making has transformed from a paternalistic model (1-way exchange of information from physician to patient), a health-provider-as-agent model (physician chooses treatment based on what he or she believes is in the patient's best interest), an informed decision-making/consumerist model (patient makes a decision after learning the risks and benefits of the options), to a shared decision-making (SDM) model (all parties [physician, patient, and patient relatives] participate in the process and all share their unbiased information and values, ending in the final step of sharing a treatment decision on which all agree).[1–11] The key to effective SDM is clear and open communication and a trusting relationship to become familiar with a patient's values. Although there are known logistical challenges and barriers to following a structured process for SDM, it is imperative to correct misconceptions and to ensure that patient choices are consistent with their values and preferences.

Interventions that improve a patient's understanding of the problem and their options can increase the likelihood that choices are consistent with their values and not based on misconceptions or biases (eg, friends, family, or surgeon). These types of interventions might also reduce surgeon-to-surgeon variation,[12–17] which can be utilized as a measure of the effectiveness of SDM and the relative influence of surgeon preferences, bias, and incentives. In addition, care based on evidence and patient values is our best opportunity to optimize stewardship of resources. For instance, an infirm patient with carpal tunnel syndrome (CTS) that is averse to surgery may choose nonsurgical treatment, despite continued nerve damage. Evidence to date shows positive results of patient-centered care — including patient participation in SDM — including improvements in health outcomes, quality of life, and satisfaction and adherence with treatment plans in part by reducing decision conflict.[1–5,7–9,11,18–20] Decision conflict — a state of uncertainty about the course of action to be taken — can be greater when there is debate regarding optimal treatment or when clinician and patient biases differ in meaningful ways.[6,21,22] Tools like decision aids are intended to reduce decision conflict.

When there is inconclusive evidence regarding diagnostic and treatment options, physicians can help patients choose options most in line with their values and preferences.[21] In the management of CTS, there are several areas of debate that can contribute to uncertainty about which course of action to take, including the role of electrodiagnostic testing, use of corticosteroid injections, or considering surgery when the electrodiag-

nostic test results are normal.[5,6] Hand surgeons consider CTS relatively straightforward and tend to have less decision conflict than their patients.[6] A study among 103 hand surgeons and 79 patients with CTS revealed that, when citing advantages of treatment, patients ranked “Does not involve surgery” highly, whereas surgeons found “No major risks or side effects” most important.[22] Tests such as electrodiagnostic tests and imaging and treatments such as orthosis wear or steroid injection are discretionary and preference-sensitive, a situation well suited to SDM.[3,5]

We wanted to test patient preferences regarding SDM for various aspects of the treatment of CTS. We therefore assessed (1) the correlation between younger age and wanting more shared decisions; (2) whether demographic and socioeconomic factors are independently associated with (A) preferences for SDM (separated into preoperative, operative, post- operative, and the full scale), and (B) the Control Preference Scale; and (3) if the SDM scale correlated with the Control Preference Scale.

Materials and Methods

Study design

After institutional review board approval of this cross-sectional, observational, cohort study, we prospectively enrolled 113 patients over the course of 5 months. Patients were evaluated by 1 of 3 hand surgeons (D.R., G.A.V., and L.M.R.) at 3 orthopedic surgery offices in a large urban area. We included all new and follow-up, English- or Spanish-speaking adult patients with electrodiagnostically confirmed CTS or with a very high likelihood of having CTS, based on a CTS-6 score of 12.5 or greater.[23] We excluded patients who were not fluent in English or Spanish or who could not provide informed consent. Research assistants, who were not involved in treatment, described the study to eligible patients before or after the visit with the surgeon. We were granted a waiver of documentation of informed consent.

Outcome measures

Patients were asked to complete a set of questionnaires in the following order: (1) a demographic illness questionnaire consisting of age, sex, native language (English or Spanish), race/ethnicity, marital status, level of education, work status, insurance, annual yearly household income, type of visit (first/ preoperative visit or follow-up/postoperative visit), side(s) of CTS, and previous carpal tunnel release; (2) the SDM scale; and (3) the Control Preference Scale.

Two fellowship-trained hand surgeons from the Hand Surgery Quality Consortium (of which one is an author [D.R.]) identified the most common decisions made during the surgical treatment course of CTS and created a process map consisting of 27 questions (Appendix A). It addresses questions for various decisions that need to be made during the course of diagnosing and treating CTS including type of imaging, surgery, date/time/location of surgery, anesthesia modality, antibiotics, suture type, dressing type, pain medication, rehabilitation protocols, and return to work. We adapted the Control Preference Scale to be scored on a scale from -5 ("Only my doctor") to 5 ("Only me"), with 0 being a preference for SDM ("My doctor and I together"). The total score is the overall decision score and is the sum of all decision ratings divided by the number of questions (27 for the full scale). We interpreted the scores as preferring the surgeon to decide (more) for scores ranging from -5 to -1.7, a preference for SDM for scores ranging from -1.7 to 1.7, and scores ranging from 1.7 to 5 as preferring letting the patient decide more. The internal consistency of this new scale was excellent (Cronbach alpha, 0.92).

The Control Preference Scale was used as an overall measure to assess patients' preferences for desiring shared-decisions (Appendix B).[24] Patients were asked to indicate 1 of 5 cards that indicated their preferred role when making medical decisions. The first 2 cards indicated preference for letting the patient decide, the third one a completely shared decision, and the final 2 a preference for letting the surgeon decide. The Control Preference Scale was developed for participants to make paired observations and calculating an overall SDM score.[24] We asked patients to indicate 1 card that best described their preferences. The scores ranged from -2 to 2 and we inverted the scores at the end to point both scales in the same direction (ie, positive scores indicate patients want to be more involved in the decisions). The Control Preference Scale can be adapted to various fields of medicine and internal consistencies have been found to be acceptable (Cronbach alpha, 0.72-0.74).[25,26]

All questionnaires were administered on an encrypted tablet via REDCap (Research Electronic Data Capture: a secure Web-based application for building and managing online surveys and data- bases), a secure, Health Insurance Portability and Accountability Act (HIPAA)–compliant electronic platform.[27]

Study sample

No patients were excluded from analysis. The mean age of the 113 patients was 56 ± 15 years, 33 (29%) were men, and the majority (n = 107; 95%) was native English-speaking (Table 1). About 1 in 5 patients (n = 24; 21%) had experienced a previous carpal tunnel release.

Table 1. Patient and Clinical Characteristics*

Variables	n = 113
Age, y (range)	56 ± 15 (21-87)
Men, n (%)	33 (29)
Native language, n (%)	
Spanish	5 (5.3)
English	107 (95)
Race/ethnicity, n (%)	
White	68 (60)
Latino/Hispanic	23 (20)
Black/African American	14 (12)
Other	8 (7.1)
Marital status, n (%)	
Married	77 (68)
Divorced/separated/widowed	21 (19)
Single	15 (13)
Level of education, n (%)	
High school or less	23 (20)
Some college	39 (35)
College graduate	32 (28)
Master's degree or more	19 (17)
Work status, n (%)	
Employed	61 (54)
Retired	35 (31)
Unemployed/disabled	17 (15)
Insurance, n (%)	
Commercial/military	65 (58)
Medicare	36 (32)
Public safety net/no insurance	12 (11)
Income, n (%)	
< $50,000	40 (35)
$50,000-$99,999	33 (29)
$100,000-$199,999	21 (19)
> $200,000	19 (17)
Type of visit, n (%)	
First/preoperative visit	77 (68)
Follow-up/postoperative visit	36 (32)

Table 1. *Continued.*

Variables	n = 113
Side CTS, n (%)	
Unilateral	56 (50)
Bilateral	57 (50)
Previous CTR, n (%)	24 (21)
Control Preference Scale, n (%)	
A: I prefer to leave the decision to my doctor	5 (4.4)
B: I prefer my doctor makes the selection after considering my opinion	28 (25)
C: My doctor and I should decide together	55 (49)
D: I prefer to make the selection after considering my doctor's opinion	23 (20)
E: I prefer to make the selection of the treatment	2 (1.7)
SDM cards continuous (possible range -2 to 2), (range)	-0.10 ± 0.83 (-2.0-2.0)
SDM total (possible range -5 to 5), (range)	-2.1 ± 1.4 (-5.0-1.5)
SDM preoperative	-1.4 ± 1.7 (-5.0-5.0)
SDM operative	-1.9 ± 1.6 (-5.0-1.7)
SDM postoperative	-2.6 ± 1.7 (-5-0.77)

*Continuous variables as mean ± SD (range); Discrete variables as number (%).
CTS: carpal tunnel syndrome; CTR: carpal tunnel release; SDM: shared decision-making.

Statistical analysis

The distributions of continuous variables and assumptions concerning normality were assessed to determine the appropriateness of the statistical tests. Continuous variables are presented as mean ± SD and discrete data as proportions. We used Pearson correlation tests for the relationships between continuous variables, 1-way analysis of variance tests to compare continuous variables between more than 2 groups, Student *t* tests to assess differences between continuous variables, and Fisher exact tests for discrete variables. We created 3 multivariable linear regression models to assess factors independently associated with (1) the full SDM scale, (2) the postoperative SDM subscale, and (3) the Control Preference Scale. We included all variables with *P* less than .10 on bivariate analysis in the final models (Appendix C). We did not create multivariable models for the preoperative and operative SDM subscales (all variables $P > .10$). The regression coefficient (b) indicates the change in the value of a dependent variable corresponding to the unit change in the independent variable. The higher the absolute value of the

coefficient, the stronger the effect of the relationship. There is no fixed cutoff score. Adjusted R^2 values indicate the amount of variability in the dependent variable accounted for by the model. Semipartial R^2 expresses the specific variability of a given independent variable in the model. We considered *P* less than .05 significant.

An a priori power analysis indicated that 113 patients would provide 90% statistical power (with alpha set at 0.05) to detect a correlation between younger age and wanting more shared decisions.

Results

Overall, the full SDM scale (-2.1 ± 1.4) and all subsets (-1.4 ± 1.7; -1.9 ± 1.6; and -2.6 ± 1.7 for preoperative, operative, and postoperative, respectively) showed a patient preference toward partially sharing the decisions for treatment with the surgeon with a moderate tendency toward more surgeon involvement (Table 1). Patients chose a neutral role (ie, surgeon and patient take equal roles in decision making) when looking at the Control Preference Scale (-0.10 ± 0.83).

Correlation of age and SDM

Age had a weak, inverse correlation with the postoperative SDM subscale only on bivariate analysis (r = -0.21; P < .05; Appendix C).

Factors associated with SDM

Having commercial or military insurance (compared with Medicare) was independently associated with wanting less surgeon involvement (ie, higher SDM scores) in decision making on the full SDM scale, after accounting for potential interaction of variables using multivariable analysis (regression coefficient [b], 0.60; 95% confidence interval [95% CI], 0.03-1.2; P < .05; partial R^2 = 0.04; adjusted R^2 full model = 0.03; Table 2). There are no fixed cutoff scores for the beta regression coefficients. For example, this model shows that patients with commercial or military insurance are expected to have a 0.60 higher score on the full SDM scale (ie, wanting to have less surgeon involvement in decision making).

No variables were independently associated with the postoperative SDM subscale (Table 2).

Table 2. Multivariable Regression Analyses of Factors Associated With the Total SDM, the SDM subscales, and With the SDM Cards*

Dependent Variables	Retained Variables	Regression Coefficient [β] (95% CI)	Standard Error	*P* Value	Semipartial R^2	Adjusted R^2
SDM total	Insurance					
	Medicare	Reference value				
	Commercial/military	0.60 (0.03 to 1.2)	0.28	**< 0.05**	0.04	0.03
	Public safety net/no insurance	-0.13 (-1.0 to 0.77)	0.46	0.77		
SDM postoperative	Age	-0.02 (-0.05 to 0.01)	0.01	0.17		0.06
	Native language					
	Spanish	Reference value				
	English	1.6 (-0.05 to 3.2)	0.81	0.06		
	Insurance					
	Medicare	Reference value				
	Commercial/military	0.42 (-0.45 to 1.3)	0.44	0.34		
	Public safety net/no insurance	0.35 (-0.98 to 1.7)	0.67	0.60		
CPS	Insurance					
	Medicare	Reference value				
	Commercial/military	0.11 (-0.23 to 0.45)	0.17	0.52		0.03
	Public safety net/no insurance	-0.47 (-1.0 to 0.07)	0.27	0.09		

*Bold indicates statistically significant difference.

CI: Confidence Interval; only the semipartial R^2 of significant variables is displayed; CPS: Control Preference Scale; SDM: shared decision-making; No multivariable model for SDM preoperative or SDM operative.

Correlation of the SDM measures

The SDM scale and the Control Preference Scale correlated moderately (r = 0.35; P < .05; not in table). Other interquestionnaire correlations between the full SDM scale, the SDM subscales, and the Control Preference Scale ranged from weak to strong correlations (r = 0.24-0.89) and were all P < .05 (not in table).

Discussion

Patients with CTS have more uncertainty about which course of action to take (so-called decision conflict) than hand surgeons.[6] The choice of treatment strategy is based on one's values and assessment of the probabilities of various outcomes. In other words, CTS is a preference-sensitive condition in which SDM is important. We found that patients with commercial or military insurance wanted less surgeon involvement in the decision-making process.

This study has some limitations. First, the majority of our patients visited their hand surgeon for the first time. It might be that patients have not yet built a solid, trusting relationship with their hand surgeon and initially want to decide more themselves until they have established this relationship with their hand surgeon. Second, we did not assess symptom severity. It might be that patients who have more symptoms want to be more involved in decision making than patients with minimal symptoms, as Roh et al[9] found in a study of 149 patients with CTS using the Control Preference Scale. Third, we did not assess health literacy. Poor health literacy is sometimes related to a more passive patient role in surgical decision-making in CTS.[9] Fourth, the original Control Preference Scale was made for participants to make paired observations of preferences for SDM or to put them in ranking order. However, we asked patients to only address their most preferred role in the decision-making process. This might have skewed some of the data. In addition, whereas one might assume that most patients would prefer to share the decision equally with their surgeon, many patients preferred more or less involvement: 4.4% surgeon only, 25% (surgeon decides with patient's opinion in mind, 49% neutral, 20% patient decides with surgeon's opinion in mind, and 1.8% patient only, respectively). Fifth, because of the limited associations on bivariate analysis, we only created 3 out of 5 possible multivariable models to assess independent factors associated with SDM and the Control Preference Scale. It might be that other patient factors not assessed in this study have associations with SDM. For example, the geographical location of patients could influence decision-making because costs for treatments vary substantially within

and between countries. Because this study was done in one large urban area, we were not able to test these influences on SDM. Finally, the SDM scale was adapted from the Control Preferences Scale specifically for this study; its internal consistency was excellent (Cronbach a, 0.92). Although the process map was made for common decisions during care for CTS, it is possible that patient involvement would have identified additional decisions that warrant exploration.

The finding that most patients want to share decisions equally with their surgeon is consistent with a study of 78 patients who underwent carpal tunnel release that found 76% preferred a shared decision for surgery, 6% to decide more on their own, and 18% wanted the surgeon to decide.[3] In a study surveying hand surgeons and patients with a trigger finger, surgeons wanted to share decisions, but patients preferred to make their own choices after receiving all information from the surgeon.[21] Among 101 patients undergoing elective vascular surgery, 90% of patients wanted to discuss all treatment options and wanted to make the final choice for treatment together with their physician.[2] Several factors may account for these varied preferences for SDM. For instance, patients with greater out-of-pocket expenses may seek greater involvement in decision making. In addition, perhaps older patients and patients with greater socioeconomic deprivation are more deferential. A recent study surveying 117 orthopedic patients seeing surgeons of all subspecialties found no patient demographic factors associated with either observed or perceived patient involvement in decision making.[11] The weight of evidence – in both CTS and other diagnoses – suggests that surgeons should take specific steps to ensure that patients feel involved in decision making.

Age had no independent influence on decision preference in this study, perhaps because it is confounded with Medicare insurance. This is consistent with a study of adults aged 65 years and older with hand conditions that found that 81% preferred a more patient-directed role on the Control Preference Scale.[7] Because age and Medicare are associated, we cannot discern whether the type of insurance is a factor beyond age. In a tertiary (exploratory) analysis, we checked a multivariable model excluding insurance and age was not significant, suggesting that age did not influence SDM.

This study, and the weight of evidence to date, suggests that patients with CTS generally prefer to share decisions with their surgeon. In our opinion, one potential reason for the notable observed variations in care between surgeons may be surgeon biases and perhaps uncorrected misconceptions are having more influence on decision-making than patients desire. It can be difficult to convey expertise based on current best evidence in an unbiased way with limited time in the office. All humans (both surgeons and patients) have biases. It may take some effort to identify patient values and ensure that

decisions are consistent with those values. Future research might measure the influence of specific communication strategies or tools intended to help patients feel welcomed in the decision process, and specifically to help them explore their values, understand surgeon habits and biases, and neutralize biases and misconceptions using adjuncts to the clinician-patient discussion. The use of decision aids, preference elicitation tools, question prompt lists, and other tools merit additional study.

Acknowledgments

We would like to thank the Hand Surgery Quality Consortium for their help initiating this study and creating the SDM scale.

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Appendix A. Shared Decision-Making Questions

The following questions include examples of various decisions that need to be made during the course of diagnosing and treating carpal tunnel syndrome. We are asking you to give us your opinion on who should be making these decisions: you, your doctor, or a shared decision between the two of you for each of the following decisions. Scores range from 0 to 10:

Only my doctor				My doctor and I together						Only me
-5	-4	-3	-2	-1	0	1	2	3	4	5

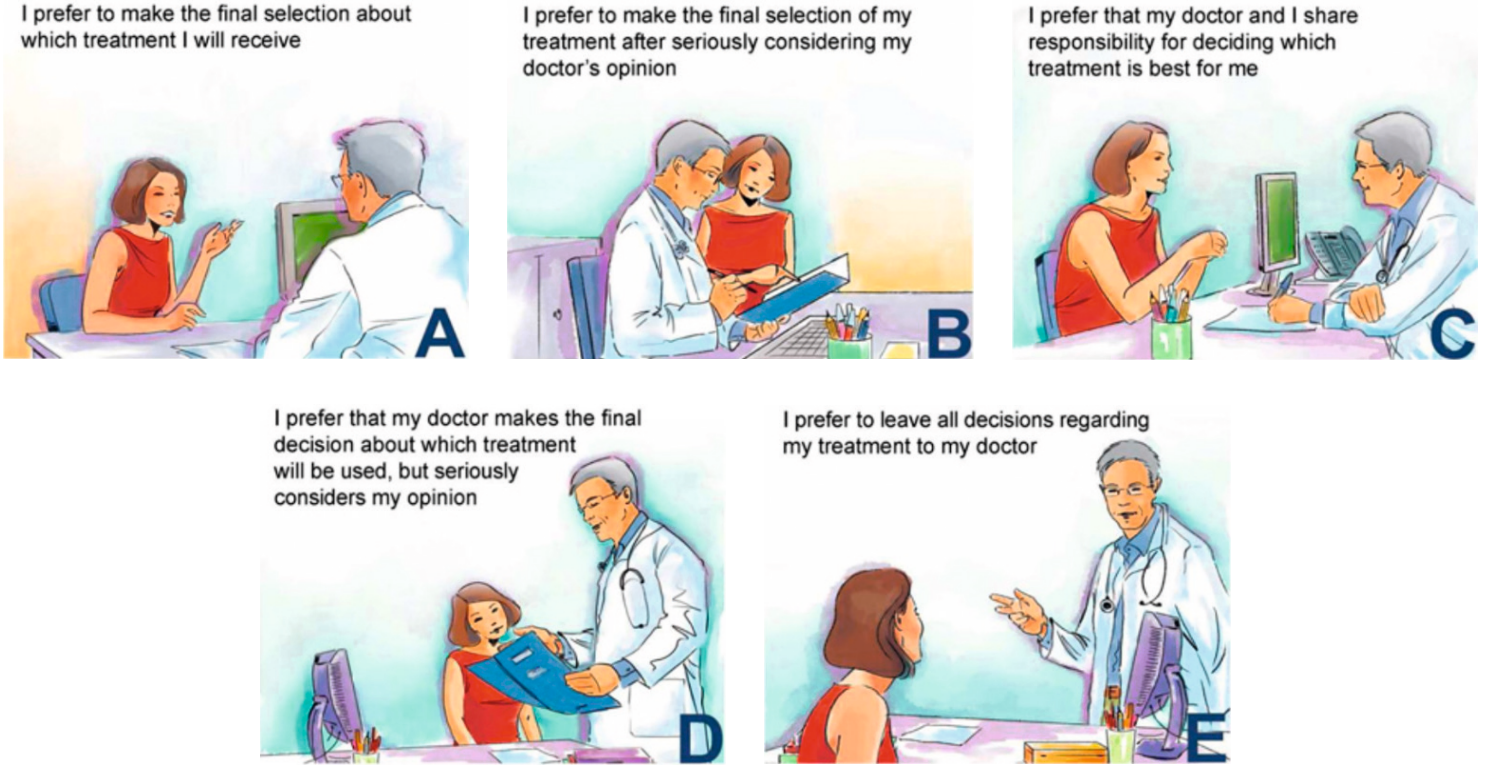
1. Who should decide about the use of additional testing to confirm the diagnosis from the physical exam? Examples of additional tests include a nerve test or an ultrasound.
2. Who should make the decision if I should have surgery?
3. Who should decide if I receive a steroid injection into the carpal tunnel as an alternate to surgery?
4. Who should decide if I need to immobilize my wrist prior to surgery and when to wear it? Examples of wrist immobilization include a wrist brace, which can be worn at night only or all the time.
5. Who should decide which lab tests are needed before surgery?
6. Who should make the decision if I need to see my primary care provider or a specialist before surgery to make sure I'm safe for surgery?
7. Who should decide whether or not I use a special soap to clean my skin at home before surgery?
8. Who should decide if I need to see a hand therapist before surgery?
9. Who should decide when my surgical treatment is scheduled? Examples include time of the day and day of the week.
10. Who should decide where my surgery takes place?
11. Who should decide what type of anesthesia I receive for surgery? Examples of anesthesia include asleep during surgery, sedation, and local.
12. Who should decide what type of surgical technique and approach is used? Examples of surgical techniques include an open carpal tunnel release and an endoscopic carpal tunnel release.
13. Who should make the decision if I need to have pre-surgery antibiotics?
14. Who should decide what type of suture is used to close the incision? Examples include dissolvable and non-dissolvable sutures.
15. Who should decide if I need to immobilize my wrist right after surgery with a wrist brace?
16. Who should decide how long the dressing stays on my wound? Examples include 3 days after surgery or 2 weeks after surgery.
17. Who should decide when I can start using my hand for daily function?

18. Who should decide when I can start moving my wrist?
19. Who should decide when I can get my wound wet in the shower?
20. Who should decide how I do my therapy? Examples include seeing a physical therapist OR being taught by my surgeon to do my own exercises.
21. Who should decide what type of post-surgery pain medication I receive?
22. Who should decide when my first return visit is to the surgeon's office?
23. Who should decide whether or not I use virtual care after surgery?
24. Who should decide when I stop seeing my surgeon for follow up appointments?
25. Who should decide when I can start doing forceful things like heavy lifting?
26. Who should decide when I can return to work or school?
27. Who should decide when I can return to normal activities? Examples of activities include sports.

Questions 1-8 are preoperative, questions 9-14 are operative, and questions 15-27 are postoperative.

Appendix B. The Control Preference Scale

Please circle the card that indicates your preferred role when making medical decisions.



Appendix C. Bivariate Analyses of Factors Associated With the Total SDM, the SDM Subscales, and With the SDM Cards*

Variables	SDM Total	*P* Value	SDM Preoperative	*P* Value	SDM Operative	*P* Value	SDM Postoperative	*P* Value	CPS	*P* Value
Age (*r*)	-0.15	0.12	-0.05	0.63	-0.03	0.73	-0.21	**< 0.05**	-0.13	0.18
Sex										
Women	-2.1 ± 1.4	0.97	-1.3 ± 1.8	0.67	-1.9 ± 1.5	0.77	-2.6 ± 1.6	0.94	-0.04 ± 0.80	0.24
Men	-2.1 ± 1.5		-1.5 ± 1.4		-1.9 ± 1.7		-2.5 ± 1.8		-0.24 ± 0.90	
Native language										
Spanish	-2.8 ± 1.5	0.19	-1.3 ± 2.9	0.84	-2.7 ± 2.0	0.20	-3.8 ± 1.7	0.06	-0.50 ± 0.55	0.23
English	-2.0 ± 1.4		-1.4 ± 1.6		-1.9 ± 1.6		-2.5 ± 1.6		-0.07 ± 0.84	
Race/ethnicity										
White	-2.1 ± 1.3	0.76	-1.6 ± 1.4	0.33	-1.8 ± 1.4	0.56	-2.6 ± 1.7	0.22	-0.04 ± 0.84	0.86
Latino/Hispanic	-2.2 ± 1.5		-0.83 ± 2.2		-2.2 ± 1.6		-3.1 ± 1.6		-0.17 ± 0.83	
Black/African American	-2.0 ± 1.6		-1.3 ± 1.9		-2.1 ± 1.8		-2.3 ± 1.7		-0.21 ± 0.97	
Other	-1.6 ± 1.5		-1.6 ± 1.3		-1.4 ± 2.3		-1.7 ± 1.5		-0.13 ± 0.64	
Marital status										
Married	-2.0 ± 1.4	0.39	-1.2 ± 1.8	0.21	-1.8 ± 1.6	0.35	-2.5 ± 1.7	0.76	-0.09 ± 0.76	0.86
Divorced/separated/ widowed	-2.2 ± 1.3		-1.7 ± 1.5		-2.1 ± 1.4		-2.6 ± 1.5		-0.05 ± 1.1	
Single	-2.4 ± 1.3		-1.8 ± 1.2		-2.4 ± 1.9		-2.8 ± 1.7		-0.20 ± 0.86	
Level of education										
High school or less	-2.6 ± 1.5	0.15	-1.9 ± 1.3	0.27	-2.5 ± 1.8	0.14	-3.1 ± 1.8	0.22	-0.43 ± 0.90	0.19
Some college	-2.0 ± 1.4		-1.1 ± 2.1		-1.9 ± 1.5		-2.6 ± 1.7		0.00 ± 0.89	
College graduate	-2.0 ± 1.2		-1.5 ± 1.3		-1.7 ± 1.3		-2.4 ± 1.5		-0.03 ± 0.69	
Master's degree or more	-1.7 ± 1.4		-1.2 ± 1.7		-1.4 ± 1.7		-2.1 ± 1.5		0.00 ± 0.82	
Work status										
Employed	-1.9 ± 1.3	0.23	-1.2 ± 1.7	0.46	-1.7 ± 1.5	0.26	-2.3 ± 1.5	0.28	0.02 ± 0.72	0.10
Retired	-2.3 ± 1.5		-1.5 ± 1.6		-2.1 ± 1.6		-2.9 ± 1.8		-0.11 ± 1.0	
Unemployed/disabled	-2.4 ± 1.5		-1.8 ± 1.6		-2.3 ± 1.7		-2.8 ± 1.7		-0.47 ± 0.72	

Appendix C. *Continued.*

Variables	SDM Total	*P* Value	SDM Preoperative	*P* Value	SDM Operative	*P* Value	SDM Postoperative	*P* Value	CPS	*P* Value
Insurance										
Commercial/military	-1.8 ± 1.3	0.06	-1.1 ± 1.7	0.19	-1.7 ± 1.6	0.33	-2.2 ± 1.5	**< 0.05**	0.00 ± 0.71	0.08
Medicare	-2.4 ± 1.4		-1.6 ± 1.5		-2.1 ± 1.5		-3.0 ± 1.7		-0.11 ± 1.0	
Public safety net/no insurance	-2.5 ± 1.6		-1.9 ± 1.5		-2.4 ± 1.8		-3.0 ± 1.8		-0.58 ± 0.67	
Income										
< $50,000	-2.1 ± 1.6	0.98	-1.2 ± 1.8	0.93	-1.9 ± 1.9	1.0	-2.7 ± 1.9	0.75	-0.33 ± 1.0	0.18
$50,000-$99,999	-2.1 ± 1.1		-1.5 ± 1.7		-1.9 ± 1.2		-2.5 ± 1.4		0.03 ± 0.68	
$100,000-$199,999	-2.1 ± 1.4		-1.4 ± 1.7		-1.9 ± 1.5		-2.6 ± 1.5		-0.05 ± 0.80	
> $200,000	-1.9 ± 1.4		-1.5 ± 1.3		-2.0 ± 1.8		-2.2 ± 1.8		0.11 ± 0.66	
Type of visit										
First/preoperative visit	-2.1 ± 1.4	0.96	-1.3 ± 1.7	0.33	-1.9 ± 1.5	0.57	-2.7 ± 1.6	0.35	-0.10 ± 0.85	0.90
Follow-up/ postoperative visit	-2.1 ± 1.4		-1.6 ± 1.5		-2.0 ± 1.8		-2.4 ± 1.7		-0.08 ± 0.81	
Side CTS										
Unilateral	-2.1 ± 1.2	0.80	-1.4 ± 1.6	0.73	-2.0 ± 1.5	0.51	-2.6 ± 1.5	0.95	-0.05 ± 0.77	0.58
Bilateral	-2.0 ± 1.6		-1.3 ± 1.7		-1.8 ± 1.7		-2.6 ± 1.8		-0.14 ± 0.90	
Previous CTR										
No	-2.1 ± 1.4	0.48	-1.4 ± 1.6	0.45	-1.9 ± 1.6	0.75	-2.6 ± 1.7	0.37	-0.11 ± 0.82	0.71
Yes	-1.9 ± 1.3		-1.2 ± 1.8		-2.0 ± 1.6		-2.3 ± 1.5		-0.04 ± 0.91	

*Bold indicates statistically significant difference; Pearson correlation indicated by *r*; interquestionnaire correlations (SDM total, SDM preoperative, SDM operative, SDM postoperative, and SDM cards all $P < 0.05$; continuous variables as mean ± SD (range), unless otherwise indicated; discrete variables as number (%).

CPS: Control Preference Scale; CTS: carpal tunnel syndrome; CTR: carpal tunnel release; SDM: shared decision-making.

Chapter 7

Does Societal Cost Information Affect Patient Decision-Making in Carpal Tunnel Syndrome? A Randomized Controlled Trial

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2021 Jul;16(4):439-446
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Abstract

Background

Despite studies demonstrating the effects of out-of-pocket costs on decision-making, the effect of societal cost information on patient decision-making is unknown. Given the considerable societal impact of cost of care for carpal tunnel syndrome (CTS), providing societal cost data to patients with CTS could affect decision-making and provide a strategy for reducing national health care costs. Therefore, we assessed the following hypotheses: (1) there is no difference in treatment choice (surgery vs no surgery) in a hypothetical case of mild CTS between patients randomized to receive societal cost information compared with those who did not receive this information; (2) there are no factors (eg, sex, experience with a previous diagnosis of CTS, or receiving societal cost information) independently associated with the choice for surgery; and (3) there is no difference in attitudes toward health care costs between patients choosing surgery and those who did not.

Methods

In this randomized controlled trial using a hypothetical scenario, we prospectively enrolled 184 new and return patients with a nontraumatic upper extremity diagnosis. We recorded patient demographics, treatment choice in the hypothetical case of mild CTS, and their attitudes toward health care costs.

Results

Treatment choice was not affected by receiving societal cost information. None of the demographic or illness factors assessed were independently associated with the choice for surgery. Patients declining surgery felt more strongly that doctors should consider their out of-pocket costs when making recommendations.

Conclusions

Providing societal cost information does not seem to affect decision-making and may not reduce the overall health care costs. For patients with CTS, health policy could nudge toward better resource utilization and finding the best care pathways for nonoperative and invasive treatments.

Introduction

Americans spend more than twice as much per capita on health care than other developed countries.[1] In the United States, health care costs are more than $10,000 per capita, surpassing $3 trillion of national expenses in 2016.[2] Because of this rise of health care expenditures without demonstrated improvement in quality of care, it is increasingly important to optimize treatment strategies and patient outcomes without increasing costs.[3–6] A survey in 2012 among 2,556 physicians revealed that most believed trial lawyers, health insurance companies, hospitals and health systems, pharmaceutical and device manufacturers, and patients should take responsibility to reduce health care costs.[5] Although aware of the costs of care, only 36% of physicians believed they themselves had a major responsibility to reduce them.[5] Health policy research suggests that a major part of expenses (30%-50%) comes from waste: overuse of services, preventable complications, and inefficient health care processes.[1,4] Cost-conscious decisions thus seem necessary for health care sustainability. Many options exist to divide responsibility of stewardship, including the larger stakeholders, such as the government and insurance companies, and on a smaller clinical or provider patient level.[4,5,7,8]

Despite some studies demonstrating the effects of out-of-pocket costs on patient decision making,[9,10] evidence is lacking on whether patients consider societal costs when they decide on treatment options for themselves in orthopedic surgery. In conditions where there is notable variation in the diagnostic and treatment strategies, patient education to understand the condition and the costs and benefits associated with each option has the potential to help optimize resource utilization. Carpal tunnel syndrome (CTS) is a common condition,[3,11–20] with about 600,000 carpal tunnel release (CTR) procedures accounting for more than $2 billion annually in the United States.[3,11,13,14,17–22] In England, between 2014 and 2015, 54,000 surgical decompressions of the carpal tunnel were performed at a cost of £46 million (a little over $58 million) to the National Health Service (NHS) and are predicted to increase 2-fold by 2030.[16] Multiple studies have been conducted about the cost-effectiveness of the different treatment methods, showing trends that nonoperative treatments are a relatively inexpensive means to reduce symptoms in the short term, but CTR appears to be, both in clinical outcomes and in cost-effectiveness, better in the long term.[3,13,23,24]

Given the notable financial impact of CTS treatment and known variation in care, it serves as an opportunity to reduce national health care costs. Especially for patients with mild CTS, studying different factors like the influence of patients wanting to try nonoperative treatments initially, taking the risks of surgery, or out-of-pocket and societal

costs into consideration, could direct patient decision-making to a more cost-effective treatment (while still delivering patient-centered care). The purpose of this study was to determine whether the provision of total annual societal cost information for CTR would affect patients' decisions to undergo surgical management in CTS, using a hypothetical scenario. Therefore, we assessed whether patients randomized to receive total societal cost information were equally likely to choose CTR over splinting in a case of mild CTS, compared with those who did not receive this information. Second, we evaluated factors (eg, sex, experience with a previous diagnosis of CTS, or receiving societal cost information) independently associated with the choice for CTR. Finally, we assessed whether attitudes toward health care costs differed between patients choosing CTR and those who did not. As it has been shown that patients often give higher valuations when they have a certain condition than participants presented with hypothetical cases,[25] we included both patients presenting with CTS and patients presenting with another diagnosis to test for differences in treatment decisions.

Materials and methods

Study design

After institutional review board approval of this observational, randomized controlled trial (RCT), we prospectively invited 184 adult, new or follow-up, English-speaking patients with a nontraumatic upper extremity condition over the course of 3 months. Patients were seen by 1 of the 6 hand surgeons at 4 orthopedic surgery offices in 2 large urban areas. We included patients aged 18 to 89 years, with or without CTS, and able to give informed consent. We excluded patients with a traumatic mechanism of injury or with language barriers. Research assistants who were not involved in treatment described the study to eligible patients before or after the visit with the surgeon. We were granted a waiver of documentation of informed consent. After consent, on-site, simple unblocked randomization using an Excel random number generator was performed to direct the patient to the respective cohorts: cost versus control cohort (Figure 1). This study is registered in clinicaltrials.gov (ID NCT03880812).[26]

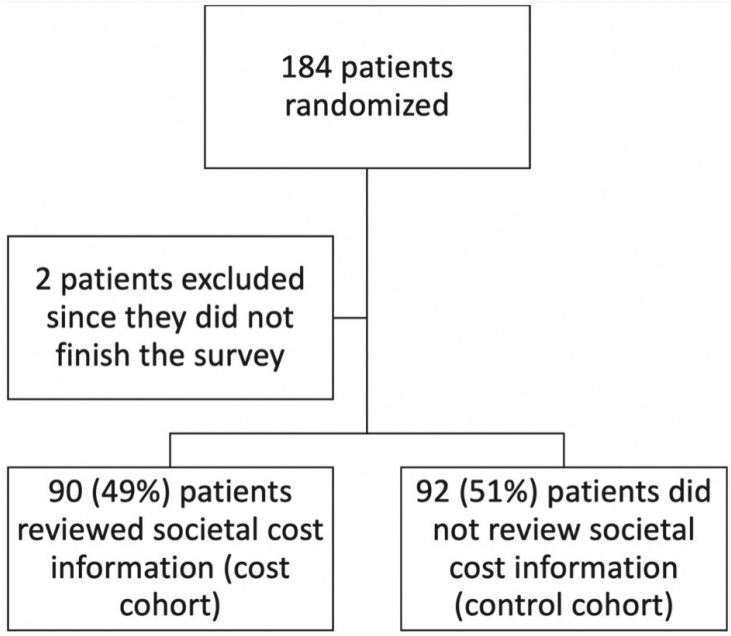

Figure 1. Randomization scheme of reviewing societal cost information for the included patients.

Outcome measures

Based on similar other studies,[6,27] we designed a survey with a hypothetical scenario. Patients were asked to complete a set of questionnaires in the following order: (1) a demographics and illness questionnaire consisting of age, sex, race/ethnicity, marital status, level of education, work status, insurance, annual household income, currently visiting their surgeon for CTS, and experience with previous contralateral diagnosis of CTS – if so, previous contralateral CTR; (2) choice for initial treatment based on a hypothetical mild CTS scenario and a short rationale for the choice; and (3) attitudes toward health care costs.

All patients, whether currently visiting their surgeon for CTS or not, were presented a hypothetical case of mild CTS (Appendix 1). We developed this scenario based on clinical experience that described (nocturnal) symptoms of numbness and tingling and 2 treatment choices: CTR or wrist splinting, with pros and cons for each option. In addition, patients were randomized to review total annual societal cost information for CTR procedures in the United States. This information was based on current data.[19,20] We did not distinguish between different surgical approaches (open vs endoscopic) or number of subsequent visits needed. After reviewing the case, patients were asked to indicate

whether they would choose surgery (more expensive) or splinting (less expensive). Scoring was measured on a 6-point ordinal Likert scale (ranging from 1 = “definitely not” to 6 = “definitely”). Patients were asked to give a short rationale for their choice. Two researchers independently grouped patients’ rationale, and consensus was made in case of discrepancy (Appendix 2).

Finally, we assessed attitudes toward health care costs by measuring agreement with various statements. These statements were similar to those previously used to test differences between patients choosing more expensive treatments and those who did not in other specialties.[6,27] Each statement was answered on a 6-point ordinal Likert scale (ranging from 1 = “strongly disagree” to 6 = “strongly agree”).

All questionnaires were administered on an encrypted tablet via secure, Health Insurance Portability and Accountability Act–compliant electronic platform: REDCap (Research Electronic Data Capture: a secure Web-based application for building and managing online surveys and databases).[28]

Study population

Two (0.01%) patients were excluded from analysis because they did not complete the survey. The mean age of the patients was 52 ± 16 years, and 83 (46%) were men (Table 1). Fifty-two (29%) presented with CTS, and 28 (15%) had experience with a previous contralateral diagnosis of CTS. Randomization to reviewing annual societal cost information ended up in a near 50-50 distribution, with 90 (49%) patients in the cost cohort. Only 9 patients (4.9%) mentioned costs in the rationale for their treatment choice, of which 7 (78%) were in the cost cohort.

Table 1. Patient and Clinical Characteristics

Variable	n = 182
Age, y	52 ± 16 (18-80)
Men	83 (46)
Race (self-described)	
White	131 (72)
Non-white	51 (28)
Marital status	
Married/domestic partnership	115 (64)
Single	33 (18)
Divorced/separated/widowed	33 (18)

Table 1. *Continued.*

Variable	n = 182
Level of education	
High school or less	46 (25)
2-years of college	34 (17)
4-years of college	44 (24)
Post-college graduate	58 (32)
Work status	
Employed	126 (69)
Retired	38 (21)
Unemployed/disabled	18 (10)
Insurance status	
Private/commercial	111 (61)
Medicare	47 (26)
Other	16 (8.8)
None	8 (4.4)
Yearly income[1]	
Less than $50,000	37 (21)
$50,000-$99,999	48 (28)
$100,000-$149,999	38 (22)
$150,000-$199,999	18 (10)
More than $200,000	32 (19)
Presenting with CTS	52 (29)
Previous contralateral diagnosis of CTS	28 (15)
Contralateral prior CTR	14 (50)
Viewing cost information	90 (49)
Mentioning costs in rationale	9 (5.0)

Continuous variables as mean ± SD (range); Discrete variables as number (percentage); [1]n = 173 (95%); CTS: Carpal tunnel syndrome; CTR: Carpal tunnel release.

Statistical analysis

Continuous variables are presented as mean ± standard deviation and discrete data as proportions. Differences between demographics for the cost and control cohort were not assessed as per standard practice for RCTs. We used Student *t* tests to assess differences between continuous variables and dichotomous variables, Fisher exact tests for discrete variables, and Mann-Whitney U tests for categorical variables. We dichotomized

our primary dependent variable (treatment choice) for bivariate and multivariate analysis, with choices of 1 to 3 ("definitely not, probably not, and maybe not," respectively) indicating "no surgery" and 4 to 6 ("maybe, probably, and definitely," respectively) indicating "surgery." We created a multivariate logistic regression model to assess factors independently associated with the choice for CTR. We included all variables with $P < .10$ on bivariate analysis for the entire cohort in the final model (Appendix 3). As no variables were associated with the choice for CTR on bivariate analysis with the subcohort of the CTS population nor with the non-CTS subcohort, we did not create multivariable models for those. The odds ratio indicates the odds of choice for surgery in one group compared with another for categorical variables, or a per-unit increase for continuous variables. The higher the absolute value of the ratio, the stronger the effect of the relationship. The C statistic is a measure of model fit and is similar to the area under the receiver operating characteristic curve. We considered $P < .05$ significant. When an out-of-pocket cost information about a new chemotherapy drug was shown in a study by Howe et al,[9] the smallest change in decision was 24%. It has been estimated that surgery is performed in approximately 40% of all CTS cases, which is consistent with most hand surgeons reporting that more than 50% of patients with CTS are managed nonoperatively prior to surgery.[15,18] Assuming that a base rate of 50% of patients choose surgery, a total of 168 (84 per cohort) patients were needed to provide 90% power, with α set at .05, to detect a difference of at least that magnitude in proportions between the 2 cohorts. To account for 5% to 10% incomplete data and to include enough patients with a history of CTS, we enrolled 184 patients. We aimed for a 50-50 randomization into each cohort (ie, cost vs control cohort).

Results

Treatment choice based on societal cost information

Treatment choice was not affected by receiving societal cost information (Table 2). This was also the case in a subgroup analysis of patients presenting with CTS and patients presenting without CTS. After dichotomization of the 6-point ordinal scale into a yes or no in favor of surgery, the results remained the same.

Table 2. Difference in Choice for Surgery Between Cost and Control Cohort*

Variable		Entire cohort n = 182[1]			CTS cohort n = 52			Non-CTS cohort n = 128		
Choice for surgery	Overall	Control cohort	Cost cohort	*P* value	Control cohort	Cost cohort	*P* value	Control cohort	Cost cohort	*P* value
Definitely not	27 (15)	17 (18)	10 (11)		3 (13)	2 (7.1)		14 (21)	8 (13)	
Probably not	34 (19)	13 (14)	21 (23)		1 (4.2)	5 (18)		12 (18)	16 (26)	
Maybe not	13 (7.1)	9 (9.8)	4 (4.4)	0.732	2 (8.3)	1 (3.6)	0.734	7 (10)	3 (4.8)	0.638
Maybe	23 (13)	10 (11)	13 (14)		3 (13)	5 (18)		7 (10)	8 (13)	
Probably	45 (25)	23 (25)	22 (24)		8 (33)	7 (25)		15 (22)	15 (24)	
Definitely	40 (22)	20 (22)	20 (22)		7 (29)	8 (29)		13 (19)	12 (19)	
Dichotomous choice for surgery										
No	74 (41)	39 (42)	35 (39)	0.653	6 (25)	8 (29)	1.00	33 (49)	27 (44)	0.601
Yes	108 (59)	53 (58)	55 (61)		18 (75)	20 (71)		35 (51)	35 (56)	

*Bold indicates statistically significant difference; Discrete variables as number (percentage); [1]Two patients did not complete this questionnaire; CTS: Carpal tunnel syndrome.

Factors associated with choice for CTR

Level of education, presenting with CTS, and experience with a previous contralateral diagnosis of CTS were included in the multivariable logistic regression model based on bivariate analyses. We also included reviewing the annual societal cost information because this was the variable of interest. However, none of these factors were independently associated with initially choosing CTR over splinting (Table 3).

Attitudes toward health care costs

Patients not opting for CTR had more definite agreement on the statement "My doctor should consider my out-of-pocket costs as he or she makes a medical decision" than patients opting for CTR (P = .016; Table 4). Overall, patients had high agreement (minimum 57%) with most health care attitude statements, with 94% of patients indicating that the cost of health care is one of the biggest problems facing the United States.

Table 3. Difference in Health Attitudes Between Choice for Surgery vs Not*, n = 180 (99%)

Variable	Strongly disagree	Disagree	Somewhat disagree	Somewhat agree	Agree	Strongly agree	*P* value
1. "Health care is a human right."							
Choice for no surgery	2 (2.7)	6 (8.1)	2 (2.7)	8 (11)	20 (27)	36 (49)	0.521
Choice for surgery	4 (3.8)	4 (3.8)	3 (2.8)	9 (8.5)	31 (29)	55 (52)	
2. "The cost of health care is one of the biggest problems facing this country."							
Choice for no surgery	1 (1.4)	3 (4.1)	2 (2.7)	11 (15)	21 (28)	36 (49)	0.441
Choice for surgery	1 (0.94)	2 (1.9)	2 (1.9)	14 (13)	31 (29)	56 (53)	
3. "Consumers can help lower the cost of health care."							
Choice for no surgery	1 (1.4)	5 (6.8)	8 (11)	30 (41)	16 (22)	14 (19)	0.859
Choice for surgery	3 (2.8)	8 (7.6)	9 (8.5)	37 (35)	33 (31)	16 (15)	
4. "Doctors should consider the country's health care costs as they make medical decisions."							
Choice for no surgery	5 (6.8)	11 (15)	8 (11)	16 (22)	23 (31)	11 (15)	0.569
Choice for surgery	11 (10)	13 (12)	8 (7.6)	16 (15)	41 (39)	17 (16)	
5. "I consider the country's health care costs when I make a decision about my treatment."							
Choice for no surgery	7 (9.5)	17 (23)	4 (5.4)	19 (26)	22 (30)	5 (6.8)	0.602
Choice for surgery	17 (16)	20 (19)	12 (11)	21 (20)	22 (21)	14 (13)	
6. "My doctor should consider my out-of-pocket costs as he or she makes a medical decision."							
Choice for no surgery	2 (2.7)	7 (9.5)	7 (9.5)	19 (26)	25 (34)	14 (19)	**0.016**
Choice for surgery	8 (7.6)	14 (13)	8 (7.6)	43 (41)	19 (18)	14 (13)	
7. "I consider my out-of-pocket costs when I make a decision about my treatment."							
Choice for no surgery	1 (1.4)	6 (8.1)	2 (2.7)	13 (18)	32 (43)	20 (27)	0.309
Choice for surgery	5 (4.7)	11 (10)	6 (5.7)	19 (18)	37 (35)	28 (26)	

*Bold indicates statistically significant difference; Discrete variables as number (percentage).

Table 4. Multivariable Logistic Regression Analyses of Factors Associated With Choice for Surgery*

Dependent variable	Retained variable	Odds Ratio 95% CI	Standard error	*P* value	C statistic[1]
Choice for surgery	Level of education				0.62
	High school or less	Reference value			
	2-years of college	0.84 (0.32 to 2.2)	0.41	0.727	
	4-years of college	0.74 (0.31 to 1.8)	0.33	0.506	
	Post-college graduate	0.61 (0.27 to 1.4)	0.26	0.249	
	Presenting with CTS	1.8 (0.74 to 4.4)	0.82	0.197	
	Previous contralateral diagnosis of CTS	1.4 (0.45 to 4.4)	0.83	0.553	
	Viewing cost information	1.1 (0.61 to 2.1)	0.35	0.710	

*Bold indicates statistically significant difference; CI: Confidence Interval; [1]The C statistic is a measure of model fit and is the area under the receiver operating characteristics curve.

Discussion

As CTS and its treatment account for a notable amount of health care costs in hand surgery, studying different strategies to reduce costs without compromising quality of care can inform to improve value of care. We studied the influence of showing annual societal costs associated with CTR to patients with and without CTS, using a scenario of mild CTS, and assessed patients' overall attitudes toward health care costs. We found that treatment choice was not affected by receiving societal cost information, and patients indicated high agreement with most health care statements, especially those indicating that the cost of health care in the United States is a major problem.

This study has some limitations. First, this study and the societal cost information included in the hypothetical scenario are based on US data only, therefore limiting generalizability to other (developed) countries. For example, in the United States, cost for nonoperative treatment of CTS by itself is less expensive than operative treatment; however, cost effectiveness in the long term favors CTR.[3,20] In contrast, in the Netherlands, the cost of CTR might be the same or even lower than the cost of a (custom) wrist splint.[29] When comparing the United States with Canada, we also find differences in health care systems: the United States tries to minimize wait times but has increased costs, whereas Canada has extended wait times but has a publicly funded, single-payer, universal health insurance with lower overall health care costs and similar life expectancy and outcomes for certain conditions.[30] A study comparing the health care systems for CTS using all direct and indirect costs associated with treatment favored the cost-effectiveness of the US system, with a gain in quality-adjusted life years based on the shorter wait times.[30] These examples highlight the heterogeneity of societal costs associated with CTS. Second, patients' preferences can vary based on perspective. Preferences and priorities can change when patients are asked to choose for themselves, for others, or for society.[25] Responses to hypothetical scenarios may not correspond with actual decisions when truly facing these symptoms.[6] Therefore, we included both patients with and without CTS to test these differences. In addition, these results might also defer when questioning patients presenting with a different – than an upper extremity musculoskeletal – problem. Third, we only tested the influence of societal costs and the choice for treatment if the insurance company would cover all costs. The results might differ with added out-of-pocket cost information, deductibles, personal income and debts, or even month of visit (patients might choose CTR more at the end of the year when the deductibles have been met). Fourth, we did not ask about previous experience with CTR or splinting in patients who already had experienced CTS in the past. Past experience

might have an influence on future treatment choices and merits further study. Finally, the attitude questions were asked at the end of the survey. This could have potentially introduced social desirability bias.

Societal cost information did not have an influence on treatment choice in the entire cohort nor in the non-CTS and CTS subcohorts. Our results are similar to a study examining the effect of total cost information on choosing left ventricular assist device (LVAD) implantation.[27] When analyzing patients deciding for themselves only, no effect of exposure to cost information was found. However, when analyzing the entire cohort including people choosing for another, they found that receiving cost information while choosing for another increased the odds (by 42%) of choosing LVAD implantation. In addition, when reviewing rationale for treatment choice, we found that only 9 patients (5.0%) of the entire cohort mentioned costs, of which 7 (78%) chose CTR as their preferred treatment (included insurance coverage in rationale). This might indicate that there are differences in the effect of costs between potential lifesaving versus elective surgeries, and this warrants additional studies.

Although we did mention in the cost cohort that insurance would cover all costs associated with the surgery, we did not find insurance status as a predictor of choosing surgery. This is in contrast to previous studies that found that people fully covered for medical costs spend about 50% more on medical services, probably taking greater risks knowing that they are covered for these expenses.[7,10] A cross-sectional study of costs and patient-reported CTS severity revealed that NHS and societal costs in the 3 months prior to enrollment, anxiety, depression, and quality of life were (positively) independently associated with self-reported severity (6-item CTS Symptoms Scale [CTS-6]).[16] This indicates that patients use more resources when self-reported symptom intensity is more severe, in addition to the presence of psychological factors.

Patients agreed (both with and without exposure to cost information) that the cost of health care is one of the biggest problems facing the United States, and patients not opting for CTR thought their doctor should consider their out-of- pocket costs more than patients opting for CTR. This is similar to previous findings[6,27] and might indicate a patient's personal financial health situation (rather than an attitude toward society) or an understanding of a financial burden to society, but with the belief that the patient should not be accountable for cost containment. In a survey among previous breast cancer patients, disclosure of out-of-pocket costs and provider profits had a significant impact on patients' expressed interest in an array of cancer care services, prompting them to prefer less invasive care options.[9] It is suggested that patients should play a role in the stewardship of resources,[5,6] and the increasing transparency of health care costs allows

patients to have more input in decision-making that affects their own out-of-pocket costs. However, a focus group study found participants were unwilling to consider costs when deciding between nearly comparable options (marginally different effectiveness, but substantial price difference), acting out of self-interest though recognizing that they may be depleting limited resources.[8]

Providing societal cost information did not seem to affect decision-making and may not reduce overall health care costs in patients with CTS. However, this is only one part studied in the cost process, and patients might choose differently when considering other costs such as the out-of-pocket expenses and deductibles. To address increasing health care costs, health systems are looking for alternate payment models and more efficient and cost-effective health care models.[1,5,8,17,19,30] England recently set forth a proposal to reduce coverage for many procedures as a way of eliminating waste.[31] However, eliminating waste is easier said than done.[4] Cost reduction could take place in conditions where there is a notable variation in diagnostic and treatment strategies, as is the case with (mild) CTS in hand surgery. In England, NHS and societal costs increase with 8% and 18%, respectively, for every point increase on the self-reported CTS-6 scale,[16] indicating a potential area of lowering costs by identifying and treating the problem at an earlier stage. In the United States, substantial cost reductions could take place by using a different value-based health care approach. For example, for patients with CTS, health policy could nudge toward better resource utilization by regulating surgery locations (freestanding ambulatory surgery center vs hospital), techniques (open vs endoscopic), anesthesia (local or local with sedation vs general), and finding the best care pathways for nonoperative and invasive treatments.[14,15,17,19–21,29,30]

Acknowledgments

The authors thank Jacob Gire, Matthew Burn, and Sara Eppler for their help in initiating and setting up this project.

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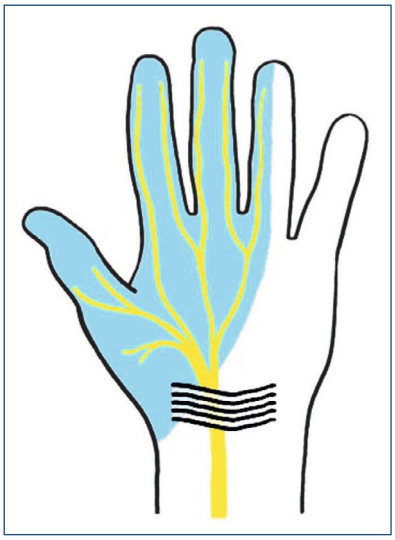
Appendix 1. Case Scenario With Randomized Cost Information

Imagine your thumb, index, and middle fingers get numb at night. This wakes you up at night and you lose sleep. The doctor tells you that you have mild carpal tunnel syndrome.

You have 2 treatment options:



Option 1: Surgery. Surgery cures carpal tunnel syndrome. A 1-to-2 inch cut in your palm is made and the ligament pressing on the nerve is cut. After surgery, you'll sleep better and keep your nerve function. There is a very small risk of injuring the nerve permanently. The wound might open a little or get a small infection and the scar is tender for 6 to 12 months.

Option 2: Splint. Wearing a splint at night can help you sleep. It keeps your wrist straight and your fingers won't go numb. The splint does not cure carpal tunnel syndrome. A splint may be able to delay surgery for many years.

(Randomized cost information)

Assume the cost of surgery is about $2,000. There are over 400,000 carpal tunnel release surgeries performed in the United States each year. That's around $1 billion in costs to society. Assume your insurance will pay for all the cost.

Now that you have learned about the benefits, risks, and alternatives of surgery, we want to know what decision you would make if you were in this situation. Keep in mind that there is no right or wrong answer. This is a decision that should be based on your personal values, goals, and preferences.

Should you have the surgery right now?

1. Definitely not
2. Probably not
3. Maybe not
4. Maybe
5. Probably
6. Definitely

Briefly, why did you make the choice you did?

Appendix 2. Choice for Surgery Rationale[1]

Rationale	Choice for surgery					
	Definitely not n = 26	Probably not n = 33	Maybe not n = 12	Maybe n = 21	Probably n = 45	Definitely n = 37
Avoid surgery: e.g. *"I try to avoid surgery"*	6 (23)	2 (6.1)	2 (17)	1 (4.8)	-	-
Last resort: e.g. *"I would want to try other options first if the surgery is not emergent"*	17 (65)	20 (61)	7 (58)	4 (19)	-	-
Testimonial: e.g. *"I hear a lot of positive/ negative feedback about this"*	1 (3.9)	-	-	1 (4.8)	2 (4.4)	-
Values: e.g. *"I wonder how long I would be in recovery. I live alone and have a lot of physical chores to do each day"*	1 (3.9)	9 (27)	1 (8.3)	7 (33)	4 (4.9)	-
Values + cost: e.g. *"It depends on how much pain/annoyance wearing the splint is and the cost of surgery"*	-	-	1 (8.3)	1 (4.8)	-	-
Cost: e.g. *"Costs"*	1 (3.9)	-	-	-	-	-
Symptom intensity: e.g. *"I want full function of my hands without the numbness and tingling"*	-	2 (6.1)	1 (8.3)	6 (29)	11 (24)	23 (62)
Symptom intensity + cost: e.g. *"Severity of the issue and insurance coverage"*	-	-	-	-	1 (2.2)	-
Put it behind me: e.g. *"I would rather try to resolve the issue, even with a risk, than wait"*	-	-	-	1 (4.8)	25 (56)	11 (30)
Put it behind me + cost: e.g. *"If the insurance would cover the cost, then I see the benefits as outweighing the risks"*	-	-	-	-	2 (4.4)	3 (8.1)

Discrete variables as number (percentage); [1]n = 8 (4.4%) did not report rationale for their treatment choice.

Appendix 3. Bivariate Analyses of Factors Associated With Choice for Surgery*

Variable	Entire cohort n = 182[1]			CTS cohort n = 52			Non-CTS cohort n = 128		
	Choice for no surgery	Choice for surgery	*P* value	Choice for no surgery	Choice for surgery	*P* value	Choice for no surgery	Choice for surgery	*P* value
Age, y	53 ± 16	51 ± 15	0.362	55 ± 14	53 ± 15	0.685	53 ± 17	50 ± 16	0.335
Sex									
Women	38 (51)	61 (56)	0.546	10 (71)	26 (68)	1.00	28 (47)	35 (50)	0.728
Men	36 (49)	47 (44)		4 (29)	12 (32)		32 (53)	35 (50)	
Race (self-described)									
White	55 (74)	76 (70)	0.616	11 (79)	29 (76)	1.00	44 (73)	47 (67)	0.565
Non-white	19 (26)	32 (30)		3 (21)	9 (24)		16 (27)	23 (33)	
Marital status									
Married/domestic partnership	45 (61)	70 (65)		8 (57)	22 (59)		37 (62)	48 (69)	
Single	15 (20)	18 (17)	0.575	3 (21)	6 (16)	0.971	12 (20)	12 (17)	0.403
Divorced/separated/widowed	14 (19)	19 (18)		3 (21)	9 (24)		11 (18)	10 (14)	
Level of education									
High school or less	15 (20)	31 (29)		4 (29)	16 (42)		11 (18)	15 (21)	
2-years of college	13 (18)	21 (19)	0.103	4 (29)	5 (13)	0.779	9 (15)	16 (23)	0.211
4-years of college	18 (24)	26 (24)		4 (29)	10 (26)		14 (23)	16 (23)	
Post-college graduate	28 (38)	30 (28)		2 (14)	7 (18)		26 (43)	23 (33)	

Appendix 3. *Continued.*

Variable	Entire cohort n = 182[1]			CTS cohort n = 52			Non-CTS cohort n = 128		
	Choice for no surgery	Choice for surgery	*P* value	Choice for no surgery	Choice for surgery	*P* value	Choice for no surgery	Choice for surgery	*P* value
Work status									
Employed	50 (68)	76 (70)		8 (57)	27 (71)		42 (70)	49 (70)	
Retired	17 (23)	21 (19)	0.325	3 (21)	9 (24)	0.235	14 (23)	12 (17)	0.821
Unemployed/disabled	7 (9.5)	11 (10)		3 (21)	2 (5.3)		4 (6.7)	9 (13)	
Insurance status									
Private/commercial	43 (58)	68 (63)		10 (71)	24 (63)		33 (55)	44 (63)	
Medicare	22 (30)	25 (23)	0.641	3 (21)	9 (24)	0.556	19 (32)	16 (23)	0.470
Other	6 (8.1)	10 (9.3)		-	2 (5.3)		6 (10)	8 (11)	
None	3 (4.1)	5 (4.6)		1 (7.1)	3 (7.9)		2 (3.3)	2 (2.9)	
Yearly income[1]									
Less than $50,000	13 (19)	24 (23)		5 (38)	8 (23)		8 (14)	16 (23)	
$50,000-$99,999	20 (29)	28 (27)		3 (23)	16 (46)		17 (30)	12 (17)	
$100,000-$149,999	21 (30)	17 (16)	0.705	5 (38)	4 (11)	0.473	16 (29)	13 (19)	0.480
$150,000-$199,999	6 (8.7)	12 (12)		-	3 (8.6)		6 (11)	9 (13)	
More than $200,000	9 (13)	23 (22)		-	4 (11)		9 (16)	19 (28)	
Presenting with CTS									
No	60 (81)	70 (65)	**0.020**	-	-	-	60 (100)	70 (100)	**-**
Yes	14 (19)	38 (35)		14 (100)	38 (100)		-	-	

Appendix 3. *Continued.*

Variable	Entire cohort n = 182[1]			CTS cohort n = 52			Non-CTS cohort n = 128		
	Choice for no surgery	Choice for surgery	*P* value	Choice for no surgery	Choice for surgery	*P* value	Choice for no surgery	Choice for surgery	*P* value
Previous contralateral diagnosis of CTS									
No	67 (91)	87 (81)	0.093	7 (50)	19 (50)	1.00	60 (100)	68 (97)	0.499
Yes	7 (9.5)	21 (19)		7 (50)	19 (50)		0 (0)	2 (2.9)	
Viewing cost information									
Control cohort	39 (42)	53 (58)	0.653	6 (43)	18 (47)	1.00	33 (55)	35 (50)	0.601
Cost cohort	35 (39)	55 (61)		8 (57)	20 (53)		27 (45)	35 (50)	

*Bold indicates statistically significant difference; [1] N=173 (95%).

Chapter 8

The Influence of Cost Information on Treatment Choice: A Mixed-Methods Study

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The Journal of Hand Surgery American Volume
2020 Oct;45(10):899-908.e4
Editor's choice
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Abstract

Purpose

To test the null hypothesis that exposure to societal cost information does not affect choice of treatment for carpal tunnel syndrome (CTS).

Methods

We enrolled 304 participants using the Amazon Mechanical Turk platform to complete a survey in which participants were given the choice between carpal tunnel release (CTR) or a less-expensive option (orthosis wear) in a hypothetical mild CTS scenario. Patients were randomized to receive information about the societal cost of CTR (cost cohort) or no cost information (control). The primary outcome was the probability of choosing CTR measured on a 6-point ordinal scale. We employed qualitative content analysis to evaluate participants' rationale for their choice. We also explored agreement with various attitudes toward health care costs on an ordinal scale.

Results

Participants in the cost cohort exhibited a greater probability of choosing surgery than those in the control cohort. The relative risk of choosing surgery after exposure to societal cost information was 1.43 (95% confidence interval, 1.11-1.85). Among participants who had not previously been diagnosed with CTS (n = 232), the relative risk of choosing surgery after exposure to societal cost information was 1.55 (95% confidence interval, 1.17-2.06). Lack of personal monetary responsibility frequently emerged as a theme in those in the cost cohort who chose surgery. The majority (94%) of participants expressed at least some agreement that health care cost is a major problem whereas only 58% indicated that they consider the country's health care costs when making treatment decisions.

Conclusions

Participants who received societal cost information were more likely to choose the more expensive treatment option (CTR) for mild CTS.

Clinical relevance

Exposure to societal cost information may influence patient decision making in elective hand surgery. A complete understanding of this influence is required prior to implementing processes toward greater cost transparency for diagnostic/treatment options. Sharing out-of-pocket costs with patients may be a beneficial approach because discussing societal cost information alone will likely not improve value of care.

Introduction

Carpal tunnel syndrome (CTS) is a common upper extremity condition for which both orthosis wear and surgery have demonstrated clinical efficacy when the symptoms are nocturnal and mild.[1] Carpal tunnel release (CTR) has been shown to produce better clinical outcomes than wrist orthosis wear alone and is often recommended in patients who have failed nonsurgical management and/or initially present with moderate to severe symptoms.[2] In contrast, wrist orthosis wear is a less-expensive treatment for CTS that can provide symptomatic relief for a substantial proportion of patients while preserving the option for future surgery if symptoms progress.[2–4] When a treatment decision is preference-sensitive, shared decision making can strengthen the physician-patient relationship and may lead to improved outcomes.[5–7] However, when presenting options to patients, the physician should fully consider which treatment characteristics to present because the selection or omission of certain characteristics can affect decision making.[8,9] Despite extensive literature characterizing the importance of out-of-pocket (OOP) costs in patient decision making[10–13], little is known about the influence of knowing societal costs on decision making.

Given the rising annual health care expenditures in the United States, surpassing $3 trillion or more than $10,000 per capita,[14] and finite health care resources, health care cost containment is increasingly important. An overarching goal of value-based health care is the reduction of the total cost of care while maintaining care quality.[15] In a value-based care model, multiple stakeholders can assume stewardship over health care resources, including government, insurance, hospitals, physicians, and patients.[16–19] However, no consensus has been reached on how the responsibility for stewardship should be allocated.[17] An early focus group study found that patients were generally unwilling to consider costs, especially costs borne by others, in medical decision making.[20] However, participants were not asked to make a specific decision and the influence of societal costs on decision making is likely condition dependent. A later randomized study found that an explicit plea to reduce societal health care costs did not reduce requests for low-value back imaging in a hypothetical scenario.[21] In another randomized study on left ventricular assist device (LVAD) implantation for heart failure, presenting societal cost information resulted in an increased probability of choosing the more-expensive, high-risk treatment option, an effect the authors attributed to the lack of personal financial responsibility (direct costs were borne by insurers) and participants equating cost with quality of care.[22] However, these choices involved either a clearly low-value option (back imaging) or a

life-or-death choice (LVAD) and, thus, may not be generalizable to decisions in elective hand surgery that are more preference-sensitive.

Despite the large societal costs of CTS[23], the influence of providing patients with information about societal costs on treatment decision making in elective hand surgery remains unknown. Providing societal cost information in addition to OOP cost information might be used as a strategy to improve value of care and drive stewardship of limited health care resources. In this study, we tested the null hypothesis that exposure to societal cost information does not alter the probability of choosing the more expensive treatment option (CTR).

Methods

Design

We employed convergent mixed methods with an embedded integration approach in this study. After obtaining institutional review board approval, we designed an online survey using a case of mild CTS with intermittent, nocturnal symptoms in which participants were asked to choose between receiving the more-expensive treatment option (CTR) or a less-costly option (orthosis wear). Participants were randomized via simple, unblocked randomization into 2 cohorts using Qualtrics software (Qualtrics, Provo, UT). Participants randomized into the control cohort received the clinical vignette only. Participants in the cost cohort received the clinical vignette and additional information about the societal costs of CTR.

We recruited participants on the Amazon Mechanical Turk (MTurk) interface, an online platform where registered, adult workers receive compensation for completing tasks. Participants were compensated $0.20 for taking the survey and were paid regardless of whether they finished the survey. A growing body of evidence has demonstrated the validity of MTurk as a participant recruitment tool for behavioral research, including prior work in hand surgery.[24–28]

Survey

The structure of our survey was based on surveys used in similar previous studies.[21,22] We developed a hypothetical scenario that described the symptoms of mild CTS with nocturnal symptoms and 2 treatment options (CTR or wrist orthosis wear). In addition, the cost cohort was presented with the following statement based on prior work[23,29]: "The cost of this surgery varies between $2,000 to $10,000. There are over 500,000 carpal

tunnel release surgeries performed in the U.S. each year. This amounts to over $1 billion in costs to society. Assume that you personally will NOT pay for the surgery and that your insurance will pay for all the cost." Owing to the difficulty of quantifying the indirect societal costs of CTR (eg, lost income/productivity, days off work), we only provided information on the direct medical costs of the procedure. Participants were also asked to provide a brief rationale for their choice. We assessed attitudes toward health care costs by measuring agreement with statements similar to those previously used to distinguish between acceptors and decliners of expensive treatments.[21,22] All surveys are available as supplemental information (Appendix A).

Variables

The primary outcome variable was the decision to have surgery, measured on a 6-point ordinal scale (1 = definitely not; 6 = definitely). For some analyses, we constructed a dichotomized outcome variable from the ordinal scale, capturing surgery ("maybe," "probably," or "definitely" have surgery) versus orthosis wear ("maybe not," "probably not," or "definitely not" have surgery) because the clinical decision is a dichotomous one. The primary explanatory variable was exposure to societal cost information. We also collected the following demographic variables to evaluate the success of randomization: age, sex, annual household income, race, employment status, education level, relationship status, and insurance type. We evaluated attitudes toward health care costs by measuring agreement with various statements on a 6-point ordinal scale (1 = strongly disagree, 6 = strongly agree).

Study sample

We randomized 304 participants into either the cost or the control cohort (Fig. 1). We subsequently excluded 23 participants (7.6%) because they either failed to finish the survey or finished the survey in under 60 seconds (indicating they may not have fully read through the text; chosen a priori), leaving 138 participants in the cost cohort and 143 participants in the control cohort for analysis. Their demographics are shown in Table 1. Forty-four participants (15.7%) had previously received a diagnosis of CTS. Of these, 9 (20.5%) had already undergone CTR. These participants with prior CTS diagnoses and/or CTR were evenly distributed over both cohorts. Five participants (1.8%) did not know whether they had been diagnosed with CTS.

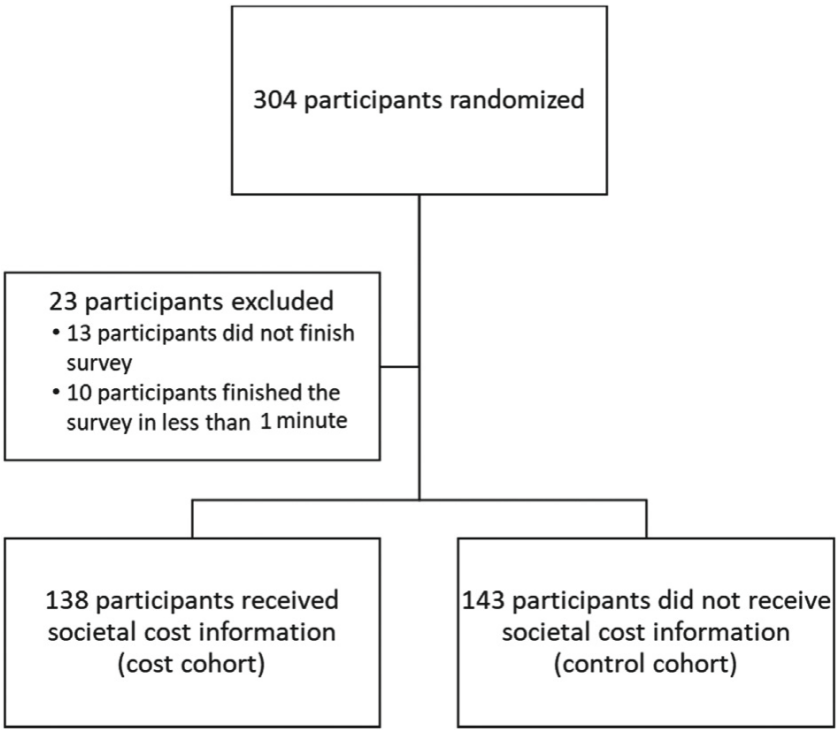

Figure 1. Randomization scheme.

Table 1. Participant Demographics*

Demographic	Cost Cohort (n = 138)	Control Cohort (n = 143)
Age, y (SD)	43.5 (13.7)	40.7 (12.1)
Sex, n (%)		
Female	76 (55.1)	85 (59.4)
Male	60 (43.5)	57 (39.9)
Other	1 (0.7)	0 (0)
Race, n (%)		
White	101 (73.2)	108 (75.5)
Black	11 (8.0)	10 (7.0)
Asian	11 (8.0)	8 (5.6)
Hispanic	3 (2.2)	3 (2.1)
Other	11 (8.0)	13 (9.1)
Income, n (%)		
<$50,000	59 (42.8)	68 (47.6)
$50,000-$99,999	63 (45.7)	59 (41.3)

Table 1. *Continued.*

Demographic	Cost Cohort (n = 138)	Control Cohort (n = 143)
$100,000-$149,999	14 (10.1)	12 (8.4)
>$150,000	2 (1.4)	4 (2.8)
Employment, n (%)		
Full-time	91 (65.9)	101 (70.6)
Part-time	27 (19.6)	21 (14.7)
Retired	7 (5.1)	6 (4.2)
Unemployed	3 (2.2)	5 (3.5)
Other	9 (6.5)	10 (7.0)
Education, n (%)		
Less than high school	2 (1.4)	1 (0.7)
High school graduate	25 (18.1)	31 (21.7)
2-year college degree	21 (15.2)	26 (18.2)
4-year college degree	63 (45.7)	59 (41.3)
Post-graduate degree	26 (18.8)	25 (17.5)
Relationship status, n (%)		
Married	54 (39.1)	74 (51.7)
Domestic partnership	5 (3.6)	7 (4.9)
Single, never married	48 (34.8)	50 (35.0)
Single, divorced or separated	23 (16.7)	7 (4.9)
Single, widowed	8 (5.8)	4 (2.8)
Insurance, n (%)		
Medicaid	16 (11.6)	16 (11.2)
Medicare	21 (15.2)	18 (12.6)
Commercial	86 (62.3)	90 (62.9)
Workers' compensation	3 (2.2)	4 (2.8)
Uninsured	12 (8.7)	15 (10.5)
Previous CTS diagnosis, n (%)		
Yes	19 (13.8)	25 (17.5)
No	117 (84.8)	115 (80.4)
Do not know	2 (1.4)	3 (2.1)
Previous CTR, n (%)		
Yes	5 (3.6)	4 (2.8)
No	14 (10.1)	19 (13.3)

*Percentages may not sum to 100% because some participants declined to answer some items.

Statistical analysis

We piloted our survey in 29 MTurk participants prior to full recruitment. In the pilot, 11 of 15 participants (73.3%) randomized into the cost cohort favored surgery compared with 6 of 14 participants (42.9%) randomized into the control cohort. We performed an a priori sample size estimation that showed that a total of 154 participants would provide 95% power to detect a difference of at least this magnitude between the cohorts (a = 0.05). Statistical significance was defined as *P* less than .05 for all analyses. For categorical variables, we reported counts with percentages and evaluated differences using Fisher exact test. We evaluated ordinal scale responses using a Mann-Whitney U test.

Qualitative data analysis

We used qualitative content analysis to evaluate participants' rationale(s) for their choice. Two members of the research team (T.Z. and L.M.S.) independently analyzed and conducted open coding of the responses. During open coding, the analysts reviewed responses and identified key ideas from each response, which were labeled as subcodes. Subsequently, the analysts met and created a codebook based on key ideas and concepts derived from the subcodes. In this process, new codes were provided until saturation was achieved, that is, no new codes emerged from the subcodes. All subcodes were classified into these codes. Any discrepancies were resolved via in-person discussion between the 2 analysts. The codes were then analyzed to identify themes. Representative responses are included (Appendix B). For convergent analysis, these qualitative data were merged with the quantitative data using an embedded integration approach.

Results

Effect of societal cost information on treatment choice

Participants in the cost cohort exhibited a greater probability of choosing surgery (*P* < .05; Table 2). The full distribution of survey responses is shown in Figure 2. Upon dichotomization of the primary outcome variable, we found that a greater proportion of those in the cost cohort chose surgery (55.1%) compared with the control cohort (38.5%), corresponding to a relative risk of 1.43 (95% confidence interval [95% CI], 1.11-1.85) for choosing surgery after exposure to societal cost information (*P* < .05). Because participants with a history of CTS have more experience with and/or knowledge of CTS, societal cost information may be weighted differently in their decision making. Thus, we then excluded all participants with a former diagnosis of CTS and reanalyzed the data.

There were no substantive changes in the observations. Among participants who had not been diagnosed with CTS, the relative risk of choosing surgery after exposure to societal cost information was 1.55 (95% CI, 1.17-2.06). In addition, owing to potential intergenerational differences, we assessed for effect modification by stratifying the entire cohort into those below or at the median age and those over the median age. The effect of societal cost information on choosing surgery was more pronounced in the younger subgroup than in the older subgroup (Table 3). In the younger subgroup, the relative risk of choosing surgery after exposure to societal cost information was 1.68 (95% CI, 1.23-2.29) compared with 1.24 (95% CI, 0.80-1.90) for the older subgroup.

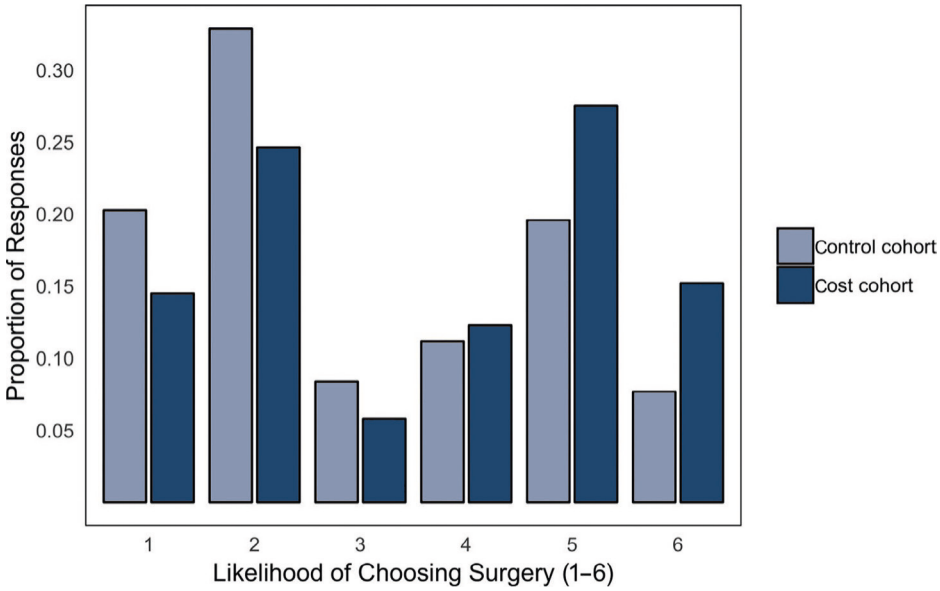

Figure 2. Distribution of survey responses by cohort. The outcome measured was the decision to have surgery, measured on a 6-point ordinal scale (1= definitely not; 6 = definitely).

We then performed a qualitative content analysis to identify themes in participants' rationales (Figure 3 and Appendix B). Monetary responsibility or concerns, specifically who would bear the cost (ie, insurance vs patients), emerged as a theme during this analysis in both cohorts. For some who chose surgery, the lack of personal financial responsibility for surgery costs drove their decision (Appendix B). For some who chose orthosis wear concern about personal costs (eg, deductibles, copays) drove their decision. Upon convergent analysis, we found that the majority of participants whose rationales included monetary responsibility as a theme were in the cost cohort and the majority of those chose surgery (Figure 3). Moreover, of the 19 participants whose responses were coded

Table 2. CTS Treatment Choice by Cohort

	Outcome	Cost Cohort	Control Cohort	*P* Value*
Entire cohort	Probability of choosing surgery, n (%)			**<.05**
	Definitely not	20 (14.5)	29 (20.3)	
	Probably not	34 (24.6)	47 (32.9)	
	Maybe not	8 (5.8)	12 (8.4)	
	Maybe	17 (12.3)	16 (11.2)	
	Probably	38 (27.5)	28 (19.6)	
	Definitely	21 (15.2)	11 (7.7)	
	Dichotomized choice, n (%)			**<.05**
	Orthosis wear	62 (44.9)	88 (61.5)	
	Surgery	76 (55.1)	55 (38.5)	
No prior CTS	Probability of choosing surgery, n (%)			**<.05**
	Definitely not	17 (14.5)	22 (19.1)	
	Probably not	25 (21.4)	39 (33.9)	
	Maybe not	7 (6.0)	11 (9.6)	
	Maybe	14 (12.0)	13 (11.3)	
	Probably	33 (28.2)	22 (19.1)	
	Definitely	21 (17.9)	8 (7.0)	
	Dichotomized choice, n (%)			**<.05**
	Orthosis wear	49 (41.9)	72 (62.6)	
	Surgery	68 (58.1)	43 (37.4)	

*Significant *P* values are in bold.

Table 3. CTS Treatment Choice by Age

	Outcome	Cost Cohort	Control Cohort	*P* Value*
Age ≤39 y†	Probability of choosing surgery, n (%)			**<.05**
	Definitely not	5 (7.8)	15 (19.2)	
	Probably not	13 (20.3)	26 (33.3)	
	Maybe not	2 (3.1)	5 (6.4)	
	Maybe	10 (15.6)	11 (14.1)	
	Probably	23 (35.9)	15 (19.2)	
	Definitely	11 (17.2)	6 (7.7)	
	Dichotomized choice, n (%)			**<.05**
	Orthosis wear	20 (31.3)	46 (59.0)	
	Surgery	44 (68.7)	32 (41.0)	
Age >39 y‡	Probability of choosing surgery, n (%)			.42
	Definitely not	15 (20.5)	14 (21.9)	
	Probably not	21 (28.8)	21 (32.8)	
	Maybe not	6 (8.2)	7 (10.9)	
	Maybe	7 (9.6)	5 (7.8)	
	Probably	14 (19.2)	12 (18.8)	
	Definitely	10 (13.7)	5 (7.8)	
	Dichotomized choice, n (%)			.38
	Orthosis wear	42 (57.5)	42 (65.6)	
	Surgery	31 (42.5)	22 (34.4)	

*Significant *P* values are in bold.

†Mean age = 31.6 y; ‡Mean age = 52.9 y. Note that 2 participants declined to provide age and were excluded.

into the “insurance covers it” or “no cost to me” categories, 18 were in the cost cohort and chose surgery. Example responses included, “You said insurance would pay. I have the insurance, why not use it? I need the surgery” and “Also, my insurance would cover the cost, so I would not have to consider financial constraints. There is the possibility that in the future, I may not have the insurance payment option.”

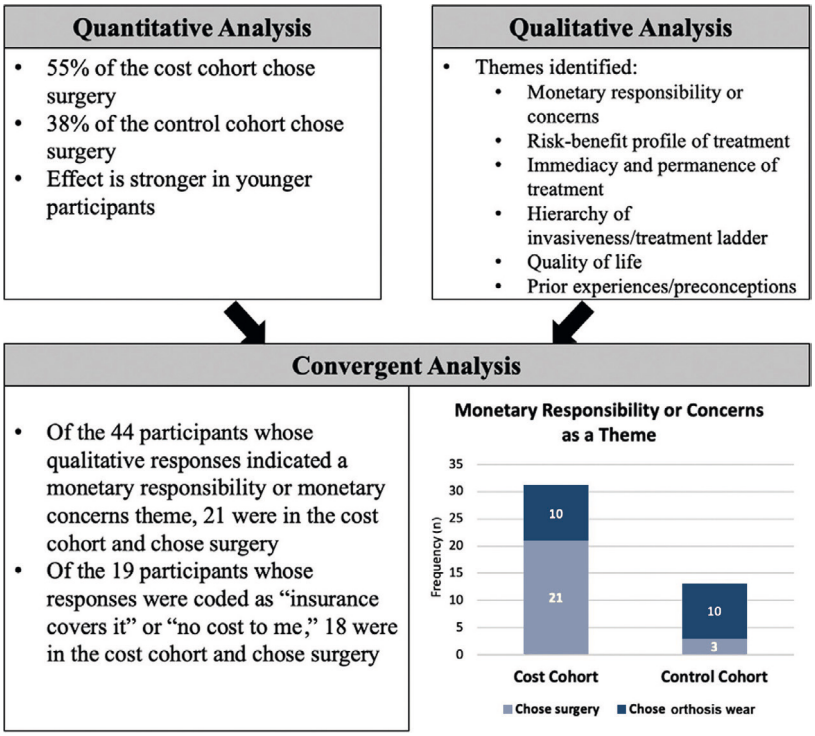

Figure 3. Convergent analysis.

Attitudes toward health care costs

Subsequently, we evaluated attitudes toward health care costs using agreement with various statements on an ordinal scale, stratified by participants who chose surgery versus those who did not (Table 4). The majority of participants expressed at least some agreement with a statement indicating that health care cost is a major national problem, with 94% in agreement. Over 60% of participants indicated that consumers can help lower health care costs but only 58% of participants indicated that they consider the country’s health care costs during personal treatment decisions. In contrast, the majority of participants indicated that they consider OOP costs when making treatment decisions, with 95% expressing agreement. No significant differences were observed between those who chose surgery and those who chose orthosis wear on any of the 7 statements presented.

Table 4. Attitudes Toward Health Care Costs by CTS Treatment Choice*†

Statement	Agreement, n (%)*		
	Choosing Surgery (n = 131)	Choosing Orthosis Wear (n = 150)	*P* Value†
1. “Health care is a human right.”	120 (91.6)	131 (87.3)	.34
2. “The cost of health care is one of the biggest problems facing this country.”	122 (93.1)	142 (94.7)	.09
3. “Consumers can help lower the cost of health care.”	88 (67.2)	97 (65.1)	.47
4. “Doctors should consider the country’s health care costs when they make medical decisions.”	78 (59.5)	99 (66.0)	.21
5. “I consider the country’s health care costs when I make a decision about my treatment.”	71 (54.2)	92 (61.3)	.08
6. “My doctor should consider my out-of-pocket costs when he or she makes a medical decision.”	110 (84.0)	125 (83.3)	.62
7. “I consider my out-of-pocket costs when I make a decision about my treatment.”	123 (94.6)	142 (94.7)	.92

*One participant who chose surgery did not answer item 7 and 1 participant who chose orthosis wear did not answer item 3.
†The P value corresponds to a Mann-Whitney U-test, which was performed using Likert scores. These are presented as dichotomized outcomes (agreement vs disagreement) for simplicity.

Discussion

In this study, we found that exposure to societal cost information increased the probability of choosing CTR by 43%. This effect was magnified after excluding participants with former CTS diagnoses and in participants who were below or at the median age. Lack of personal monetary responsibility emerged as a theme in a qualitative analysis of the participants' rationales for choosing surgery. These results inform efforts toward cost transparency with the intention of delivering high-value care and reveal the potential impact of providing societal cost information. For example, presenting patients with the total cost or insurer reimbursement for surgery to promote price shopping, as current price transparency initiatives advocate (eg, public price transparency tools created by the Centers for Medicare and Medicaid Services, publication of hospital chargemasters), may have unintended consequences because patients are often not personally responsible for the majority of health care costs.[30,31] Instead, cost transparency efforts should emphasize costs directly relevant to patients, that is, OOP costs, and institutions with presurgical financial planning could calculate OOP costs for patients undergoing elective surgery such as CTR to aid in decision making. Further, other strategies to promote stewardship such as reference pricing may be a more effective means to promote higher-value care.

Limitations to our study exist. Notably, because we only included U.S. participants, our results may not be generalizable to participants in other countries, especially those in single-payer systems. In a U.S. focus group study, Sommers et al[20] found a generally negative attitude toward insurers and an unwillingness to consider costs borne by insurers in decision-making, suggesting that patient decision making in single-payer systems could differ markedly, depending on prevailing attitudes toward the single payer. Although that study also found antagonistic attitudes toward the U.S. government, this is not generalizable across countries. Our qualitative analysis did not detect an overtly vindictive attitude toward insurers; rather, our data suggest that lack of personal monetary responsibility likely drives decision making in our study (Appendix B). In single-payer systems in which health care is a common resource funded via taxation, patients also do not face the direct costs of their care (but do bear indirect costs via taxes) and, thus, the lack of personal financial responsibility may still play a role in decision-making. However, because countries likely differ regarding societal attitudes toward shared goods and beliefs about the health care system, our results may still reflect a uniquely American frame of reference. Because single-payer systems also may have more rigid rules dictating when certain procedures are indicated[32], costs might play less of a role in the decision calculus.

Our results are based on the preferences of MTurk participants, which may not be representative of the general population. However, external validity is bolstered by MTurk's access to more diverse samples than traditional methods.[24,25,33,34] Nevertheless, MTurk participants tend to be younger, more highly educated, and have lower income than the general population.[35] The younger age of MTurk participants may have resulted in our participants being more likely to choose surgery as a whole because we found that younger age modified the effect of societal cost information on choice. In fact, several participants expressed that they would rather have surgery sooner rather than later, citing their younger age and ability to recover (Appendix B). Thus, presenting societal cost information may influence surgery choice more for younger populations. This effect warrants further investigation. Further, the unsupervised nature of online surveys may give rise to concerns about participant attentiveness and data quality. However, high-reputation MTurk workers, defined as those with approval ratings of 95% and over[27], have been shown to provide high quality data and the MTurk population may be even more attentive than traditional samples.[27,36] We attempted to ensure quality control by restricting the survey to workers with approval ratings of at least 97% and at least 5,000 former tasks completed. In addition, although the evidence on the relationship between compensation and data quality is limited, studies suggest that, whereas compensation level may affect speed of data acquisition and attrition, it does not appear to affect data quality.[33,37] Although our participants did provide rationales for their responses, we cannot definitively exclude that our results may have been affected by compensation level. Because MTurk workers choose which tasks to complete, we cannot quantify the nonresponse rate and, therefore, cannot exclude the possibility of nonresponse bias.

Although our scenario presented a case in which orthosis wear and CTR were not inferior to each other, this may not be true for all cases of CTS. However, a key strength of this study was the use of randomization to account for any unobserved confounding. Another concern relates to the brevity of the cost information provided and the exclusion of other potential societal costs that could result from CTS, such as reduced work productivity and loss of income. However, we felt it was necessary to balance brevity with guarding against biasing the participants. Nonetheless, several participants mentioned loss of income as a rationale for not getting surgery now. Future studies should explore whether providing additional cost information or information from a different perspective (eg, reduced productivity from CTS, time off work for surgery) modifies the effect. Our results are consistent with those recently reported by Kwon et al[22], who examined the effect of total cost information on choosing LVAD implantation when participants were asked to choose for themselves or for another. The authors found that exposure to

total cost information increased the odds of choosing the expensive LVAD implantation option by 42%. However, when they analyzed their data only for participants who were choosing for themselves, the effect of total cost became smaller (with an 8% difference between the cohorts).[22] Cost information may play only a small role in that study because LVAD implantation is a life preserving treatment and, therefore, cost information may be a less-important factor in participants' decision making. Riggs et al[21] found in a large online study that a direct, altruistic appeal to reduce health care costs did not influence requests for low-value back imaging tests. In prior work, patients were unwilling to consider costs borne by others in medical decision making.[20] However, these studies have not been replicated in hand surgery in which treatments are often discretionary and there is often treatment equipoise. In elective hand surgery, in which mortality is not a factor, we observed a significant difference in treatment choice between the cost and the control cohorts, with the former more likely to choose surgery. Taken together, these results suggest that increasing societal cost transparency is an ineffective means to reduce health care costs. On the contrary, exposure to societal cost information in hand surgery may lead to a "raiding of the health care commons," in which consumers deliberately choose costlier treatments knowing that society will bear the additional costs.

Although most participants in our study agreed that health care cost is a major problem in the United States, only 58% indicated that they consider the country's health care costs when making treatment decisions. These results are similar to those previously reported by Riggs et al[21] and Kwon et al[22], who found that, whereas the majority of their participants agreed that health care costs are a major problem, substantially fewer believed that patients should help control health care costs. Similarly, our participants recognized increasing health care costs as a societal problem, but many did not feel a personal responsibility to consider those costs in medical decision making. Therefore, a larger stewardship role may be required of physicians and/or health systems to curb rapidly rising health care costs. These results are relevant as health policy shifts toward increased cost transparency with both physicians and patients.[31] Where prior work has suggested that transparency with OOP costs can lead to less-discretionary, less-costly treatment options[38,39], total cost information does not lead to the same result. Although patients have demonstrated interest in understanding OOP costs[13,39–41] and including this information during shared decision making has garnered increasing support[7], discussing total cost information will likely not improve value of care.

A previous study has shown that the majority of U.S. physicians believe that patients have a "major responsibility" in reducing health care costs.[17] Subsequent efforts to reduce health care costs at the patient level have largely focused on incentivizing patients

through OOP costs. For example, reference pricing, a model in which the insurer pays a set price determined by the lower price range for a service with the remainder paid by the patient, has successfully altered patient behavior to achieve substantial cost savings in cataract surgery, shoulder and knee arthroscopy, and knee and hip arthroplasty.[42–46] However, reference pricing has only been applied to services for which there is a wide range in cost with little variation in quality. Additional efforts are needed toward the design of novel strategies to leverage cost-sharing to improve value-based care in hand surgery. Such strategies should focus on OOP costs and avoid discussing total costs because the latter increased demand for an expensive treatment option (CTR) in our study.

In conclusion, our results demonstrate that exposure to societal cost information increased a participant's probability of choosing the more expensive treatment option (CTR) compared with inexpensive orthosis wear for CTS, especially in younger participants. Although most participants agreed that health care costs are a major problem, many do not personally consider the country's health care costs in medical decision making.

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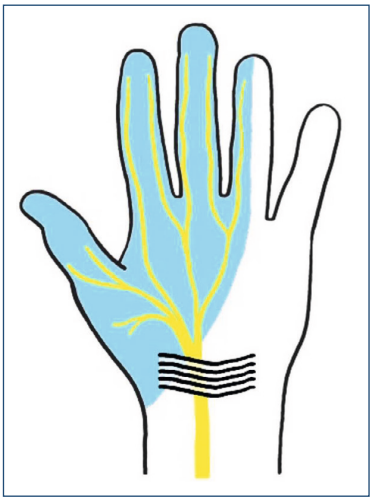
Appendix A. Surveys

1. What is your age (in years)?	2. What is your sex? ☐ Male ☐ Female ☐ Other
3. What is your yearly household income? ☐ Less than $50,000 ☐ From $50,000 to $99,999 ☐ From $100,000 to $149,999 ☐ From $150,000 to $199,999 ☐ From $200,000 to $249,999 ☐ More than $250,000	4. What is your race/ethnicity? Please check all that apply. ☐ White/Caucasian ☐ Black or African American ☐ American Indian or Alaska Native ☐ Asian ☐ Hispanic ☐ Native Hawaiian or other Pacific Islander ☐ Other
5. What is your employment status? ☐ Full-time employed ☐ Part-time employed ☐ Student ☐ Retired ☐ No work outside the home ☐ Disabled ☐ Unemployed	6. What is the highest level of education you have achieved? ☐ Less than high school ☐ High school graduate ☐ 2-year college degree ☐ 4-year college degree ☐ Postcollege graduate degree
7. What is your relationship status? ☐ Married ☐ Domestic partnership ☐ Single, never married ☐ Single, divorced, or separated ☐ Single, widowed	8. What type of insurance do you have? If multiple, please check your primary. ☐ Medicaid ☐ Medicare ☐ Private/commercial health insurance ☐ Workers' compensation insurance ☐ Uninsured

Imagine that you have mild carpal tunnel syndrome. Your thumb, index, and middle fingers get numb at night. This wakes you up at night and you lose sleep. You have 2 treatment options:



Option 1: Surgery. Surgery cures carpal tunnel syndrome. A 1-to-2 inch cut in your palm is made and the ligament pressing on the nerve is cut. After surgery, you will sleep better and keep your nerve function. There is a very small risk of injuring the nerve permanently. The wound might open a little or get a small infection and the scar is tender for 6 to 12 months.

Option 2: Orthosis. Wearing an orthosis at night can help you sleep. It keeps your wrist straight and your fingers won't go numb. The orthosis does not cure carpal tunnel syndrome but can delay the need to have surgery until the symptoms return or get worse. This can sometimes be years later.

[The cost of this surgery varies between $2,000 and $10,000. There are over 500,000 carpal tunnel release surgeries performed in the United States each year. This amounts to over $1 billion in costs to society. Assume that you personally will NOT pay for the surgery and that your insurance will pay for all the cost.]

Now that you have learned about the benefits, risks, and alternatives of surgery, we want to know what decision you would make if you were in this situation. Keep in mind that there is no right or wrong answer. This is a decision that should be based on your personal values, goals, and preferences.

Should you have the surgery right now?

1. Definitely not
2. Probably not
3. Maybe not
4. Maybe
5. Probably
6. Definitely

Briefly, why did you make the choice you did?

Have you ever been diagnosed with carpal tunnel syndrome?

☐ Yes
☐ No
☐ Don't know

If so, have you ever had surgery for carpal tunnel syndrome?

☐ Yes
☐ No
☐ Don't know

How much do you agree or disagree with the following statements?

	Strongly disagree	Disagree	Somewhat disagree	Somewhat agree	Agree	Strongly agree
"Health care is a human right."	☐	☐	☐	☐	☐	☐
"The cost of health care is one of the biggest problems facing this country."	☐	☐	☐	☐	☐	☐
"Consumers can help lower the cost of health care."	☐	☐	☐	☐	☐	☐
"Doctors should consider the country's health care costs as they make medical decisions."	☐	☐	☐	☐	☐	☐
"I consider the country's health care costs when I make a decision about my treatment."	☐	☐	☐	☐	☐	☐
"My doctor should consider my out-of-pocket costs as he or she makes a medical decision."	☐	☐	☐	☐	☐	☐
"I consider my out-of-pocket costs when I make a decision about my treatment."	☐	☐	☐	☐	☐	☐

Appendix B. Qualitative analysis

	Theme I: Monetary responsibility or concerns
Insurance covers treatment	"You said insurance would pay. I have the insurance, why not use it? I need the surgery."
	"Also, my insurance would cover the cost, so I would not have to consider financial constraints. There is the possibility that in the future, I may not have the insurance payment option."
No personal cost	"I might get it, but only since I would not have to pay for it. Normally, if I was paying, I would try every other option before surgery."
	"If it is paid for, I don't see why I would wait to delay something I will have to do anyway at some point."
Overall treatment cost	"I don't think surgery is a good alternative. I think it's also ridiculously expensive considering how many thousands have been performed."
	"Also, the cost of the surgery plays a part. There is no telling what kind of bill you would get even if outpatient and with insurance."
	"I don't know if I could afford the deductible for the surgery."
	"I shudder to think what it would cost me out of pocket."
	Theme II: Risk-benefit profile of treatment
Weighing risks and benefits	"Though the risks seemed minimal, I personally believe that all surgeries have ramifications even in subtle ways."
	"I do not like the side effects of surgery."
	"I worry about the surgery going wrong and my hand issue being made worse by the surgery."
Efficacy of treatment options	"The surgery may not work."
	"I do not see surgery as a viable option. I have yet to meet anyone who has had success with this kind of corrective surgery."
Burden of treatment	"Surgery ... would require me to be off from work for a few weeks. It would make it harder to do things around the house while recovering."
	Theme III: Immediacy and permanence of treatment
Treatment permanence	"I feel the orthosis option would just be a band aid for the issue."
	"I would do the surgery because it's the best chance for a solution that is permanent."
	"I would want my carpal tunnel cured."
Prevent worsening of symptoms	"I do not want to wait to make it worse."
	"I would just do the surgery because I know it will just get worse over time."

Appendix B. *Continued.*

	Theme V: Hierarchy of invasiveness/treatment ladder
Invasiveness of treatment	"I never opt for the most invasive treatment at first and usually it's not necessary."
	"I chose not to have the surgery right now because I would rather try the less invasive method of using a orthosis for the time being. If the orthosis does not cure the condition, then I might consider having the surgery."
Timing of treatment	"I would still eventually need the surgery later. I think it is best to have surgery while you are younger rather than older."
	"I would put off the surgery as long as absolutely possible. Particularly being young, getting any sort of surgery should not be taken lightly."
	Theme VI: Quality of life
Symptom relief	"I think the surgery would stop the pain and suffering. Not sleeping at night is very bad, especially if you are employed."
	"I would probably get the surgery if it was going to help my quality of life (getting better sleep)."
Severity of condition	"Because it was not severe enough for me to want to get surgery." "The ailment does not seem to be debilitating and there's always the chance that the condition never worsens."
	Theme VII: Prior experiences and preconceptions
Personal preference to avoid surgery	"I don't want to have surgery, it scares me."
	"I will not have surgery unless it is absolutely needed."
Personal experience	"If one rests the hand and eliminates the actions causing the pain, the hand naturally heals. I actually did this. No brace or surgery was needed and the inflammation left."
	"I do have carpal tunnel syndrome and I am not sure surgery would help. I have heard it can come back and I would have to think long and hard about such a thing before I did it."
Gut feeling	"Went with my gut."

Part IV Treatment

Chapter 9

Radiographs and Corticosteroid Injections at a New Patient Visit for Care of Carpal Tunnel Syndrome and Ulnar Neuropathy at the Elbow

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Journal of Hand and Microsurgery
2022 Oct;14(02):170-176

Abstract

Introduction

The benefit of radiographs or steroid injection for idiopathic carpal tunnel syndrome (CTS) or ulnar neuropathy at the elbow (UNE) is open to debate. We assessed: (1) Radiographs ordered and injections performed at a new patient visit for patients presenting with either idiopathic CTS or UNE; (2) The estimated payment reduction if we omit these interventions; and (3) Patient age, sex, geographic region, and work status associated with radiographs or injections at a new patient visit for patients presenting with either idiopathic CTS or UNE.

Materials and methods

Using a large database of commercial insurance claims, we identified patients with a new visit for either CTS (N = 9,522), UNE (N = 2,507), or both (N = 962; 8.7%). We identified injections and radiographs, and estimated total payments for these interventions. We created three multivariable logistic regression models for each diagnosis to identify factors associated with the interventions.

Results

Nearly one third of patients had radiographs at a new patient visit (30% and 32% for idiopathic CTS and UNE, respectively). Nearly 10% of patients with CTS and 2.6% with UNE received an injection. Both radiographs and injections representing annual minimum payments of over $345,000 and $294,000, respectively. Among people with CTS, radiographs were independently more common in the South and less common in the West. Injection for CTS was associated with younger age; North, Central, and South regions; and retired employment status. For people with UNE, radiographs were independently associated with younger age; South or West region; and retired or working employment status. Injection for UNE was associated with retired employment status.

Conclusion

The prevalence of radiographs and injections suggests opportunities for savings, which might benefit clinicians with bundled or capitated payments and patients with large copayments or deductibles. The observed variation may reflect debate about whether these interventions are worthwhile.

Introduction

Disparities and variation in treatment are described for several diseases and procedures, such as carotid endarterectomy and carotid stenting,[1] lung cancer care,[2] distal radius fractures,[3] and hand osteoarthritis.[4,5] This variation seems to primarily result from differences in physician beliefs and the extent to which patient preferences are incorporated into treatment decisions[6,7] rather than variations in pathophysiology, comorbidities, and other medical factors. Decision-making is also affected by the availability of technology and specialists, local training frameworks, regulatory factors, and financial incentives.[7] Where there is uncertainty, and therefore acceptable grounds for variation in diagnostic and treatment interventions, it can be argued that such variation ought to arise from variation in patient rather than clinician values and motivators.

Idiopathic carpal tunnel syndrome (CTS; i.e., idiopathic median neuropathy at the carpal tunnel)[8–14] and idiopathic ulnar neuropathy at the elbow (UNE)[9,12,14–17] often present with typical signs and symptoms and can be confirmed with electrodiagnostics. The role of radiographic imaging and steroid injections in CTS and UNE can be debated. Radiographs seem to be of limited value, given that changes to the bones and joints are unlikely to contribute to median or ulnar nerve symptoms if the examination of those joints is normal (i.e., if we are expecting idiopathic CTS or UNE).[18] Some surgeons opine that radiographs might be useful in the assessment of recurrent or unrelieved symptoms or to identify underlying skeletal abnormalities,[13,17–20] but these seem unnecessary and potentially misleading if symptoms and signs do not lead to a notable probability of such disorders.[21] There is no benefit to steroid injections for UNE.[9]

The basis for our consideration of corticosteroid injections for CTS as potentially low value hinges on several concepts that are supported by evidence, but are difficult to study definitively and can therefore be debated: (1) The natural history of idiopathic median neuropathy at the carpal tunnel is progression to irreversible nerve damage; (2) Surgery to divide the transverse retinacular ligament (carpal tunnel release [CTR]) may be the only treatment that can alter that natural history; and (3) Corticosteroid injection seems at best palliative, and there is limited evidence that corticosteroid injection is better at relieving symptoms than a simulated corticosteroid injection. Support for the concept that the natural history is progressive idiopathic median neuropathy, resulting in permanent nerve damage, comes from the fact that the disease is structural (consensus that the pathophysiology is compression in the carpal canal and that division of the transverse carpal ligament relieves that pressure) and the evidence that the disease is largely genetically mediated (which is characteristic of structural variations such as

ligamentous laxity, bone pathologies)[22,23]; eventually bilateral[24–27]; that neurophysiology deteriorates with age[25,26]; that the more advanced the neuropathology on one side, the more likely there is neuropathology and the more advanced it is on the other[26]; and that in the studies of steroid injection, splint immobilization, and other nonoperative treatments, a substantial percentage end up choosing surgery (and the percentage is higher [usually greater than 50% after 18 months] the longer the studies follow patients).[28] Support for the concept that surgery may be the only treatment that can alter the natural history comes from the evidence of high rates of surgery during or after trials of corticosteroid injection and other treatments[28]; the evidence of neurophysiological improvement after surgery[29–33]; and with the observation that recurrence of symptoms after surgery is likely most often a misinterpretation of persistence of symptoms in people with advanced nerve damage[34] and true recurrence is very uncommon. The trials of corticosteroid injection into the carpal tunnel also leave their ability to relieve symptoms (palliate) open to debate: the trials comparing corticosteroid injection with placebo suggest a slight transient decrease in symptoms and improved neurophysiology that deteriorates over about a year, but they are limited by dichotomizing the primary outcome in most analyses (i.e., satisfied or not)[28,35]; the trials compared with other injections that might be considered placebo (e.g., procaine,[36,37] progesterone,[38,39] or dextrose solution[40]) show no benefit; and trials that compare injection into the car- pal tunnel with oral steroids, splints, nonsteroidal anti-inflammatory medications, and several other treatments tend to show no relative benefit to injection.[28,35]

This study calculated the rate of radiographs and cortico- steroid injections for a new diagnosis of CTS or UNE at a new patient visit, estimated the potential reduction in payments if these interventions are omitted, and determined whether patient age, sex, geographic region, or work status are independently associated with these interventions.

Materials and methods

Study design

This study used the Truven Health Analytics MarketScan Databases.[41] This database contains claims and payments from over 250 medium or large employers and insurance plans, representing approximately 56 million covered employees and family members per year.[41] Patients are tracked throughout the entire United States (U.S.) and grouped by region (e.g., Northeast, South, or West).[41] The database contains no identifiable patient information, so institutional review board approval was not required.

We analyzed claim data from October to December 2015.[41] All data of patients aged 18 years and older with an International Classification of Diseases-10th revision (ICD-10)[42] code for (1) CTS and/or (2) UNE and a current procedural terminology (CPT) code for a new patient visit. A majority of coded new patient visits for these codes are likely to be with specialists. Within these cases, we specifically assessed the use of radiographs and therapeutic injections using CPT[43] codes tied to the ICD-10 codes specific for CTS and UNE (Appendix A). We excluded duplicate claims (N = 6,493) and claims with an unknown region (N = 21).

Measures

Variables retrieved from the database were as follows: age, gender, geographic region, work status, laterality for each claim, and radiographs and injections at the new patient visit (Table 1). We identified the number of patients coded with (bilateral) CTS and (bilateral) UNE within our cohort.

Table 1. Patient and clinical characteristics

Variable	N=11,067
Age in years	52 ± 13 (18-100)
Men	3,953 (36)
Region	
Northeast	1,966 (18)
North Central	2,384 (22)
South	5,228 (47)
West	1,489 (13)
Work status	
Employed	6,460 (58)
Retired	2,907 (26)
Other	1,700 (15)
Radiographs	3,335 (30)
Injections	929 (8.4)
CTS	N=9,522
Unilateral	5,375 (56)
Bilateral	4,147 (44)
Radiographs	2,826 (30)
Injections	922 (9.7)

Table 1. *Continued.*

Variable	N=11,067
UNE	N=2,507
Unilateral	2,135 (85)
Bilateral	372 (15)
Radiographs	804 (32)
Injections	64 (2.6)
Both CTS and UNE	962 (8.7)
Both bilateral CTS and bilateral UNE	150 (1.4)
Both radiographs and injections	399 (3.6)

Continuous variables as mean ± standard deviation (range); Discrete variables as number (percentage); CTS: Carpal tunnel syndrome; UNE: Ulnar neuropathy at the elbow.

Payments were estimated from the searchable physician fees provided by the Centers for Medicare and Medicaid Services, using the 2015-B (April to December 2015 codes) non-facility (meaning in-office procedures rather than in-hospital) priced national payment amount.[44] We used the lowest prices for both radiographs and injections (Appendix B) to make an estimate of the yearly payments.

Study population

We identified 11,067 patients who had a new outpatient visit within our timeline and 3,953 (36%) were men (Table 1). Nine thousand five hundred twenty-two patients were diagnosed with CTS, 2,507 with UNE, and 962 (8.7%) with both diagnoses at a new patient visit.

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD) and discrete data as proportions. We created three multivariable logistic regression models for each diagnosis to identify factors associated with (1) radiograph, (2) injection, and (3) both radiograph and injection at the new patient visit. We reported the C-statistic for each model, which is a measure of model fit and is equal to the area under the receiver operating characteristics curve. Scores of 0.5 indicate that the model is no better than predicting an outcome than random chance; 0.7 indicates a good model; 0.8 a strong model; and 1.0 indicates a perfect prediction model. We considered $P < 0.05$ significant.

We did not perform an a priori power analysis, since we included all eligible patients in our database.

Results

Radiographs and injection rates

Nearly one third of the patients received radiographs at the new patient visit for both CTS (30%) and UNE (32%) (Table 1). Almost 10% (N = 922) of patients with CTS received a therapeutic injection, whereas only 2.6% (N = 64) had one for UNE at the new patient visit.

Payment estimates

Using the lowest payments ($25.87), we calculated total yearly payments of about $345,000 for radiographs (N = 3,335 in 3 months) at a new patient visit for CTS or UNE. Using the lowest payments ($79.05) for injections (N = 929 in 3 months), the annual total payments are estimated at about $294,000.

Factors associated with radiographs, injections, or both for CTS

Among people with CTS, radiographs were independently more common in the South and less common in the West, and injection was associated with younger age, North Central and South regions, and retired employment status (Table 2).

Factors associated with radiographs, injections, or both for UNE

For people with UNE, radiographs were independently associated with younger age, South or West region, and retired or working employment status, and injection was associated with retired employment status (Table 3).

Table 2. Multivariable logistic regression analyses of factors associated with getting a radiograph, an injection, or both for CTS

Dependent variables	Retained variables	Odds ratio	95% Confidence interval	Standard error	*P* value	C statistic*
Radiograph at new patient visit	Age	1.0	0.99 to 1.0	0.00	0.142	0.58
	Male	1.0	0.91 to 1.1	0.05	0.958	
	Region					
	Northeast		Reference value			
	North Central	1.1	0.93 to 1.2	0.08	0.306	
	South	1.5	1.3 to 1.7	0.09	**<0.001**	
	West	0.63	0.53 to 0.76	0.06	**<0.001**	
	Work status					
	Employed		Reference value			
	Retired	0.91	0.82 to 1.0	0.05	0.089	
	Other	0.96	0.83 to 1.1	0.07	0.587	
Injection at new patient visit	Age	0.99	0.98 to 1.0	0.00	**<0.001**	0.60
	Male	0.87	0.75 to 1.0	0.07	0.068	
	Region					
	Northeast		Reference value			
	North Central	1.4	1.1 to 1.8	0.18	**0.009**	
	South	1.9	1.5 to 2.3	0.20	**<0.001**	
	West	1.0	0.77 to 1.4	0.15	0.803	
	Work status					
	Employed		Reference value			
	Retired	1.3	1.1 to 1.6	0.11	**<0.001**	
	Other	1.0	0.80 to 1.3	0.13	0.890	

Table 2. *Continued.*

Dependent variables	Retained variables	Odds ratio	95% Confidence interval	Standard error	*P* value	C statistic*
Radiograph and injection at new patient visit	Age	0.99	0.98 to 1.0	0.00	**0.036**	0.65
	Male	0.99	0.80 to 1.2	0.11	0.923	
	Region					
	Northeast	Reference value				
	North Central	1.6	1.1 to 2.5	0.36	**0.022**	
	South	3.1	2.1 to 4.4	0.57	**<0.001**	
	West	0.99	0.59 to 1.7	0.27	0.974	
	Work status					
	Employed	Reference value				
	Retired	1.5	1.2 to 1.8	0.17	**0.001**	
	Other	1.0	0.73 to 1.5	0.20	0.795	

Bold indicates statistically significant difference; *The C statistic is a measure of model fit and is the area under the receiver operating characteristics curve.

Table 3. Multivariable logistic regression analyses of factors associated with getting a radiograph, an injection, or both for ulnar neuropathy

Dependent variables	Retained variables	Odds ratio	95% Confidence interval	Standard error	*P* value	C statistic*
Radiograph at new patient visit	Age	0.99	0.98 to 1.0	0.00	**0.001**	0.62
	Male	0.83	0.70 to 0.99	0.07	**0.037**	
	Region					
	Northeast		Reference value			
	North Central	0.94	0.71 to 1.2	0.13	0.669	
	South	1.4	1.1 to 1.8	0.17	**0.005**	
	West	0.52	0.38 to 0.72	0.09	**<0.001**	
	Work status					
	Employed		Reference value			
	Retired	0.92	0.74 to 1.1	0.10	0.403	
	Other	0.74	0.55 to 0.99	0.11	**0.045**	
Injection at new patient visit	Age	1.0	0.98 to 1.0	0.01	0.842	0.63
	Male	0.69	0.41 to 1.1	0.18	0.152	
	Region					
	Northeast		Reference value			
	North Central	1.6	0.64 to 3.8	0.71	0.330	
	South	1.7	0.79 to 3.7	0.68	0.173	
	West	0.65	0.21 to 2.0	0.37	0.453	
	Work status					
	Employed		Reference value			
	Retired	2.2	1.3 to 3.8	0.62	**0.004**	
	Other	1.2	0.49 to 2.9	0.54	0.701	

Table 3. *Continued.*

Dependent variables	Retained variables	Odds ratio	95% Confidence interval	Standard error	*P* value	C statistic*
Radiograph and injection at new patient visit	Age	0.98	0.95 to 1.0	0.01	0.107	0.67
	Male	0.86	0.40 to 1.8	0.33	0.697	
	Region					
	Northeast	Reference value				
	North Central	1.4	0.30 to 6.3	1.1	0.675	
	South	2.5	0.75 to 8.6	1.6	0.135	
	West	1.0**	-	-	-	
	Work status					
	Employed	Reference value				
	Retired	2.7	1.2 to 6.2	1.1	**0.014**	
	Other	1.8	0.43 to 7.2	1.3	0.431	

Bold indicates statistically significant difference; *The C statistic is a measure of model fit and is the area under the receiver operating characteristics curve; **Predicts failure perfectly and omitted from model.

Discussion

Radiographs and steroid injections are among the most common diagnostic and treatment interventions in a hand surgeon's office. Among patients with symptoms of idiopathic CTS or UNE, their role is debated, and they might prove to be of little or no benefit. There is relative consensus that radiographs are not useful for either condition and that steroid injection is not useful for UNE. There is some debate about the role of injections for CTS. This study tested the rate of radiographs being ordered and injections performed at an initial visit and found that nearly one third of the patients received radiographs at the new patient visit for both CTS and UNE. In addition, almost 10% of patients with CTS received a therapeutic injection, whereas only 2.6% had one for UNE.

This study has some limitations. First, this is a retrospective claims database study with the following recognized shortcomings: the completeness or accuracy of the data are limited by a certain rate of coding errors; tests and treatments the patient received, which were not billed through the tracked insurance or occurred prior to the visit we studied; inability to distinguish specialist or nonspecialist clinician, although it seems safe to assume that a majority of new patient visits specifically for these coded diagnoses are with specialists; and the possibility that some of these patients had a prior fracture, which would make radiographic examination more appropriate. Second, using claims data, there is no way to account for personal factors (psychological and circumstantial), symptom severity, physician confidence in the diagnosis, and other factors. Third, the codes do not specify the substance injected, although we believe it is safe to assume that the majority were steroid injections. Fourth, some of the injection procedure codes are nonspecific, although the link to the diagnosis code should limit errors. Fifth, we did not have data on electrodiagnostic results acquired before the new patient visit. Finally, we could not study variation among specific clinicians.[45] We are unable to determine the degree to which variation is determined by surgeon beliefs and incentives or variations in pathology.

Nearly one third of patients received radiographs for both CTS and UNE at a new patient visit with a clinician, and almost 10% and 3% for CTS and UNE, respectively, received an injection, representing a minimum combined payment of over $639,000 per year. We also documented regional variations. This study adds to the evidence that greater use of resources seems to be related more to variations in care between clinicians than to pathophysiology or patient preferences and values.[5] For example, the U.S. occupies top usage ranks, with annual CT and MRI scans that are five and three times higher than those in Finland, respectively.[45] There are several potential reasons

for this varied and notable utilization including financial incentives, cultural norms and expectations, ineffective communication strategies, medicalization of aspects of human life such as the changes in the body which accompany aging, habits that are passed on in training (the so-called shadow curriculum), among other potential reasons.[6,7,46]

Radiographs and injections are common during a new patient visit for CTS and UNE in the U.S. The role of both is open to debate. When alternative payment models such as bundled payments or capitation are considered, and as the patient begins to pay for a higher proportion of their care through higher insurance deductibles and copayments, both clinicians and patients may consider omitting these interventions if evidence confirms the opinion of us and many others that they have limited benefit.

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Appendix A

ICD-10 codes CTS and UNE

G56 Mononeuropathies of upper limb

G56.0 Carpal tunnel syndrome

G56.00 Carpal tunnel syndrome, unspecified upper limb

G56.01 Carpal tunnel syndrome, right upper limb

G56.02 Carpal tunnel syndrome, left upper limb

G56.03 Carpal tunnel syndrome, bilateral upper limbs

G56.2 Lesion of ulnar nerve

G56.20 Lesion of ulnar nerve, unspecified upper limb

G56.21 Lesion of ulnar nerve, right upper limb

G56.22 Lesion of ulnar nerve, left upper limb

G56.23 Lesion of ulnar nerve, bilateral upper limbs

CPT codes radiographs and injections

CPT 73000-73225 Diagnostic Radiology (Diagnostic Imaging) Procedures

CPT 73070 Radiologic examination, elbow; 2 views

CPT 73080 Radiologic examination, elbow; complete, minimum of 3 views

CPT 73090 Radiologic examination, forearm; 2 views

CPT 73100 Radiologic examination, wrist; 2 views

CPT 73110 Radiologic examination, wrist; complete, minimum of 3 views

CPT 73120 Radiologic examination, hand; 2 views

CPT 73130 Radiologic examination, hand; complete, minimum of 3 views

CPT 20500-20697 General Surgical Procedures on the Musculoskeletal System

CPT 20526 Injection, therapeutic (e.g. local anesthetic, corticosteroid), carpal tunnel

CPT 64450 Injection, anesthetic agent; other peripheral nerve or branch

CPT codes new office or outpatient office visit

CPT 99201-99205 Office or Other Outpatient Services

CPT 99201 Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature

of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family.

CPT 99202 Office or other outpatient visit for the evaluation and management of a new patient, which requires these three key components: An expanded problem focused history; An expanded problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.

CPT 99203 Office or other outpatient visit for the evaluation and management of a new patient, which requires these three components: A detailed history; A detailed examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to- face with the patient and/or family.

CPT 99204 Office or other outpatient visit for the evaluation and management of a new patient, which requires these three components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.

CPT 99205 Office or other outpatient visit for the evaluation and management of a new patient, which requires these three components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.

Appendix B

Centers for Medicare and Medicaid Services Physician Fees

Radiographs and injections

73070 X-ray exam of elbow; $27.67
73080 X-ray exam of elbow; $31.62
73090 X-ray exam of forearm; $25.87
73100 X-ray exam of wrist; $29.47
73110 X-ray exam of wrist; $35.57
73120 X-ray exam of hand; $26.23
73130 X-ray exam of hand; $30.54
20526 Therapeutic injection CTS; $79.05
64450 Other peripheral nerve; $81.93

Visits

99201 Office/outpatient visit new; $44.20
99202 Office/outpatient visit new; $75.46
99203 Office/outpatient visit new; $109.60
99204 Office/outpatient visit new; $166.73
99205 Office/outpatient visit new; $209.49

Chapter 10

A Randomized Controlled Trial of Decision Aids for Upper-Extremity Conditions

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The Journal of Hand Surgery American Volume
2021 Apr;46(4):338.e1-e15

Abstract

Purpose

Decision aids (DAs) are tools designed to correct misconceptions, help people weigh the pros and cons of each option, and choose an option consistent with their values. This randomized controlled trial tested the difference in decision regret between patients who reviewed a DA at the end of the visit and those who did not. Secondary study questions addressed differences in pain self-efficacy, pain intensity, satisfaction, physical function, and treatment choice.

Methods

We enrolled 147 patients who visited an orthopedic upper-extremity surgeon for a condition that could be treated surgically or non-surgically. We randomized 76 of these patients to review a DA as part of the visit (52%). At baseline, we measured results using the Pain Self Efficacy short form, PROMIS Physical Function computer adaptive test, pain intensity on an 11-point ordinal scale, and satisfaction with the visit on an 11-point ordinal scale, as well as whether patients understood all received information and felt adequately educated to decide (no/yes), and choice of surgery, injection, or another treatment. Four to six weeks later, the survey by phone consisted of the PROMIS Physical Function computer adaptive test, pain intensity, satisfaction with the visit, the sense of a well-informed decision, and the Decision Regret Scale. We assessed factors independently associated with each measure.

Results

People who reviewed a DA had significantly less decision regret 4 to 6 weeks after the visit compared with those who did not. High pain self-efficacy was associated with lower likelihood to choose surgery during the initial visit, better physical function rates, and lower reported pain.

Conclusions

Decision aids reduce decision regret, which suggests that they help people organize their thoughts and make decisions more consistent with their values.

Clinical relevance

Hand surgeons can consider the use of DAs as a method for improving the quality of shared decisions.

Introduction

It is important to ensure that health choices are consistent with what matters most to a person (his or her values) and are not based on misconceptions or bias (ie, from the clinician, patient, or family). Most musculoskeletal conditions have more than one treatment option, one of which may be to adapt to permanent changes or be patient with a self-limiting condition. Evidence about potential benefits and harms is often limited and imprecise.

Decision aids (DAs) are tools that inform patients about their condition and choices, help patients become aware of how their values might determine which treatments are best for them, and correct mis- conceptions and neutralize clinician bias so that their choices are consistent with their values. Patient perceptions of treatment options for trigger finger[1] and carpal tunnel syndrome[2] differ, on average, from surgeon perceptions. Evidence of a 2- to 5-fold variation in rates of surgery in different regions suggests the possibility of differences in informed patient preferences, geographic, socioeconomic, insurance, employment, and other social factors as well as surgeon bias and incentives.[3]

A 2017 Cochrane review[4] found that DAs improve knowledge, risk perception, and congruency between informed values and care choices compared with usual care. Decision aids also limit decision conflict and indecision about personal values, increase participation in the decision-making process, and contribute to higher ratings of patient-clinician communication effectiveness. There is some evidence that DAs reduce discretionary surgery in specific situations such as knee and hip arthritis.[5–8] There is growing hand surgeon awareness of the nuance and importance of correcting common misconceptions about symptoms, helping patients become aware of their values, and guiding them to test and treatment decisions consistent with their values. Most hand surgeons have heard of DAs, and they may wonder how these tools can be helpful to their patients and their practice. Additional evidence specific to hand and upper-extremity surgery regarding the ability of DAs to improve decision quality, corresponding with values most importantly (measured in this study as lower decision regret), might help hand specialists develop strategies for care that contribute to better outcomes and experience.

We performed a randomized controlled trial hypothesizing that (1) there would be no difference in decision regret between patients who reviewed a DA at the end of the visit and those who did not; (2) there would be no factors independently associated with treatment choice; and (3) there would be no factors independently associated with satisfaction with the visit (both directly after the visit and after 2 weeks), decision regret (after 2 weeks), the Patient-Reported Outcomes Measurement Information System Physical

Function measure (PROMIS PF) both directly after the visit and after 2 weeks, and pain intensity (both directly after the visit and after 2 weeks).

Patients and methods

Study design

After we obtained approval from our institutional review board and registration on clinicaltrials.gov (NCT03643978),[9] we enrolled 147 patients visiting 1 of 3 orthopedic surgeons in a large urban area in the United States (Table 1). Enrollment took place over 4 months. We were granted a waiver of written informed consent. Patients indicated consent by completing the surveys. All English-speaking patients aged 18 to 89 years, presenting for a first specialist visit for a specific condition, for whom the choice was injection or surgery or other nonsurgical treatments, and for whom a DA was available (Table 2), were asked to participate in this study. Exclusion criteria were non-English speakers or a clear preference for a treatment option by either the surgeon or patient, both of which were uncommon. Patients were randomly assigned to either the intervention (viewing a DA) or the control (not viewing a DA) group in a 1:1 ratio, using a random number generator (Figure 1). We used DAs co-developed by our research group,[10] according to International Patient DA Standards criteria[11] and the Ottawa Decision Support Framework.[12] Patients in the intervention group went over the DA during the visit once the surgeon had identified the diagnosis. After the diagnosis was made, the surgeon stepped out of the visit and returned when the patients had reviewed the DA. People took as much time as they wanted to review the DA. The surgeon and the patient went over the treatment options, and a decision was made.

Table 1. Patient and Clinical Characteristics*

Variable	n = 147
Baseline	
Age, y	55 ± 14 (18-84)
Male	49 (33)
Race/ethnicity	
White	101 (69)
Nonwhite	46 (31)
Marital status	
Married/unmarried couple	89 (61)
Single	30 (20)

Table 1. *Continued.*

Variable	n = 147
Divorced/separated/widowed	28 (19)
Level of education	
High school or less	40 (27)
2-year college	21 (14)
4-year college	55 (37)
Post-college graduate degree	31 (21)
Work status	
Employed	88 (60)
Unemployed/other	59 (40)
Current use of opioids	8 (5.4)
PSEQ-2	9.8 ± 2.3 (0-12)
PROMIS PF	48 ± 7.4 (31-70)
Pain intensity	4.7 ± 2.3 (0-10)
Satisfaction with the visit	9.2 ± 1.6 (0-10)
Information understood	147 (100)
Enough information for decision	145 (99)
Reviewed decision aid	76 (52)
Decision for surgery	25 (17)
After 2 weeks[1]	
Days until follow up	36 ± 18 (12-90)
Final treatment choice[2]	
Surgery	16 (16)
Injection	36 (36)
Medication	9 (11)
Brace	24 (28)
Physical therapy	2 (2.4)
Other conservative treatment	27 (32)
PROMIS PF	49 ± 7.9 (34-73)
Pain intensity	2.8 ± 2.5 (0-8)
Satisfaction with the visit	9.0 ± 1.5 (3-10)
Felt assisted in decision-making	86 (85)
Decision Regret Scale	13 ± 14 (0-55)

Continuous variables as mean ± SD (range); Discrete variables as n (%); [1] N=101; [2] Can be multiple choices; PSEQ-2: Pain Self-Efficacy Questionnaire short form; PROMIS PF: Patient-Reported Outcomes Measurement Information System Physical Function.

Table 2. Diagnoses and Frequencies*

Diagnoses	Frequency (n = 147)
Trigger finger	43 (29)
Carpal tunnel syndrome	29 (20)
Thumb osteoarthritis	26 (18)
Wrist ganglion	14 (10)
De Quervain tenosynovitis	12 (7)
Lateral epicondylitis	10 (7)
Distal radius fracture	6 (4)
Olecranon bursitis	2 (1)
Scaphoid fracture	2 (1)
Radial head fracture	1 (1)
Mallet fracture	1 (1)
Dupuytren disease	1 (1)

*Discrete variables as number (percentage).

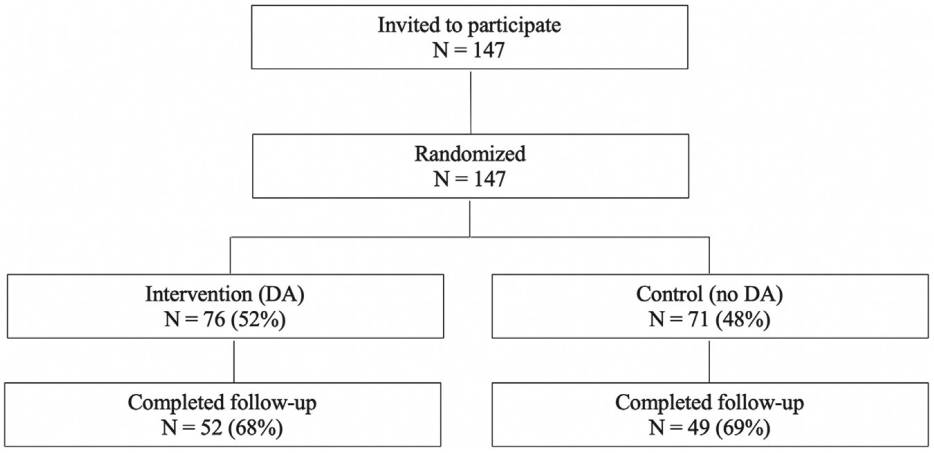

Figure 1. Patient flow in trial.

Outcome measures

After the visit, patients in the intervention and control groups were asked to complete questionnaires on an encrypted tablet via a secure, Health Insurance Portability and Accountability Act-compliant electronic platform (REDCap Research Electronic Data Capture, Nashville, TN)[13]: (1) about demographics (age, sex, race/ethnicity, marital status,

level of education, employment status, opioid use, and preferred mode of contact); (2) on the Pain Self-Efficacy Questionnaire short form (PSEQ-2); (3) on the PROMIS PF computer adaptive test; (4) about pain intensity on an 11-point ordinal scale; (5) about their satisfaction with the visit on an 11-point ordinal scale; (6) whether they understood all received information and felt adequately educated to make a decision (no/yes); and (7) the final choice about surgery, injection, or another treatment. Patients were also asked an open-ended question: "What made you decide on your final choice of treatment?"

Four to six weeks later, a research assistant helped subjects complete the following questionnaires by phone: (1) PROMIS PF, (2) pain intensity; (3) the Decision Regret Scale; and (4) satisfaction with the visit. People who received a DA were asked, "Do you think the DA (1) gave you enough information? and (2) helped you make a decision?" People who did not receive a DA were asked, "Do you think the surgeon (1) gave you enough information? and (2) helped you make a decision?"

The PSEQ-2 quantified the degree to which pain limited daily activities and the achievement of one's goals. It is used as a measure of effective coping strategies in response to nociception. The total score ranges from 0 to 12, in which 12 is more adaptive.[14] The PROMIS PF computer adaptive test is a scale that measures physical limitations, with items based on previous answers.[15] Higher scores indicate better physical function. Pain intensity was scored on an 11-point ordinal scale from no pain at all (0) to most pain possible (10). Satisfaction with the visit was scored on an 11-point ordinal scale from not satisfied at all (0) to most satisfied (10).

Treatment choice at baseline was a choice between surgical and nonsurgical treatment. After 4 to 6 weeks, we asked patients about the final choice of treatment, choosing among surgery, injection, pain medication, brace, referral to physical therapy, and other nonsurgical therapy.

The Decision Regret Scale measures distress or remorse after a health care decision. It contains 5 statements, the level of agreement of which is measured on a 5-point scale.[16] The final score is converted to a scale of 0 to 100, in which higher scores indicate more decision regret.

Patient characteristics

We enrolled a total of 147 patients (Table 1) with 12 different diagnoses (Table 2). Mean age was 55 ± 14 years; 49 were men (33%; Table 1). We randomized 76 patients to review a DA (52%). Twenty-five patients chose a surgical approach to the problem (17%). A total of 101 patients were available for a second evaluation after 4 to 6 weeks (69%).

Statistical analysis

All continuous variables are presented as mean ± SD, and discrete data as proportions. We used Pearson correlation tests for relationships between continuous variables, one-way analysis of variance tests for categorical variables, Student *t* tests to assess differences between continuous variables, and Fisher exact tests for discrete variables. We created 2 multivariable logistic and 6 multivariable linear regression models to assess factors independently associated with (1) treatment choice (initial and final), (2) satisfaction with treatment and decision regret after 4 to 6 weeks, and (3) physical function and pain intensity (both initially and after 4-6 weeks). We included all variables with $P < .10$ on bivariate analysis in the final models (Appendix 1-3). We considered $P < .05$ to be significant.

Answers to the open-ended question about reasons for deciding on the final choice of treatment were analyzed by a research assistant for both the DA and the control group and could be clustered in 13 categories (Appendix 4). An a priori power analysis indicated that to find a difference in decision regret with an effect size of 0.5, we would need 128 patients, with a set at 0.05 and 80% power. To account for 10% to 15% loss to follow-up, we aimed to enroll 141 to 147 patients.

Results

Difference decision regret

Patients who reviewed a DA had less decision regret 4 to 6 weeks after a specialist visit than those who did not (8.0 ± 13 vs 18 ± 13; $P < .05$) (Table 3).

Table 3. Outcomes Between Patients Reviewing a DA and Those Who Did Not*

Variable	Did Not Review DA (n = 71, 48%)	Reviewed DA (n = 76, 52%)	*P* value
Baseline			
PSEQ-2	10 ± 2.1	9.6 ± 2.5	0.310
PROMIS PF	48 ± 7.7	48 ± 7.1	0.467
Pain intensity	4.6 ± 2.3	4.9 ± 2.3	0.429
Satisfaction with the visit	9.2 ± 1.3	9.2 ± 1.9	0.991
Information understood	71 (100)	76 (100)	1.00
Enough information received	71 (100)	74 (97)	0.497

Table 3. *Continued.*

Variable	Did Not Review DA (n = 71, 48%)	Reviewed DA (n = 76, 52%)	*P* value
Decision to have surgery			
No	63 (89)	59 (78)	0.083
Yes	8 (11)	17 (22)	
After 2 weeks			
PROMIS PF	48 ± 8.3	49 ± 7.4	0.417
Pain intensity	2.7 ± 2.5	2.9 ± 2.5	0.591
Satisfaction with the visit	8.8 ± 1.7	9.2 ± 1.4	0.216
Felt assisted in decision-making	42 (86)	44 (84)	1.00
Decision Regret Scale	18 ± 13	8.0 ± 13	**<.05**

*Bold indicates statistically significant difference; Continuous variables as mean ± SD; Discrete variables as number (percentage); DA: Decision aid; PSEQ-2: Pain Self-Efficacy Questionnaire short form; PROMIS PF: Patient-Reported Outcomes Measurement Information System Physical Function.

Factors associated with treatment choice

An initial preference for surgical rather than nonsurgical treatment before enrollment was associated with completion of 2 years of college (odds ratio = 4.3; 95% confidence interval [CI], 1.1-17; $P < .05$) and lower pain self-efficacy (ie, lower PSEQ-2 scores; OR = 0.77; 95% CI, 0.63-0.94; $P < .05$), but not with reviewing a DA (Table 4).

No factors were independently associated with the final choice of injection, surgery, or other treatments at the end of the visit (Table 4).

Factors associated with satisfaction

No factors were independently associated with satisfaction with the visit at baseline (Table 5).

Patients who were already using opioids before the visit (b = 1.2; 95% CI, 0.07-2.4; $P < .05$) and who eventually chose an injection (b = 0.82; 95% CI, 0.20-1.4; $P < .05$) were more satisfied with the visit after 4 to 6 weeks (Table 5). Men were less satisfied than women (b = -0.65; 95% CI, -1.2 to -0.06; $P < .05$). For example, this model shows that patients who chose an injection scored 0.82 points higher on the satisfaction scale than did patients who chose nonsurgical treatment.

Factors associated with decision regret

Patients who reviewed a DA (b = -10; 95% CI, -15 to -5.0; *P* < .05) and who felt the surgeon helped them make a well-considered decision (b = -7.5; 95% CI, -15 to -0.49, *P* < .05) had less decision regret after 4 to 6 weeks (Table 5).

Factors associated with physical function

Patients with more pain self-efficacy (ie, higher PSEQ-2 scores) independently had better physical function both at baseline (b = 1.1; 95% CI, 0.61-1.6; *P* < .05) and during the second evaluation (b = 0.87; 95% CI, 0.24-1.5; *P* < .05) (Table 6). Older patients had lower physical function both at baseline (b = -0.09; 95% CI, -0.18 to -0.01; *P* < .05) and during the second evaluation (b = -0.20; 95% CI, -0.31 to -0.09; *P* < .05). Patients who chose to have surgery had worse physical function during the second evaluation (b = -5.0; 95% CI, -8.9 to -1.1; *P* < .05).

Factors associated with pain intensity

Patients with a post-college graduate degree (b = -1.4; 95% CI, -2.5 to -0.25; *P* < .05) and those with greater self-efficacy had less pain at baseline (b = -0.18; 95% CI, -0.34 to -0.02; *P* < .05) (Table 6). During the second evaluation, older patients reported more pain (b = 0.04; 95% CI, 0.01-0.07; *P* < .05) and patients treated with an injection reported less pain (b = -1.9; 95% CI, -2.8 to -0.88; *P* < .05).

Discussion

We conducted a randomized controlled trial to study the impact of a diagnosis-specific DA in orthopedic upper-extremity specialty visits. We found that patients who reviewed a DA had less decision regret 2 weeks after a specialist visit compared with those who did not.

We acknowledge some limitations to this study. First, the 11-point ordinal satisfaction scale has a substantial ceiling effect (mean satisfaction for patients reviewing a DA and not reviewing a DA was 9.2 and 9.3, respectively, Table 3). This finding is consistent with prior research[17] and hinders the analysis of factors associated with satisfaction. Second, the Decision Regret Scale also has a strong floor effect. Most people have little regret. In our opinion, this makes the findings of this study more notable. When regret is already low, to be able to lower it by 10 points on average with a DA suggests an important effect. When an outcome mean is closer to the highest or lowest score, there is proportionately less room for a difference to be demonstrated. To our knowledge, there is little known

Table 4. Multivariable Logistic Regression Analyses of Factors Associated With Treatment Choice*

Dependent variable	Retained variable	Odds ratio (95% Confidence interval)	Standard error	*P* value	C statistic[1]
Initial decision for surgery	Education				0.73
	High school or less	Reference value			
	2-year college	4.3 (1.1-17)	3.1	**<.05**	
	4-year college	1.8 (0.53-6.3)	1.2	0.337	
	Post-college graduate degree	0.52 (0.09-3.1)	0.47	0.472	
	PSEQ-2	0.77 (0.63-0.94)	0.08	**<.05**	
	Reviewed decision aid	2.2 (0.84-5.8)	1.1	0.111	
Final decision for invasive treatment	Reviewed decision aid	1.4 (0.65-3.1)	0.57	0.375	0.54

*Bold indicates statistically significant difference; [1] The C statistic is a measure of model fit and is the area under the receiver operating characteristics curve.

Table 5. Multivariable Linear Regression Analyses of Factors Associated With Satisfaction and Decision Regret*

Dependent variable	Retained variable	Regression coefficient [β] (95% Confidence interval)	Standard error	*P* value	Semipartial R^2	Adjusted R^2
Satisfaction baseline	Male	-0.54 (-1.1 to 0.02)	0.29	0.060		0.01
	Reviewed decision aid	-0.02 (-0.55 to 0.52)	0.27	0.951		
Satisfaction after 2 weeks	Male	-0.65 (-1.2 to -0.06)	0.30	**<.05**	0.04	0.15
	Current use of opioids	1.2 (0.07 to 2.4)	0.60	**<.05**	0.04	
	Reviewed decision aid	0.30 (-0.26 to 0.86)	0.28	0.286		
	Final treatment choice					
	Conservative	Reference value				
	Injection	0.82 (0.20 to 1.4)	0.31	**<.05**	0.06	
	Surgery	0.51 (-0.30 to 1.3)	0.41	0.214		
	Felt assisted in decision	0.90 (0.12 to 1.7)	0.40	**<.05**	0.04	
Decision Regret Scale	Reviewed decision aid	-10 (-15 to -5.0)	2.5	**<.05**	0.13	0.15
	Felt assisted in decision	-7.5 (-15 to -0.49)	3.5	**<.05**	0.04	

*Bold indicates statistically significant difference; R^2: R-squared; Only the semipartial R^2 of significant variables is displayed.

Table 6. Multivariable Linear Regression Analyses of Factors Associated With PROMIS PF and Pain Intensity*

Dependent variable	Retained variable	Regression coefficient [β] (95% Confidence interval)	Standard error	*P* value	Semipartial R^2	Adjusted R^2
PROMIS PF	Age, y	-0.09 (-0.18 to -0.01)	0.04	**<.05**	0.03	0.15
	PSEQ-2	1.1 (0.61 to 1.6)	0.25	**<.05**	0.11	
	Reviewed decision aid	1.4 (-0.82 to 3.7)	1.1	0.209		
	Decision to have surgery	-1.6 (-4.7 to 1.5)	1.6	0.313		
PROMIS PF after 2 weeks	Age, y	-0.20 (-0.31 to -0.09)	0.06	**<.05**	0.09	0.27
	Male	2.1 (-0.69 to 5.0)	1.4	0.137		
	Unemployed/other	0.53 (-2.6 to 3.6)	1.6	0.737		
	PSEQ-2	0.87 (0.24 to 1.5)	0.32	**<.05**	0.05	
	Reviewed decision aid	2.1 (-0.64 to 4.8)	1.4	0.133		
	Final treatment choice					
	Conservative	Reference value				
	Injection	2.9 (-0.04 to 5.9)	1.5	0.053		
	Surgery	-5.0 (-8.9 to -1.1)	2.0	**<.05**	0.05	
Pain intensity baseline	Male	-0.41 (-1.2 to 0.39)	0.41	0.315		0.09
	Non-white race	0.61 (-0.18 to 1.4)	0.40	0.131		
	Education					
	High school or less	Reference value				
	2-year college	-0.09 (-1.3 to 1.1)	0.62	0.882		
	4-year college	-0.47 (-1.4 to 0.49)	0.49	0.339		
	Post-college graduate degree	-1.4 (-2.5 to -0.25)	0.56	**<0.05**	0.03	
	PSEQ-2	-0.18 (-0.34 to -0.02)	0.08	**<0.05**	0.03	
	Reviewed decision aid	0.23 (-0.51 to 0.97)	0.37	0.540		

Table 6. *Continued.*

Dependent variable	Retained variable	Regression coefficient [β] (95% Confidence interval)	Standard error	*P* value	Semipartial R^2	Adjusted R^2
Pain intensity after 2 weeks	Age, y	0.04 (0.01 to 0.07)	0.02	**<0.05**	0.04	0.22
	Education					
	High school or less	Reference value				
	2-year college	1.0 (-0.45 to 2.5)	0.74	0.173		
	4-year college	-0.77 (-1.9 to 0.39)	0.58	0.190		
	Post-college graduate degree	-1.2 (-2.4 to 0.10)	0.64	0.071		
	Reviewed decision aid	0.26 (-0.62 to 1.1)	0.45	0.553		
	Final treatment choice					
	Conservative	Reference value				
	Injection	-1.9 (-2.8 to -0.88)	0.49	**<0.05**	0.11	
	Surgery	0.83 (-0.47 to 2.1)	0.65	0.210		

*Bold indicates statistically significant difference; R^2: R-squared; Only the semipartial R^2 of significant variables is displayed.

about clinically important differences in decision regret; such differences are more difficult to interpret near the limits of the score or in settings where there is a notable chance of ceiling or floor effects. We also addressed decision regret only in the short term. Third, study inclusion was limited to new specialist consultations for which surgical and non-surgical treatment were options. Given the small number of people choosing surgery, especially during the initial visit, this setting is inadequate for assessing the influence of DAs on treatment choice. Fourth, most people had one of a few common diagnoses, and this study applies best to those problems. Fifth, because injection was not available for all diagnoses, a choice for injection is confounded with diagnosis; nevertheless, because that injection was an option for all but 11 patients (7%), we think this had little influence on the findings. Sixth, surgeons were not blinded to the study protocol, although that is probably appropriate because the effect of the DA on the interaction between patient and surgeon (with both using the DA as a point of discussion) was part of what we wanted to study. Seventh, 31% did not complete the second evaluation, which may have left some of the analyses underpowered. There were no differences between responders and non-responders at enrollment, but there may be differences in satisfaction and decision regret. Finally, consistent with a pragmatic study design, there was no accounting for what happened before the specialist visit or afterward (eg, additional calls, portal messages, e-mails, or visits).

Overall decision regret was low in both groups (8.0 ± 13 vs 18 ± 13), which may account for the difficulty in showing a notable difference with the use of DAs as we had. One might interpret the low overall decision regret as a representation that guidance by the surgeon is sufficient and DAs have a limited role. We caution against that interpretation because of the notable ceiling effect (tendency toward top scores) of measures of decision regret and other experience measures. The study of interventions to improve experience (such as more satisfying decisions; perceived empathy; trust; and communication effectiveness) would benefit from instruments with limited loss of useful variation in data owing to floor or ceiling effects. Our own bias, based on evidence and experience to date, is that quality surgeon communication strategies can be more effective than DAs for helping people reorient common misconceptions, become aware of their values, and make choices consistent with their values rather than misconceptions. We consider DAs to be a tool that surgeons and patients use for assistance while they work to enhance the ability to identify and discuss common misconceptions, as well as patient values and congruent and incongruent decisions. A study comparing usual care (a visit with surgeon plus an information folder) with usual care and a DA for patients with trapeziometacarpal arthritis reported a significant difference in decisional conflict measured directly after

the visit, but no significant difference in decision regret after 6 weeks' and 6 months' follow-up.[18] A study on postsurgical decision regret in breast cancer showed a significant decrease in decision regret when using a DA.[19] Other clinical trials on the effects of a DA on decision regret 3 months after treatment choice for pelvic organ prolapse[20] and 6 months after decisions about medical treatment options for diabetes mellitus[21] and genetic testing[22] show no significant difference.

The finding that patients with more self-efficacy were less likely to choose surgery is consistent with evidence that an ability maintain a daily routine and achieve one's goals despite nociception decreases symptoms and limitations.[23] The CIs were wide, so we cannot be sure of the magnitude of the association. Previous research[24] showed that greater pain interference (the tendency to limit activities owing to pain) is associated with a greater likelihood of discretionary surgery. Pain interference is strongly correlated with pain self-efficacy, and it was suggested that it measures the same underlying concept of cognitive coping strategies in response to nociception.[25] As mentioned, this study was not designed to detect the influence of DAs on surgery rate; a larger and more specific trial is needed to answer that question.

As expected, the magnitude of physical limitations was greater in older patients and also among people who chose to have surgery, which may be the result of recovery time, because many patients in our practices who chose surgery would likely have had the surgery before the 4- to 6-week evaluation. The association that was found between high pain self-efficacy and better physical function at baseline and after 4 to 6 weeks is consistent with prior research[26] and supports the key role of effective cognitive coping strategies in musculoskeletal health. High self-efficacy was also associated with lower pain intensity.

The results of our study suggest that patients with upper-extremity musculoskeletal illness who review a DA have less decision regret. The finding of lower decision regret among patients who review a DA suggests that DAs help people make decisions that are more consistent with their values. Future research could help select diagnoses for which a DA is most beneficial. There may be specific situations in which organizing one's thoughts and addressing common misconceptions via a DA might affect the rate of discretionary surgery. For example, people with distal biceps rupture often initially have a misconception that they need surgery to be able to bend the elbow, or that when things are broken, they should always be fixed. People who see a clavicle fracture out of place on a radiograph and feel the bones moving might similarly find it difficult to believe that nonsurgical treatment is an option. Relative to the diagnoses we studied, a high percentage of people with these injuries choose surgery, which provides an opportunity to test the impact of a DA on treatment choice.

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Appendix 1. Bivariate Analyses of Factors Associated With Treatment Choice for Baseline and Follow-Up Data*

Variable	Initial decision for no surgery	Initial decision for surgery	*P* value	Final decision for no invasive treatment	Final decision for invasive treatment	*P* value
Baseline						
Age, y (*r*)	56 ± 14	55 ± 13	0.828	55 ± 14	55 ± 14	0.774
Gender						
Female	81 (66)	17 (68)	1.00	30 (61)	36 (69)	0.412
Male	41 (34)	8 (32)		19 (39)	16 (31)	
Race/ethnicity						
White	87 (71)	14 (56)	0.157	37 (76)	34 (65)	0.285
Non-white	35 (29)	11 (44)		12 (24)	19 (35)	
Marital status						
Married/unmarried couple	74 (61)	15 (60)	0.710	31 (63)	29 (56)	0.789
Single	26 (21)	4 (16)		9 (18)	12 (23)	
Divorced/separated/widowed	22 (18)	6 (24)		9 (18)	11 (21)	
Level of education						
High school or less	34 (28)	6 (24)	0.100	10 (20)	17 (33)	0.598
2-year college	13 (11)	7 (28)		8 (16)	7 (13)	
4-year college	45 (37)	10 (40)		19 (39)	17 (33)	
Post-college graduate degree	29 (24)	2 (8.0)		12 (24)	11 (21)	
Work status						
Employed	73 (60)	15 (60)	1.00	31 (63)	30 (58)	0.684
Unemployed/other	49 (40)	10 (40)		18 (37)	22 (42)	

Appendix 1. *Continued.*

Variable	Initial decision for no surgery	Initial decision for surgery	*P* value	Final decision for no invasive treatment	Final decision for invasive treatment	*P* value
Current use of opioids						
No	117 (96)	22 (88)	0.136	45 (92)	50 (96)	0.428
Yes	5 (4.1)	3 (12)		4 (8.2)	2 (3.9)	
PSEQ-2 (*r*)	10 ± 2.0	8.6 ± 3.3	**<.05**	10 ± 2.0	9.6 ± 2.3	0.303
PROMIS PF (*r*)	49 ± 7.3	46 ± 7.7	0.081	48 ± 7.7	47 ± 7.2	0.488
Pain intensity (*r*)	4.7 ± 2.3	4.8 ± 2.5	0.878	4.4 ± 2.5	5.12.3	0.151
Satisfaction with the visit (*r*)	9.1 ± 1.8	9.6 ± 0.64	0.106	9.4 ± 1.1	9.1 ± 2.0	0.330
All information understood	-	-	-	-	-	-
Enough information received						
No	2 (1.6)	0 (0)	1.00	2 (4.1)	0 (0)	0.233
Yes	120 (98)	25 (100)		47 (96)	52 (100)	
Reviewed decision aid						
No	63 (52)	8 (32)	0.083	26 (53)	23 (44)	0.428
Yes	59 (48)	17 (62)		23 (47)	29 (56)	
Decision to have surgery						
No	-	-	-	-	-	-
Yes	-	-		-	-	

Appendix 1. *Continued.*

Variable	Initial decision for no surgery	Initial decision for surgery	*P* value	Final decision for no invasive treatment	Final decision for invasive treatment	*P* value
After 2 weeks						
Final treatment choice						
Conservative	-	-		-	-	
Injection	-	-	-	-	-	-
Surgery	-	-		-	-	
PROMIS PF (*r*)	-	-	-	49 ± 7.9	49 ± 7.9	0.990
Pain intensity (*r*)	-	-	-	3.3 ± 2.5	2.3 ± 2.5	0.065
Satisfaction with the visit (*r*)	-	-	-	8.6 ± 1.8	9.4 ± 1.0	**<.05**
Assisted in decision making						
No	-	-	-	9 (18)	6 (12)	0.407
Yes	-	-		40 (82)	46 (88)	
Decision Regret Scale (*r*)	-	-	-	14 ± 15	11 ± 12	0.225

*Bold indicates statistically significant difference; Continuous variables as mean ± SD; Discrete variables as number (percentage); PSEQ-2: Pain Self-Efficacy Questionnaire short form; PROMIS PF: Patient-Reported Outcomes Measurement Information System Physical Function.

Appendix 2. Bivariate Analyses of Factors Associated With Physical Function and Pain Intensity for Baseline and Follow-Up Data*

Variable	PROMIS PF baseline	*P* value	PROMIS PF after 2 weeks	*P* value	Pain intensity baseline	*P* value	Pain intensity after 2 weeks	*P* value
Baseline								
Age, y (*r*)	-0.18	**<.05**	-0.33	**<.05**	0.06	0.472	0.17	0.092
Gender								
Female	47 ± 6.8	0.140	48 ± 7.6	0.075	5.0 ± 2.3	0.083	2.9 ± 2.5	0.470
Male	49 ± 8.4		51 ± 8.1		4.3 ± 2.3		2.5 ± 2.5	
Race/ethnicity								
White	47 ± 7.0	0.122	48 ± 7.9	0.154	4.5 ± 2.2	0.089	2.6 ± 2.4	0.187
Non-white	49 ± 8.2		50 ± 7.7		5.2 ± 2.6		3.3 ± 2.8	
Marital status								
Married/unmarried couple	49 ± 8.0	0.606	49 ± 8.4	0.600	4.6 ± 2.4	0.499	3.0 ± 2.6	0.150
Single	48 ± 6.3		49 ± 7.5		4.8 ± 2.1		1.9 ± 2.2	
Divorced/separated/widowed	47 ± 6.6		47 ± 6.5		5.2 ± 2.3		3.2 ± 2.4	
Level of education								
High school or less	46 ± 7.1	0.224	46 ± 7.2	0.280	5.5 ± 2.4	**<.05**	3.3 ± 3.0	0.067
2-year college	47 ± 7.3		49 ± 7.3		5.0 ± 2.4		3.9 ± 2.7	
4-year college	49 ± 7.0		50 ± 7.8		4.7 ± 2.2		2.5 ± 2.1	
Post-college graduate degree	50 ± 8.4		50 ± 8.9		3.7 ± 2.2		1.9 ± 2.1	
Work status								
Employed	49 ± 7.2	0.173	50 ± 7.9	0.071	4.8 ± 2.4	0.500	2.6 ± 2.5	0.405
Unemployed/other	47 ± 7.7		47 ± 7.6		4.6 ± 2.2		3.1 ± 2.5	

Appendix 2. *Continued.*

Variable	PROMIS PF baseline	*P* value	PROMIS PF after 2 weeks	*P* value	Pain intensity baseline	*P* value	Pain intensity after 2 weeks	*P* value
Current use of opioids								
No	48 ± 7.4	0.222	49 ± 7.8	0.366	4.7 ± 2.3	0.154	2.7 ± 2.5	0.479
Yes	45 ± 8.1		46 ± 9.1		5.9 ± 1.6		3.5 ± 3.2	
PSEQ-2 (*r*)	0.36	**<.05**	0.26	**<.05**	-0.23	**<.05**	-0.10	0.331
PROMIS PF (*r*)	-	-	0.68	**<.05**	-0.40	**<.05**	-0.30	**<.05**
Pain intensity (*r*)	0.40	**<.05**	-0.36	**<.05**	-	-	0.41	**<.05**
Satisfaction with the visit (*r*)	-0.01	0.886	0.04	0.687	0.11	0.17	0.09	0.379
All information understood	-	-	-	-	-	-	-	-
Enough information received								
No	48 ± 1.8	0.936	56 ± 1.8	0.204	4.0 ± 0.0	0.654	3.0 ± 4.2	0.906
Yes	48 ± 7.5		49 ± 7.9		4.7 ± 2.3		2.8 ± 2.5	
Reviewed decision aid								
No	48 ± 7.7	0.467	48 ± 8.3	0.417	4.6 ± 2.3	0.429	2.7 ± 2.5	0.591
Yes	48 ± 7.1		49 ± 7.4		4.9 ± 2.3		2.9 ± 2.5	
Decision to have surgery								
No	49 ± 7.3	0.081	50 ± 7.9	**<.05**	4.7 ± 2.3	0.888	2.5 ± 2.4	**<.05**
Yes	46 ± 7.7		44 ± 6.2		4.8 ± 2.5		4.2 ± 2.5	

Appendix 2. *Continued.*

Variable	PROMIS PF baseline	*P* value	PROMIS PF after 2 weeks	*P* value	Pain intensity baseline	*P* value	Pain intensity after 2 weeks	*P* value
After 2 weeks								
Final treatment choice								
Conservative	-	-	49 ± 7.9	**<.05**	-	-	3.3 ± 2.5	**<.05**
Injection	-		51 ± 7.3		-		1.6 ± 2.1	
Surgery	-		43 ± 6.2		-		4.1 ± 2.4	
PROMIS PF (*r*)	-	-	-	-	-	-	-0.39	**<.05**
Pain intensity (*r*)	-	-	-0.39	**<.05**	-	-	-0.19	0.059
Satisfaction with the visit (*r*)	-	-	0.04	0.686	-	-	-	-
Assisted in decision making								
No	-	-	48 ± 7.9	0.700	-	-	3.4 ± 3.1	0.311
Yes	-		49 ± 7.9		-		2.7 ± 2.4	
Decision Regret Scale (*r*)	-	-	-0.22	**<.05**	-	-	0.27	**<.05**

*Bold indicates statistically significant difference; Continuous variables as mean ± SD; Discrete variables as number (percentage); PSEQ-2: Pain Self-Efficacy Questionnaire short form; PROMIS PF: Patient-Reported Outcomes Measurement Information System Physical Function.

Appendix 3. Bivariate Analyses of Factors Associated With Satisfaction and Decision Regret for Baseline and Follow-Up Data*

Variable	Satisfaction baseline	*P* value	Satisfaction after 2 weeks	*P* value	Decision Regret Scale	*P* value
Baseline						
Age, y (*r*)	-0.01	0.883	-0.03	0.748	0.12	0.234
Gender						
Female	9.3 ± 1.5	0.059	9.2 ± 1.3	**<.05**	12 ± 13	0.304
Male	8.8 ± 1.9		8.5 ± 1.8		15 ± 15	
Race/ethnicity						
White	9.1 ± 1.7	0.763	8.9 ± 1.7	0.300	12 ± 13	0.563
Non-white	9.2 ± 1.5		9.2 ± 1.1		14 ± 15	
Marital status						
Married/unmarried couple	9.3 ± 1.2	0.287	9.0 ± 1.5	0.878	12 ± 14	0.748
Single	8.7 ± 2.2		9.1 ± 1.1		15 ± 13	
Divorced/separated/widowed	9.3 ± 2.1		9.0 ± 2.0		12 ± 15	
Level of education						
High school or less	9.4 ± 1.3	0.718	9.1 ± 1.8	0.589	15 ± 15	0.140
2-year college	9.0 ± 2.3		9.0 ± 1.5		19 ± 16	
4-year college	9.2 ± 1.8		9.1 ± 1.2		10 ± 12	
Post-college graduate degree	8.9 ± 1.3		8.6 ± 1.7		11 ± 12	
Work status						
Employed	9.1 ± 1.7	0.556	9.0 ± 1.4	0.633	13 ± 14	0.836
Unemployed/other	9.3 ± 1.6		8.9 ± 1.7		13 ± 14	

Appendix 3. *Continued.*

Variable	Satisfaction baseline	*P* value	Satisfaction after 2 weeks	*P* value	Decision Regret Scale	*P* value
Current use of opioids						
No	9.1 ± 1.7	0.408	8.9 ± 1.6	0.095	13 ± 14	0.724
Yes	9.6 ± 0.74		10 ± 0.0		11 ± 9.2	
PSEQ-2 (*r*)	-0.07	0.431	0.03	0.768	0.04	0.674
PROMIS PF (*r*)	-0.01	0.886	0.20	**<.05**	-0.18	0.067
Pain intensity (*r*)	0.11	0.171	0.06	0.520	0.06	0.564
Satisfaction with the visit (*r*)	-	-	0.27	**<.05**	-0.07	0.472
All information understood	-	-	-	-	-	-
Enough information received						
No	9.0 ± 1.4	0.893	8.5 ± 2.1	0.649	10 ± 14	0.775
Yes	9.2 ± 1.6		9.0 ± 1.5		13 ± 14	
Reviewed decision aid						
No	9.2 ± 1.3	0.991	8.8 ± 1.7	0.216	18 ± 13	**<.05**
Yes	9.2 ± 1.9		9.2 ± 1.4		8.0 ± 13	
Decision to have surgery						
No	9.1 ± 1.8	0.106	8.9 ± 1.6	0.390	13 ± 14	0.682
Yes	9.6 ± 0.64		9.3 ± 0.99		14 ± 14	
After 2 weeks						
Final treatment choice						
Conservative	-	-	8.6 ± 1.8	**<.05**	14 ± 15	0.224
Injection	-		9.5 ± 1.0		9.6 ± 11	

Appendix 3. *Continued.*

Variable	Satisfaction baseline	*P* value	Satisfaction after 2 weeks	*P* value	Decision Regret Scale	*P* value
Surgery	-		9.2 ± 0.98		15 ± 13	
PROMIS PF (*r*)	-	-	0.04	0.686	-0.22	**<.05**
Pain intensity (*r*)	-	-	-0.19	0.059	0.27	**<.05**
Satisfaction with the visit (*r*)	-	-	-	-	-0.36	**<.05**
Assisted in decision making						
No	-	-	8.2 ± 2.1	**<.05**	19 ± 17	0.057
Yes	-		9.1 ± 1.4		12 ± 13	
Decision Regret Scale (*r*)	-	-	-0.36	**<.05**	-	-

*Bold indicates statistically significant difference; Continuous variables as mean ± SD; Discrete variables as number (percentage); PSEQ-2: Pain Self-Efficacy Questionnaire short form; PROMIS PF: Patient-Reported Outcomes Measurement Information System Physical Function.

Appendix 4. Rationale for Treatment Choice

Rationale	No DA	DA	Total
Doctor's advice	16	14	30
Wanting direct solution for the problem	14	15	29
Faith in success of less-invasive treatment	11	16	27
Not wanting surgery	5	8	13
Prior experiences	2	7	9
Fear of recovery time	4	2	6
Need more time to make final decision	3	2	5
Based on DA	n/a	3	3
Combination of doctors' advise and DA	n/a	3	3
Own research	1	1	2
Fear of side effects/complications	2	0	2
Costs of treatment	2	0	2
No answer given by patient	*10*	*4*	*14*

DA: Decision aid; n/a: not available.

Chapter 11

General Discussion

This PhD thesis comprises several aspects of diagnosis and treatment of patients with two of the most common idiopathic mononeuropathies of the upper extremity, MNCT and UNE. While common in upper extremity surgery clinics, there is still debate on diagnostic and treatment options. The aims of this thesis were to aid surgeons in choosing measures that quantify patients' subjective aspects of health, highlight some of the debatable diagnostic and treatment options, and clarify what matters most for patients with idiopathic mononeuropathy of the upper extremity. Specific study aims are divided in four main parts: patient-reported outcome measures, electrodiagnosis, shared decision-making, and treatment.

Part I – Patient-Reported Outcome Measures

Patients with idiopathic mononeuropathy of the upper extremity present with varying symptom intensity. Quantifying subjective aspects of health (i.e. comfort and capability) with the use of PROMs and the experience of care (using PREMs) can be helpful, both in patient care and in research.[1-15] Often, these measures are used to compare a patient's state before and after an intervention.[3,6,11,15] Besides general comfort and capability measures, musculoskeletal questionnaires can be grouped in extremity-, region-, condition-, or even tissue-specific tools and evidence shows that PROMs of varying specificity are correlated.[1,5,7-14] There are myriad measures available and choosing the 'best one' can be difficult, especially because each patient and its values is different.

In our first study (Chapter 2), we included 130 patients with any upper extremity nerve-related condition and each completed measures of demographics, psychological limitations, quality of life, comfort and capability, and pain intensity. We found strong interquestionnaire correlations between the comfort and capability measures and moderate correlations with pain intensity and quality of life. We also found that symptoms of depression accounted for 53-84% of the variability in the PROMs. Our next study focused on 150 patients with CTS and/or CubTS (Chapter 3) and – besides correlation and multivariable testing – compared several PROMs based on their instrument properties. Similar moderate to strong interquestionnaire correlations were found and, again, self-reported symptoms of depression were best able to account for variations in comfort and capability and symptom intensity (68-100%). Our correlations are consistent with the evidence to date.[1,3,5,8-14] In various studies looking at upper extremity patients it seems that we get a better understanding of the fact that comfort and capability and symptom intensity is mainly driven by psychosocial factors, such as anxiety, depression, pain interference, self-efficacy, and catastrophic thinking.[3-6,10,14,16-18]

All PROMs tested had comparable floor effect (i.e. percentage of patients scoring at the lowest possible score). The measure that was shortest to complete (PROMIS PF-UE-7) was 5 times shorter than the longest measure (I-HaND) and had some expected ceiling effect (16%). We believe this was because we were not able to use the CAT version. The advantage of a CAT is that it tries to balance efficiency (i.e. few questions) with limited floor and ceiling effects.[1,7,8,10,12,13]

These findings suggest there may be limited advantage to disease- or tissue-specific PROMs, perhaps because they are all so closely tied to mental health. It also adds to the evidence that psychosocial factors have more influence on comfort and capability than pathophysiology. Future studies should assess if there are advantages of specific PROMs in terms of correlation with pathology, discerning (small) improvements in response to treatment, or recovery. Pending these results, we prefer to use simple, brief, and general PROMs, preferably based on a CAT model.

Part II – Electrodiagnosis

There is no consensus reference standard for diagnosing idiopathic mononeuropathy of the upper extremity. However, it is important to distinguish between a clinical diagnosis based on symptoms and signs and a diagnosis based on true neuropathy in order to choose the best treatment option available fitting a patient's values. Next to symptoms and clinical signs, diagnostic scales can be used to estimate the probability of neuropathy and EDx could be used to determine nerve pathology. Though, EDx results could be misleading, especially discerning patients with no to mild pathology. Knowing the diagnostic performance characteristics might aid surgeons and patients in their diagnostic and treatment plan and reduce the potential for unnecessary surgery.

Chapter 4 describes our retrospective study where we reviewed EDx results and demographics of 537 patients evaluated for possible idiopathic MNCT. We found that (1) in 2.6% to 33% of patients the nerve conduction study parameters were within 10% of the threshold for the diagnosis of MNCT; (2) overall, 3 out of 4 patients had EDx results consistent with MNCT; and (3) patients with normal EDx results were younger, did not report paresthesias, were more likely to have a prior normal EDx, and less likely to have had a previous contralateral CTR. In Chapter 5 we retrospectively looked at the EDx results and demographics of 133 patients with a clinical diagnosis of CubTS and found that 61% of EDx identified UNE, 14% identified other neuropathology, and 26% no neuropathology. Next to a prior electrodiagnosis of UNE on either side, older age and men were independently associated with positive EDx results of UNE.

There are practice recommendations but no definitive thresholds for interpreting EDx results in MNCT and UNE.[19-22] Therefore, we used thresholds in line with most other studies and the AAEM standards and guidelines[12,19-34] and found that up to a third of patients were within 10% of some of the threshold values for MNCT. Our results also demonstrated that only 76% of patients had MNCT and 61% had UNE, and 19% to 26% of patients had no neuropathy. Other studies looking at patients with CTS report up to 10% to 40% of normal EDx[25-29,35-37], and for CubTS these are around a third as well.[19,33] These numbers suggest the need for more stringent NCS criteria, supplemental NCS, or improved diagnostic scales. The Dutch guideline for CTS from 2017 reports that clear CTS (they do not refer to it as MNCT) is based on symptoms and signs and when there is doubt, additional testing should be done using ultrasonography and/or EDx.[38] The Dutch guideline for CubTS from 2011 reports an added value of EDx in patients with a clinical suspicion of UNE, especially to check for the location of compression, and in case of negative EDx ultrasonography could be considered.[39]

Both studies add to the evidence that neuropathology is more present in older patients, in patients with paresthesias, and in patients with a history of abnormal EDx on either side[3,19,25,27,32,33,40–45], supporting the concept that MNCT and UNE are structural and slowly progressive diseases.

Other studies could also look at differences in PREMs (like decision regret) when testing patients who chose treatment options based on clinical evaluation alone versus undergoing objective measures of neurophysiology. For patients with no to mild neuropathology we might be more comfortable addressing this as a less specific of nonspecific diagnosis and treat it conservatively, limiting additional tests and potential harmful interventions.

Part III – Shared Decision-Making

Decision-making in medicine has transformed from a directive, 1-way exchange of information from physician to patient (i.e. paternalistic model) to a SDM model where physician, patient, and patient confidants are involved and share their information and values to arrive at decisions.[46-58] Evidence to date shows involving patients in decisions improves health outcomes, quality of life, satisfaction, and adherence with treatment plans in part by reducing decision conflict.[46–48,51,52,54–56,58–63] Decision conflict is a state of uncertainty about the course of action to take and can be greater when there is more bias or debate about treatment options.[53,64,65] Key aspects include reorientation of common misconceptions, neutralization of physician bias, and clear and open communication to ensure choices are made based on patients' values (what matters most to them).[50]

Because there is debate in several areas of treating patients with CTS (for example, the use of EDx and corticosteroid injections or considering surgery when EDx is normal), this is a preference-sensitive condition in which SDM is important.

In Chapter 6 we studied 113 patients and their preferences regarding SDM for various aspects of the treatment for CTS. We found that patients with CTS generally prefer to share decisions with their surgeon with a tendency for more surgeon involvement especially in the operative and postoperative period. A study of 78 patients who underwent CTR found similar results; 76% preferred SDM for surgery, 18% wanted the surgeon to decide, and 6% wanted to decide themselves.[51] Variable conditions might influence thoughts on SDM. For instance, in a study surveying both patients with trigger finger and hand surgeons, surgeons preferred SDM, whereas patients preferred to make their own choices after receiving all necessary information.[64] In another field, 89 out of 101 (90%) patients undergoing elective vascular surgery wanted to make a final treatment choice together with their physician.[47]

Health care costs are continuously increasing[66-72] and a major part seems to come from a overuse of services, preventable complications, and inefficient health care processes.[66,69] To keep health care sustainable cost-conscious decisions seem necessary while maintaining care quality.[73] Evidence is lacking if patients consider societal costs (besides out of pocket costs) when they decide on treatment options. Especially in conditions where there is a variation in care, like (mild) CTS, insights in costs and benefits without compromising quality of care could aid in resource utilization and cost-effective treatments.

Chapters 7 & 8 look at the effect of societal cost information on treatment choice for CTS. First, we did a clinical RCT using a hypothetical scenario of mild CTS in 184 patients with any nontraumatic upper extremity diagnosis. Patients were randomized to review this case with or without showing societal costs for CTR and were asked their choice of treatment (splint or CTR [less expensive vs more expensive]). We found that patient treatment choice was not affected by societal cost information and no patient factors were independently associated with the choice for surgery. Following this, we performed an online RCT using Amazon Mturk and using the same hypothetical case of mild CTS, assessed treatment choice, and additionally, we qualitatively analyzed participants' rationale for their choice. Contrary to the clinical study, we found participants who reviewed societal cost information were more likely to choose surgery (the more expensive treatment option). Lack of personal costs frequently emerged as a theme in those in the cost cohort who chose surgery. In a study of 1,211 surveyed participants choosing between LVAD implantation or not in a hypothetical case of end-stage heart

failure, participants were more likely to accept an LVAD when shown total costs and when choosing for someone else.[74] Based on these 2 chapters, providing societal cost information may or may not influence treatment choice for patients with CTS, possible explanations might be: (1) a limited practice variation in our clinical sample of specialists showed no differences in patient treatment choice but a more general population that sees other physicians (with other opinions) or patients who do not see a physician (because of an online survey) might think otherwise; (2) age could be of influence, in our clinical study participants had a mean age of 50 years old and choice for surgery was not affected by societal costs, while in our online study we found that patient age of 39 years and younger modified the effect of societal cost information on choice for surgery, expressing their younger age and ability to recover; (3) DAs that hold information on treatment costs show differences in treatment choice based on the type of condition (i.e. maybe treatment choices for more life threatening conditions are less influenced by costs than other conditions); (4) treatment choice is more influenced by out-of-pocket costs, deductibles, or income than societal costs (because it affects patients directly); (5) people might answer differently when deciding for themselves or for others; (6) responses to hypothetical scenarios may not correspond with actual decisions that patients would make when facing these clinical problems.[71]

Patients had high agreement on health care attitude statements in chapters 7 & 8, indicating the costs of health care is one of the biggest problems facing the U.S, lack of personal monetary responsibility when choosing surgery, and many do not consider the country's health care costs in decision-making. To address the increasing costs in health care, health systems are looking for alternate payment models and more efficient health care models[66,70,75-78], likely with a value-based health care approach. Health care for patients with CTS for example could nudge toward better resource utilization and finding the best care pathways for (non)operative treatments.[76-83]

Future studies could assess SDM preferences and rationale for treatment choices by looking for factors that might influence this, like symptom intensity, health literacy, other aspects of cost of treatment like out-of-pocket costs and loss of income following time off work for surgery, geographical location, demographic factors, patient comfort and capability, and surgeon communication strategies.

Part IV – Treatment

The likely natural history of idiopathic MNCT and UNE is progression to nerve damage and surgical treatment is the only disease modifying treatment. Surgery is best done before there is permanent impairment (i.e. residual symptoms after surgery[41,84]). However,

as is the case in other conditions like distal radius fractures[85] and hand osteoarthritis[86,87], there is still treatment variation in these compression mononeuropathies. Among others, physician and patient beliefs seem to cause this variation[88-90], rather than variations in pathophysiology and other medical factors like comorbidities. This uncertainty can lead to the use of debatable diagnostic and treatment interventions and associated costs. Informing patients with or without the use of a decision aid (DA; a tool that informs patients about their condition and choices) might help patients become aware of their values, correct misconceptions, and neutralize clinician bias.

In Chapter 9 we studied a large commercial insurance claim database with new patient visits for either CTS, UNE (no CubTS since the ICD-10 codes were limited to CTS and UNE), or both, and identified the used of radiographs and injections and estimated total payments. Nearly 1 in 3 of 11,067 patients had radiographs for either condition, 9.7% of patients with CTS received an injection, and 2.6% with UNE, leading to a minimum $600k in payments. We also documented regional variations in the U.S.

Chapter 10 describes a RCT were 147 patients visiting an upper extremity surgeon were tested for difference PROMs, PREMs, treatment choice, and decision regret if they reviewed a DA or not. We found less decision regret 4-6 weeks after the visit in patients who reviewed a decision aid and who felt the surgeon helped them make a well-considered decision. Patients with less pain self-efficacy opted initially more for surgical intervention, were less comfortable and capable, and reported more pain.

The use of radiographs and injections at a new patient visit for CTS and UNE are common in the U.S. and the role for both is open to debate because they might prove to be of little or no benefit. If the examination of bones and joints is normal in patients with idiopathic CTS or CubTS, changes to these bones are unlikely to contribute to median or ulnar nerve symptoms making radiographic imaging unnecessary.[91] Some physicians opine that radiographs are useful to assess recurrent or unrelieved symptoms or to identify underlying skeletal abnormalities[91-95], but these seem potentially misleading if the probability of such disorders is low based on the symptoms and signs.[96]

There is no benefit to corticosteroid injections for UNE.[97] The evidence for injections that might be considered placebo (e.g. procaine[15,98], progesterone[99,100], or dextrose[23]) for MNCT show no or only short term (<6 months) benefit; for corticosteroid injections they show a slight decrease in symptoms that seems to deteriorate over about a year.[15,90,98,101-103] A retrospective study of 774 hands in 525 patients who received a corticosteroid injection for CTS (of which 8% had normal EDx and 15% were not tested on) found a median time to failure of treatment of 259 days and that 63% eventually underwent (median follow-up time of 7.3 years).[103]

Geographical diagnostic and treatment variation indicates there is a variation in care not based on pathophysiology or patient values, but on physician and patient beliefs.[87,104] This overutilization of possible unnecessary interventions might – among others – result from financial incentives, cultural expectations, or ineffective communication strategies.[88,89,103]

We found low decision regret scores but patients who reviewed a DA or who felt the surgeon assisted in making a well-considered decision had less decision regret. It seems important to identify and discuss common misconceptions – with or without a DA – as well as discovering patient values. The effectiveness of a DA for decision regret is variable for different diagnoses.[105-109] We believe DAs can be an assisting tool to help inform patients and organize their thoughts, especially correcting misconceptions patients might have about their condition before seeing their physician because they read conflicting information online or heard different from friends and family. For instance, patients with suspected idiopathic MNCT to undergo EDx or surgery.

Future studies should test if the beforementioned interventions truly have no or limited benefit in order to not only reduce costs, but to optimally treat patients according to the best available evidence and fitting their values. Finding out for which diagnoses a DA is beneficial to help inform patients about their condition and correct misconceptions could also affect the rate of discretionary surgery and help reduce decision regret. For example, people who see a clavicle fracture out of place on a radiograph might find it difficult to believe that nonsurgical treatment is an option and think that it should be fixed.

Eventually, the key is to distinguish between pathophysiology and illness or discomfort and incapability. We feel comfortable in holding off surgery when patients have symptoms but there is no to mild measurable neuropathy.

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Chapter 12

Summary

Nerves transmit impulses from the spinal cord to effector organs (like muscles) and from specialized sensory organs in the skin and deeper tissues towards the spinal cord. Nerves can be affected by either injury or compression, leading to temporary or permanent nerve damage and dysfunction (neuropathy). Usually, the clinical signs of compression neuropathies are tingling or numbness (paresthesia) and weakness. For most compression neuropathies the cause is unknown (idiopathic) and is ascribed largely to a tight anatomical space. This thesis focuses on the 2 most common idiopathic mononeuropathies in the upper extremity: median neuropathy at the carpal tunnel (MNCT) and ulnar neuropathy at the elbow (UNE). The umbrella term for the symptoms and signs characteristic of these conditions are carpal tunnel syndrome (CTS) and cubital tunnel syndrome (CubTS), respectively. This work is divided in 4 parts: (1) patient-reported outcome measures; (2) electrodiagnosis; (3) shared decision-making; and (4) treatment.

Part I – Patient-Reported Outcome Measures

Patient-reported outcome measures (PROMs) can be used to quantify subjective aspects of health (i.e. comfort and capability). There are myriad measures available, including general tools and extremity-, region-, condition-, and tissue-specific tools. We compared a relatively new upper extremity nerve-related PROM to other upper extremity musculoskeletal PROMs, pain intensity, quality of life, and measures of psychological limitations in 130 patients presenting with any upper extremity nerve-related condition (**Chapter 2**). We found (very) strong interquestionnaire correlations between PROMs and moderate correlations between PROMs and pain intensity and quality of life. In addition, greater symptoms of depression were independently associated with less comfort and capability (on all scales) and greater pain intensity. In the next study we compared the same upper extremity nerve-related PROM to an upper extremity musculoskeletal PROM, condition-specific PROMs, and measures of psychological limitations in 150 patients with either CTS and/or CubTS (**Chapter 3**). We found similar moderate to strong interquestionnaire correlations and, again, self-reported symptoms of depression were best able to account for variations in comfort and capability and symptom intensity. These findings suggest there may be limited advantage to disease- or tissue-specific PROMs and that psychosocial factors have more influence on comfort and capability than pathophysiology.

Part II – Electrodiagnosis

In order to choose the best treatment option available fitting a patient's values, we believe it is important to distinguish pathophysiology from illness (discomfort and incapability). For the diagnosis of idiopathic MNCT and UNE there is no consensus reference stan-

dard. Electrodiagnostic testing (EDx) can be used as a diagnostic adjunct to objectively evaluate the electrophysiological health (i.e. measuring the speed and intensity of impulses) of nerves. Though, EDx results can be equivocal, especially discerning patients with no to mild pathology. To get a better understanding of the diagnostic performance characteristics of EDx we retrospectively looked at nerve conduction study measurements of 537 patients evaluated for possible idiopathic MNCT (**Chapter 4**). Up to a third of the parameters were around the borderline of the threshold for diagnosis of MNCT. Seventy-six percent of EDx results were concordant with the clinical diagnosis of CTS, 19% had normal EDx, and 5% as another diagnosis. Among others, patients with normal EDx were significantly younger and reported no paresthesia. Although a relatively strong concordance between clinician and EDx diagnosis, we confirmed the uncertainty of the diagnostic strategies for suspected MNCT.

In another retrospective study we looked at EDx results of 133 patients with a clinical diagnosis of CubTS and found that 61% of EDx identified UNE, 14% identified other neuropathology, and 26% no neuropathology (**Chapter 5**). Besides a prior EDx result of UNE on either side, older age and men were independently associated with positive EDx results of UNE. The numbers we found suggest the need for more stringent EDx criteria or improved diagnostic scales, especially in patients with no to mild neuropathology. Both studies support the concept that MNCT and UNE are structural and slowly progressive diseases, support the use of clinical prediction rules, and may help inform a patient's decision regarding whether or not to have EDx.

Part III – Shared Decision-Making

Diagnostic and treatment choices are best based on the strategy consistent with both best evidence and what matters most to a patient, this process is often referred to as shared decision-making (SDM). Because there is debate in several areas of treating patients with CTS (for example. the use of EDx and corticosteroid injections or considering surgery when EDx is normal), this is a preference-sensitive condition in which SDM is important. We studied 113 patients and their preferences regarding SDM for various aspects of the treatment for CTS and found patients generally prefer to share decisions with their surgeon with a tendency for more surgeon involvement in the operative and postoperative period (**Chapter 6**). Looking at the available evidence, it seems that variable conditions might influence thoughts on SDM.

Health care costs are also part of SDM, because to keep health care sustainable cost-conscious decisions seem necessary while maintaining quality of care. We created a hypothetical scenario of mild CTS and asked 184 patients' preferred treatment choice

(**Chapter 7**). We found that treatment choice – that was a less expensive option of a splint versus a more expensive option of surgery – was not affected by reviewing societal cost information for these options. We studied this in more detail performing an online randomized controlled trial (RCT) using Amazon MTurk and using the same hypothetical case of mild CTS in 304 participants (**Chapter 8**). In contrary to the clinical study, we found participants who reviewed societal cost information opted more for surgical treatment. In addition, we employed a qualitative content analysis to evaluate a patient's rationale for their treatment choice and found a lack of personal monetary responsibility frequently emerges as a theme in those who reviewed societal cost information and chose surgery. Based on these 2 studies, societal cost information may or may not influence treatment choice for patients with CTS. Among others, an explanation could be that treatment choice is more affected by other costs like out-of-pocket costs, deductibles, or income than societal costs, because this affects patients directly. Future studies could address this and look for other factors that possibly influence SDM like symptom intensity, health literacy, or surgeon communication strategies.

Part IV – Treatment

The likely natural history of idiopathic MNCT and UNE is progression to nerve damage. Surgery may be the only pathophysiology-altering treatment with nonoperative treatments like splinting and corticosteroid injections perhaps palliative (symptom alleviating) at best. As with other conditions, there is still treatment variation in these compression mononeuropathies. We performed a large commercial insurance claim database study where we looked at the use of radiographs and corticosteroid injections at new patient visits for patients with a clinical diagnosis of CTS or UNE (not CubTS because of the codes we used; **Chapter 9**). Nearly 1 in 3 of 11,067 patients had radiographs for either condition, 9.7% of patients with CTS received an injection and 2.6% with UNE, leading to a minimum $600k in payments. We also documented regional variations in the U.S. The use of radiographs and injections at a new patient visit for CTS and UNE are common in the U.S. and the role for both is open to debate because they might prove to be of little or no benefit. Future studies could test the efficacy of injections for CTS in the long term.

Since there are often various treatment choices for a certain condition, health choices should be based on patients' values. A decision aid (DA; a tool that informs patients about their condition and choices) can help inform patients and correct misconceptions so they can choose the treatment option consistent with their values. Therefore, we completed a RCT including 147 upper extremity patients where they either reviewed or did not review a DA about their condition, including patients with clinical CTS (**Chapter**

10). Patients who reviewed a DA had less decision regret 4-6 weeks after the visit and who felt the surgeon helped them make a well-considered decision. Patients with less pain self-efficacy opted initially more for surgical intervention, were less comfortable and capable, and reported more pain. We believe DAs can be an assisting tool to help inform patients and organize their thoughts, especially correcting misconceptions patients might have about their condition before seeing their physician. Eventually, the key is to distinguish between pathophysiology and illness or discomfort and incapability. We feel comfortable in holding off surgery when patients have symptoms but there is no to mild measurable neuropathy.

Summarized Conclusions

- There is no clear advantage of using a nerve-specific, condition-specific, or upper extremity-specific PROM for measurement of comfort and capability in patients with idiopathic mononeuropathy of the upper extremity, perhaps because of their correlation with mental health (**Chapters 2 & 3**).
- Greater self-reported symptoms of depression is independently associated with less comfort and capability and greater pain intensity in patients with idiopathic mononeuropathy of the upper extremity (**Chapters 2 & 3**). This thesis adds to the growing evidence that psychosocial factors have more influence on comfort and capability than pathophysiology.
- Seventy-six percent of patients with a clinical diagnosis of CTS had EDx results indicating idiopathic MNCT, 5% had other neuropathology, and 19% had no measurable neuropathology (**Chapter 4**). For patients with a clinical diagnosis of CubTS, 61% had EDx results indicating idiopathic UNE, 14% had other neuropathology, and 26% had no measurable neuropathology (**Chapter 5**). Basing a diagnosis of MNCT or UNE solely on signs and symptoms carries a small risk for misdiagnosis.
- In 2.6% to 33% of patients EDx criteria are within 10% of the threshold (i.e. discriminating between no and mild neuropathology) for diagnosis of MNCT (**Chapter 4**). This leaves a diagnostic uncertainty, partly created by an absence of a reference standard.
- Older age, ipsilateral or bilateral paresthesias/numbness, prior EDx results confirming median neuropathy, and having had a previous contralateral carpal tunnel release are independently associated with an EDx of idiopathic MNCT (**Chapter 4**).
- Older age, men, and prior EDx results confirming ulnar neuropathy on either side are independently associated with an EDx of idiopathic UNE (**Chapter 5**).
- Patients with a clinical diagnosis of CTS or with EDx confirmed MNCT prefer to share decisions with their surgeon with a tendency for more surgeon involvement, especially

in the operative and postoperative period (**Chapter 6**). Individual patient preferences could be revealed when using DAs or preference elicitation tools.

- Providing societal cost information may or may not influence treatment choice for patients with CTS (**Chapters 7 & 8**). It might be that treatment choice is more affected by other costs like out-of-pocket costs, deductibles, or income than societal costs, because this affects patients directly.
- No demographic factors are independently associated with the treatment decision-making in patients with idiopathic MNCT (**Chapters 7 & 8**). A lack of personal monetary responsibility could drive the choice for surgery (**Chapter 8**).
- About 3 in 10 patients had radiographs and nearly 10% versus 2.6% of patients received an injection at a new patient visit for idiopathic CTS and UNE, respectively (**Chapter 9**). It highlights room for improvement to not only save costs, but also to improve care as the role of both is open to debate.
- A DA does not influence treatment choice or satisfaction with a visit, though, patients who review a DA have less decision regret with their treatment choice (**Chapter 10**). Therefore, DA help people make decisions that are more consistent with their values.

Chapter 13

Summary in Dutch (Samenvatting in het Nederlands)

Zenuwen brengen impulsen over van het ruggenmerg naar effectororganen (zoals spieren) en van gespecialiseerde sensorische organen in de huid en diepere weefsels naar het ruggenmerg. Zenuwen kunnen worden aangetast door letsel of compressie (beklemming), wat leidt tot tijdelijke of permanente zenuwbeschadiging en disfunctie (neuropathie). De meest voorkomende klinische symptomen van compressieneuropathieën zijn tintelingen of gevoelloosheid (paresthesie) en zwakte. Voor de meeste compressieneuropathieën is de oorzaak onbekend (idiopathisch) en wordt deze grotendeels toegeschreven aan een nauwe anatomische ruimte. Dit proefschrift richt zich op de 2 meest voorkomende idiopathische mononeuropathieën in de bovenste extremiteit: mediane neuropathie bij de carpale tunnel (MNCT) en ulnaire neuropathie bij de elleboog (UNE). De overkoepelende term voor de symptomen en tekenen die kenmerkend zijn voor deze aandoeningen zijn respectievelijk carpaal tunnel syndroom (CTS) en cubitaal tunnel syndroom (CubTS). Dit proefschrift is verdeeld in 4 delen: (1) door de patiënt gerapporteerde uitkomstmaten; (2) elektrodiagnose; (3) gedeelde besluitvorming; en (4) behandeling.

Deel I – Door de patiënt gerapporteerde uitkomstmaten

Door de patiënt gerapporteerde uitkomstmaten (patient-reported outcome measures; PROMs) zijn vragenlijsten die gebruikt kunnen worden om subjectieve aspecten van gezondheid (bijvoorbeeld psychologische gesteldheid en functionele status) te kwantificeren. Er zijn talloze vragenlijsten beschikbaar, waaronder algemene vragenlijsten en extremiteit-, regio-, aandoening- en weefselspecifieke vragenlijsten. We vergeleken een relatief nieuwe bovenste extremiteit en zenuw-gerelateerde PROM met andere PROMs van het bewegingsapparaat van de bovenste extremiteit, intensiteit van pijn, kwaliteit van leven, en metingen van psychologische beperkingen bij 130 patiënten met een aandoening van de bovenste extremiteit (**Hoofdstuk 2**). We vonden (zeer) sterke correlaties tussen de PROMs en middelmatige correlaties tussen de PROMs en intensiteit van pijn en kwaliteit van leven. Bovendien waren meer symptomen van depressie onafhankelijk geassocieerd met een mindere functionele status (op alle schalen) en een hogere intensiteit van pijn. In de volgende studie vergeleken we dezelfde bovenste extremiteit en zenuw-gerelateerde PROM met een PROM van het bewegingsapparaat van de bovenste extremiteit, aandoening specifieke PROMs en metingen van psychologische beperkingen bij 150 patiënten met ofwel CTS en/of CubTS (**Hoofdstuk 3**). We vonden vergelijkbare middelmatige tot sterke correlaties tussen de vragenlijsten en, nogmaals, zelf gerapporteerde symptomen van depressie waren het best in staat om variaties in functionele status en intensiteit van symptomen te verklaren. Deze bevindingen sug-

gereren dat er mogelijk een beperkt voordeel is voor aandoening- of weefselspecifieke PROMs en dat psychosociale factoren meer invloed hebben op de functionele status dan pathofysiologie.

Deel II - Elektrodiagnose

Om de best beschikbare behandelingsoptie te kiezen die past bij de waarden van een patiënt, vinden wij het belangrijk om pathofysiologie te onderscheiden van ziekte (ongemak en onvermogen). Voor de diagnose van idiopathische MNCT en UNE is er geen consensus over de referentiestandaard. Elektrodiagnostische tests (EDx) kunnen worden gebruikt als een diagnostisch hulpmiddel om de elektrofysiologische gezondheid (door het meten van de snelheid en intensiteit van impulsen) van zenuwen objectief te evalueren. Echter kunnen EDx resultaten ook onzeker zijn, vooral om het onderscheid te maken tussen patiënten zonder en met milde pathologie. Om de diagnostische kenmerken van EDx te begrijpen hebben we retrospectief gekeken naar zenuwgeleidingsmetingen van 537 patiënten die werden getest op mogelijke idiopathische MNCT (**Hoofdstuk 4**). Tot een derde van de zenuwgeleidingstestparameters bevond zich rond de grens van de afkapwaarde voor de diagnose MNCT. Zesenzeventig procent van de EDx resultaten kwam overeen met de klinische diagnose van CTS, 19% had normale EDx, en 5% had een andere diagnose. Onder andere waren patiënten met normale EDx significant jonger en rapporteerden geen paresthesieën. Hoewel er een relatief sterke overeenstemming is tussen de klinische diagnose en de EDx diagnose, laat deze studie zien dat er toch een onzekerheid is omtrent de diagnostische strategieën voor patiënten met vermoedelijke MNCT.

In een andere retrospectieve studie keken we naar EDx resultaten van 133 patiënten met een klinische diagnose van CubTS en ontdekten dat 61% van de EDx resultaten UNE identificeerde, 14% had andere neuropathologie, en 26% had geen neuropathologie (**Hoofdstuk 5**). Naast een eerder EDx resultaat van UNE aan beide kanten, waren oudere leeftijd en mannen onafhankelijk geassocieerd met positieve EDx resultaten passend bij UNE. De gevonden cijfers suggereren een noodzaak voor strengere EDx criteria of verbeterde diagnostische hulpmiddelen, vooral bij patiënten met geen tot milde neuropathologie. Beide onderzoeken ondersteunen het concept dat MNCT en UNE structurele en langzaam progressieve aandoeningen zijn, ze ondersteunen het gebruik van klinische voorspellingsregels, en kunnen helpen bij de beslissing van een patiënt over het al dan niet ondergaan van EDx.

Deel III - Gedeelde besluitvorming

Keuzes voor diagnostiek en behandeling kunnen het best gemaakt worden volgens de strategie die overeenkomt met zowel het beste wetenschappelijke bewijs als wat het meest belangrijk is voor een patiënt. Dit proces wordt vaak gedeelde besluitvorming (shared decision-making; SDM) genoemd. Omdat er op verschillende gebieden discussie is over de behandeling van patiënten met CTS (bijvoorbeeld het gebruik van EDx en corticosteroïd injecties of het overwegen van een operatie wanneer EDx resultaten normaal zijn), is dit een voorkeursgevoelige aandoening waarbij SDM belangrijk is. We bestudeerden 113 patiënten en hun voorkeuren met betrekking tot SDM voor verschillende aspecten van de behandeling van CTS en ontdekten dat patiënten over het algemeen de voorkeur geven aan het delen van beslissingen met hun chirurg, met een neiging tot meer betrokkenheid van de chirurg in de operatieve en postoperatieve periode (**Hoofdstuk 6**). Kijkend naar het beschikbare wetenschappelijke bewijs, lijkt het erop dat verschillende aandoeningen gedachten over SDM kunnen beïnvloeden.

Ook zorgkosten maken deel uit van SDM, want om de zorg duurzaam te houden lijken kostenbewuste keuzes nodig, met daarbij het behoud van kwaliteit van zorg. We creëerden een hypothetisch scenario van een milde CTS en vroegen 184 patiënten naar hun voorkeursbehandeling (**Hoofdstuk 7**). We ontdekten dat de behandelingskeuze – dit was een goedkopere optie van een spalk versus een duurdere optie van een operatie – niet werd beïnvloed door het delen van informatie over de kosten voor de maatschappij. We hebben dit in meer detail bestudeerd door een online gerandomiseerde en gecontroleerde trial (randomized controlled trial; RCT) uit te voeren met Amazon MTurk (een online platform waar mensen aan onderzoek kunnen meedoen) en met hetzelfde hypothetische geval van milde CTS bij 304 deelnemers (**Hoofdstuk 8**). In tegenstelling tot bij de klinische studie, ontdekten we dat deelnemers waarbij informatie over maatschappelijke kosten gedeeld werden, meer kozen voor (de duurdere) chirurgische behandeling. Als toevoeging hebben we een kwalitatieve analyse gedaan om de beweegredenen voor de behandelingskeuze te evalueren en ontdekten dat een gebrek aan persoonlijke financiële verantwoordelijkheid vaak naar voren kwam als thema bij diegenen waarbij informatie over maatschappelijke kosten gedeeld werden en die voor een operatie kozen. Op basis van deze 2 onderzoeken is het onduidelijk te zeggen of informatie over maatschappelijke kosten de keuze voor behandeling voor patiënten met CTS beïnvloeden. Een verklaring voor deze verschillen zou onder andere kunnen zijn dat de keuze voor een behandeling meer wordt beïnvloed door andere kosten, zoals een eigen bijdrage, het eigen risico, of inkomsten, dan door maatschappelijke kosten, omdat dit patiënten rechtstreeks treft. Toekomstige studies zouden dit kunnen testen en

ook kunnen zoeken naar andere factoren die mogelijk van invloed zijn op SDM, zoals de intensiteit van symptomen, gezondheidsvaardigheden (dit is de mate waarin mensen beschikken over het vermogen om informatie op het gebied van gezondheid te begrijpen), of communicatiestrategieën voor chirurgen.

Deel IV - Behandeling

Het waarschijnlijke natuurlijke beloop van idiopathische MNCT en UNE is progressie naar zenuwbeschadiging. Chirurgie is mogelijk de enige pathofysiologie-veranderende behandeling. Niet-operatieve behandelingen zoals spalken en corticosteroïd-injecties zijn misschien op zijn best palliatief (symptoom verlichtend). Net als bij andere aandoeningen is er nog steeds variatie in de behandeling van deze compressie mononeuropathieën. We hebben een studie uitgevoerd met gebruik van een grote commerciële database met verzekeringsclaims (uit de Verenigde Staten; VS), waarbij we hebben gekeken naar het gebruik van röntgenfoto's en corticosteroïdinjecties bij eerste bezoeken voor patiënten met een klinische diagnose van CTS of UNE (niet CubTS vanwege de codes die we gebruikten; **Hoofdstuk 9**). Bijna 1 op de 3 van de 11.067 patiënten kreeg röntgenfoto's voor beide aandoeningen, 9,7% van de patiënten met CTS kreeg een injectie en 2,6% met UNE, wat leidde tot minimaal $600.000 aan kosten. Daarnaast zagen we regionale variaties in de VS voor het gebruik van röntgenfoto's en injecties. Het gebruik van röntgenfoto's en injecties bij een nieuw patiëntbezoek voor CTS en UNE is gebruikelijk in de VS en de rol voor beide staat ter discussie omdat ze mogelijk weinig of geen voordeel geven. Toekomstige studies zouden de werkzaamheid van injecties voor CTS op de lange termijn kunnen testen.

Aangezien er vaak verschillende behandelingskeuzes zijn voor een bepaalde aandoening, moeten gezondheidskeuzes gebaseerd zijn op de waarden van de patiënt. Een keuzehulp (decision aid; DA; een hulpmiddel dat patiënten informeert over hun aandoening en opties) kan helpen om patiënten te informeren en misvattingen te corrigeren, zodat ze de behandeloptie kunnen kiezen die het best overeenkomt met hun waarden. Daarom hebben we een RCT gedaan met 147 patiënten met een aandoening aan de bovenste extremiteit. Hierbij kreeg een deel een DA over de aandoening te lezen, en het andere deel niet. In deze studie zaten ook patiënten met een klinische diagnose van CTS (**Hoofdstuk 10**). Patiënten die een DA lazen hadden 4-6 weken na het bezoek minder spijt van hun behandelkeuze en vonden dat de chirurg hen hielp een weloverwogen beslissing te nemen. Patiënten met minder zelfredzaamheid om met pijn om te gaan kozen in eerste instantie meer voor chirurgische ingrepen, hadden een slechtere functionele status, en rapporteerden meer pijn. Wij geloven dat DAs een hulpmiddel

kunnen zijn om patiënten te helpen informeren en hun gedachten te ordenen, vooral om misvattingen te corrigeren die patiënten kunnen hebben over hun aandoening voordat ze hun arts bezoeken. Uiteindelijk is het noodzakelijk om onderscheid te maken tussen pathofysiologie en ziekte of ongemak en onvermogen. Wij voelen ons comfortabel in het uitstellen van een operatie wanneer patiënten symptomen hebben, maar er geen tot milde meetbare neuropathie is.

Samengevatte conclusies

- Er is geen duidelijk voordeel voor het gebruik van een zenuw-, aandoening- of bovenste extremiteit-specifieke PROM voor het meten van de functionele status bij patiënten met een idiopathische mononeuropathie van de bovenste extremiteit, mogelijk vanwege hun correlatie met mentale gezondheid (**Hoofdstukken 2 & 3**).
- Meer zelf gerapporteerde symptomen van depressie zijn onafhankelijk geassocieerd met een slechtere functionele status en een hogere intensiteit van pijn bij patiënten met een idiopathische mononeuropathie van de bovenste extremiteit (**Hoofdstukken 2 & 3**). Dit proefschrift draagt bij aan het groeiende bewijs dat psychosociale factoren meer invloed hebben op de functionele status dan pathofysiologie.
- Zesenzeventig procent van de patiënten met een klinische diagnose van CTS had EDx resultaten die overeenkwamen met idiopathische MNCT, 5% had een andere neuropathologie, en 19% had geen meetbare neuropathologie (**Hoofdstuk 4**). Van de patiënten met een klinische diagnose van CubTS had 61% EDx resultaten die op idiopathische UNE duidden, 14% had een andere neuropathologie, en 26% had geen meetbare neuropathologie (**Hoofdstuk 5**). Een diagnose van MNCT of UNE uitsluitend baseren op klinische tekenen en symptomen brengt een klein risico op het maken van een verkeerde diagnose met zich mee.
- Bij 2,6% tot 33% van de patiënten bevinden de EDx criteria zich binnen 10% van de afkapwaarde (onderscheid makend tussen geen en milde neuropathologie) voor de diagnose van MNCT (**Hoofdstuk 4**). Dit veroorzaakt een onzekerheid wat betreft de diagnostiek, wat mede veroorzaakt wordt door het ontbreken van een referentiestandaard.
- Hogere leeftijd, ipsilaterale of bilaterale paresthesieën/gevoelloosheid, eerdere EDx resultaten die mediane neuropathie bevestigen, en eerder een contralaterale carpale tunnel operatie te hebben gehad, zijn onafhankelijk geassocieerd met een EDx passend bij idiopathische MNCT (**Hoofdstuk 4**).

- Oudere leeftijd, mannelijk geslacht, en eerdere EDx resultaten die ulnaire neuropathie aan een of beide zijden bevestigen, zijn onafhankelijk geassocieerd met een EDx passend bij idiopathische UNE (**Hoofdstuk 5**).
- Patiënten met een klinische diagnose van CTS of met EDx bevestigde MNCT geven er de voorkeur aan om beslissingen met hun chirurg te delen, met een neiging tot meer betrokkenheid van de chirurg in de operatieve en postoperatieve fase (**Hoofdstuk 6**). Individuele voorkeuren van patiënten kunnen aan het licht komen door het gebruik van DAs.
- Het verstrekken van informatie over de maatschappelijke kosten kan al dan niet van invloed zijn op de behandelingskeuze van patiënten met CTS (**Hoofdstukken 7 & 8**). Mogelijk wordt de keuze voor een behandeling meer beïnvloed door andere kosten, zoals de eigen bijdrage, het eigen risico, of inkomsten, dan door maatschappelijke kosten, omdat dit patiënten rechtstreeks treft.
- Er zijn geen demografische factoren onafhankelijk geassocieerd met de besluitvorming over de behandeling bij patiënten met idiopathische MNCT (**Hoofdstukken 7 & 8**). Een gebrek aan persoonlijke financiële verantwoordelijkheid zou de keuze voor een operatie kunnen beïnvloeden (**Hoofdstuk 8**).
- Ongeveer 3 op de 10 patiënten kregen röntgenfoto's en bijna 10% versus 2,6% van de patiënten kreeg een injectie tijdens hun eerste bezoek voor respectievelijk idiopathische CTS en UNE (**Hoofdstuk 9**). Dit wijst op ruimte voor verbetering om niet alleen kosten te besparen, maar ook om de zorg te verbeteren, aangezien de rol van beide ter discussie staat.
- Een DA heeft geen invloed op de behandelkeuze of tevredenheid met een bezoek, hoewel patiënten die een DA gezien hebben minder spijt hebben van hun behandelkeuze (**Hoofdstuk 10**). Daarom helpt DA mensen beslissingen te nemen die meer in overeenstemming zijn met hun waarden.

List of Abbreviations

AA(N)EM	American Association of (Neuromuscular &) Electrodiagnostic Medicine
AAN	American Academy of Neurology
AAPMR	American Academy of Physical Medicine and Rehabilitation
AE	above elbow
AIN	anterior interosseous neuropathy
ß	regression coefficient
BCTQ	Boston Carpal Tunnel Syndrome Questionnaire
BE	below elbow
CAT	computerized adaptive test
CI	confidence interval
CMAP	compound motor action potential
CPS	Control Preference Scale
CPT	current procedural terminology
CTR	carpal tunnel release
CTS	carpal tunnel syndrome
CTS-6	6-item CTS Symptoms Scale
CT-scan	computerized tomography scan
CubTS	cubital tunnel syndrome
CubTR	cubital tunnel release
DA	decision aid
DML	distal motor latency
DSL	distal sensory latency
EDx	electrodiagnostic test(ing)
EMG	electromyography
EQ-5D-3L	EuroQol's 5-domain and 3-level questionnaire
HIPAA	Health Insurance Portability and Accountability Act
ICD-10	International Classification of Diseases-10th revision
I-HaND	Impact of Hand Nerve Disorders
IQR	interquartile range
LVAD	left ventricular assist device
MNCT	median neuropathy at the carpal tunnel
MRI-scan	magnetic resonance imaging scan
MTurk	Amazon Mechanical Turk

NCS	nerve conduction study
NCV	nerve conduction velocity
NHS	National Health Service
NR	nonrecordable
NSAID	non-steroidal anti-inflammatory drug
OOP	out-of-pocket
OR	odds ratio
PhD	Doctor of Philosophy
PHQ-2	Patient Health Questionnaire short form
PIN	posterior interosseous neuropathy
PREM	patient-reported experience measure
PROM	patient-reported outcome measure
PROMIS PF(-UE)	Patient-Reported Outcomes Measurement Information System Physical Function (Upper Extremity)
PROMIS PF-UE-7	Shortened non-CAT version of PROMIS PF-UE
PRUNE	Patient-Rated Ulnar Nerve Evaluation
PSEQ-2	Pain Self-Efficacy Questionnaire short form
(Quick)DASH	(shortened version of) Disabilities of the Arm, Shoulder and Hand
RCT	randomized controlled trial
REDCap	Research Electronic Data Capture
SD	standard deviation
SDM	shared decision-making
TSK-4	Tampa Scale for Kinesiophobia short form
UNE	ulnar neuropathy at the elbow
U.S.	United States
VAS	Visual Analogue Scale
VS	Verenigde Staten

In addition: the term 'comfort and capability' is one that keeps on developing and will probably change in the future. Among others, we have used it as 'physical limitations' and 'activity intolerance' throughout our work. It can be read interchangeably.

Acknowledgments

Prof. D. Ring, dear David, ever since my first day in Boston you have inspired me both professionally and personally. Your out-of-the-box mindset as a researcher, comprehensive approach as a surgeon, effectiveness (as of this writing, we have exchanged over 11,000 emails), and personality are incredible. You were the reason I came to Austin for research. I feel blessed to have you as my mentor and friend.

Prof. J.H. Coert and Dr. A.H. Schuurman, dear Henk and Arnold, thank you for being my promotor and co-promotor and helping me finalize this thesis in order to obtain my PhD.

Assoc. Prof. L.M. Reichel, dear Lee, thank you for facilitating to enroll patients in your office. I always enjoyed discussing interesting cases with you, eating the various treats you brought to the office, and hearing about your craftsmanship skills (plus getting a customized pen case myself).

Asst. Prof. G.A. Vagner, dear Gregg, I believe I enrolled most patients in your offices, for which I am forever grateful. I loved hearing you talk about being a wine connoisseur, letting me taste some exquisite wines in Vegas, and had a blast spending time together at the Dell Technologies PGA Tour event.

All physicians, physician assistants, physical therapists, nurses, social workers, and supporting staff from Dell Medical School, Austin Regional Clinic, and all other collaborating offices (both locally, nationally, and internationally), thank you for your hospitality, patience, knowledge, kindness, and support in helping us do research in order to improve care. We could not have done this without you. Keep being awesome!

All co-authors and (inter)national students with whom I have had the pleasure of working with directly or indirectly. All your efforts coming up with new study ideas, enrolling patients, doing statistics, and writing papers are greatly appreciated. We definitely have created a 'Science Factory 2.0'. Also, spending time in the off-hours doing activities and going to bars was a lot of fun and made living in Austin an unforgettable experience.

All donors who contributed to the University of Texas at Austin HornRaiser Program, thank you very much for all your kind and generous donations that made it possible to continue living and doing research in Austin. Hook 'em!

Review committee, thank you for your time and interest in this thesis.

Asst. Prof. T. Teunis and Dr. S.J. Janssen, dear Teun and Stein, since the beginning of my scientific internship at MGH you have made me enthusiastic about research. You have taught me almost everything I know about statistics and helped me publish my first papers. Thank you.

My family, in-laws, and friends, thank you for always being there for me and for your support (especially when I had to miss yet another party or get-together). Most of you made efforts to visit us or reached out in other ways to be part of our amazing experience in Austin. I love you all.

Jorrit, my dear friend and paranymph, we have spent many hours together in school, playing sports, and on other occasions. I admire your interest in others, and we always end up laughing about the silly things in life. Thanks for standing next to me on this big day.

Denise, for 34 years already you have been my big sister. I am proud of you and your lovely family. I look forward to having you by my side as my paranymph during the public defense of this thesis.

Mom and Dad, I cannot thank you enough for everything you have done for me in my life. You have raised me with unconditional love and made everything that I have dreamt of possible.

Marie, two years in Austin together went by too quick but we have enjoyed every little moment of it. The great view from our balcony, trips around the city on our scooter, great places to eat and drink, and our road trip with the camper through the West of the U.S. are things we will always cherish. I admire your loving and caring personality and I am proud of everything you have accomplished. Looking forward to starting our next adventure with our little one. I love you.

Report of Scholarship

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**Equal contributions*

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- **Kortlever JTP***, Zhuang T*, Ring D, Reichel LM, Vagner GA, Kamal RN. Does Societal Cost Information Affect Patient Decision-Making in Carpal Tunnel Syndrome? A Randomized Controlled Trial. *Department of Surgery and Perioperative Care Hand Clinical Conference Dell Medical School: WALANT Carpal Tunnel Discussion and Open Case Forum.* January 18, 2019, Austin TX, USA
- Bankhead-Kendall B, **Kortlever JTP**, Ryder A, Ring D, Teixeira P, Brown CVR, Salazar R. Surgical Patients Display an Unconscious Bias Against Female Surgeons. *Dell Medical School Department of Surgery and Perioperative Care 2nd Annual Research Symposium.* March 29, 2019, Austin TX, USA
- Kleiss IIM, **Kortlever JTP**, Karyampudi P, Ring D, Brown LE, Reichel LM, Driscoll MD, Vagner GA. A Comparison of Four Single Question Measures of Patient Satisfaction. *Dell Medical School Department of Surgery and Perioperative Care 2nd Annual Research Symposium.* March 29, 2019, Austin TX, USA
- Rijk L, **Kortlever JTP**, Bandell DLJI, Zhang J, Gallagher SM, Bozic KJ, Ring D. Hinkley D. The Impact of Socioeconomic Status and Social Deprivation on Musculoskeletal Limitations. *Dell Medical School Department of Surgery and Perioperative Care 2nd Annual Research Symposium.* March 29, 2019, Austin TX, USA
- Donthula D, **Kortlever JTP**, Ring D, Donovan E, Reichel LM, Vagner GA. Does Intolerance of Uncertainty Affect Magnitude of Limitations or Pain Intensity? *Dell*

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– Jayakumar P, **Kortlever JTP**, Brown LE, Ring D. A Two Question Resiliency Measure for Screening Mental Health. *Dell Medical School Department of Surgery and Perioperative Care 2nd Annual Research Symposium.* March 29, 2019, Austin TX, USA
– Gonzalez AI, **Kortlever JTP**, Crijns TJ, Brown LE, Ring D, Reichel LM, Vagner GA. Tenderness and Fracture Healing in the Upper Extremity. *Dell Medical School Department of Surgery and Perioperative Care 2nd Annual Research Symposium.* March 29, 2019, Austin TX, USA
– **Kortlever JTP***, Zhuang T*, Ring D, Reichel LM, Vagner GA, Kamal RN. Does Societal Cost Information Affect Patient Decision-Making in Carpal Tunnel Syndrome? A Randomized Controlled Trial. *Dell Medical School Department of Surgery and Perioperative Care 2nd Annual Research Symposium.* March 29, 2019, Austin TX, USA
– **Kortlever JTP**, Brandsema B, Gradl-Dietsch G, Zhao M, Ring D. Nerve Conduction Study Results for Suspected Cubital Tunnel Syndrome. *American Shoulder and Elbow Surgeons Annual Meeting.* October 16-19, 2019, New York NY, USA
– Bankhead-Kendall B, **Kortlever JTP**, Brown CVR, Teixeira P, Ryder A, Ring D, Salazar R. Surgical Patients Display an Unconscious Bias Against Female Surgeons. *American College of Surgeons Scientific Forum at Clinical Congress 2019*. October 28, 2019, San Francisco CA, USA
– Moore M, Ring D, Gobble R, Henry S, **Kortlever JTP**. Are Articles in Plastic Surgery Journals Cited More When Published Open-Access? An Analysis over a Decade. *Virtual Plastic Surgery The Meeting 2020.* October 9, 2020, Virtueel

**Equal contributions*

Poster Presentations (Presenter)

1. **Kortlever JTP**, Witteveen P. The Third Eye Retroscope: Looking Back Could Save Your Life. *Techniek in de Geneeskunde.* May 26, 2011, Amsterdam, NL
2. **Kortlever JTP**, Ottenhoff JSE, Vagner GA, Ring D, Reichel LM. Visit Duration Does Not Correlate with Patient Perceived Empathy. *73th Annual Meeting of the American Society for Surgery of the Hand.* September 13-15, 2018, Boston MA, USA

3. Ottenhoff JSE, **Kortlever JTP**, Boersma EZ, Laverty DC, Ring D, Driscoll MD. Adverse Childhood Experiences Are Not Associated With Patient-Reported Outcome Measures in Patients with Musculoskeletal Illness. *73th Annual Meeting of the American Society for Surgery of the Hand.* September 13-15, 2018, Boston MA, USA
4. **Kortlever JTP**, Leyton-Mange A, Keulen MHF, Liu T, Janssen SJ, Bozic KJ, Schultz WR, Koenig K. PROMIS Physical Function Correlates with KOOS, JR in Patients with Knee Pain. *American Academy of Orthopaedic Surgeons Annual Meeting.* March 12-16, 2019, Las Vegas NV, USA
5. **Kortlever JTP**, Tran TTH, Ring D, Menendez ME. The Growth of Poorly Cited Articles in Peer-Reviewed Orthopaedic Journals. *American Academy of Orthopaedic Surgeons Annual Meeting.* March 12-16, 2019, Las Vegas NV, USA
6. **Kortlever JTP**, Ottenhoff JSE, Vagner GA, Ring D, Reichel LM. Visit Duration Does Not Correlate with Perceived Physician Empathy *American Academy of Orthopaedic Surgeons Annual Meeting.* March 12-16, 2019, Las Vegas NV, USA
7. **Kortlever JTP**, Ottenhoff JSE, Tran TTH, Ring D, Vagner GA, Driscoll MD. Do Patients Unconsciously Associate Suggestions for More-invasive Treatment with Better Care? *American Academy of Orthopaedic Surgeons Annual Meeting.* March 12-16, 2019, Las Vegas NV, USA
8. Boersma EZ, **Kortlever JTP**, Loeb MD, McDonald J, Vagner GA, Ring D, Driscoll MD. The Association between Patient-Reported Outcome Measurement Scores and Preference for Specific Interventions. *74th Annual Meeting of the American Society for Surgery of the Hand.* September 5-7, 2019, Las Vegas NV, USA
9. Tran THT, **Kortlever JTP**, Teunis T, Ring D, Vagner GA, Reichel LM. Attitudes Toward Aging Among Patients with Upper Extremity Illness. *74th Annual Meeting of the American Society for Surgery of the Hand.* September 5-7, 2019, Las Vegas NV, USA
10. **Kortlever JTP***, Zhuang T*, Ring D, Reichel LM, Vagner GA, Kamal RN. Does Societal Cost Information Affect Patient Decision-Making in Carpal Tunnel Syndrome? A Randomized Controlled Trial. *74th Annual Meeting of the American Society for Surgery of the Hand.* September 5-7, 2019, Las Vegas NV, USA
11. Crijns TJ, **Kortlever JTP**, Teunis T, Ring D. Differences Between Patient and Surgeon Interests in Musculoskeletal Research. *74th Annual Meeting of the American Society for Surgery of the Hand.* September 5-7, 2019, Las Vegas NV, USA
12. **Kortlever JTP**, Becker SJE, Zhao M, Ring D. Borderline Nerve Conduction Velocities for Suspected Carpal Tunnel Syndrome. *74th Annual Meeting of the American Society for Surgery of the Hand.* September 5-7, 2019, Las Vegas NV, USA

13. **Kortlever JTP**, Tripathi S, Ring D, McDonald J, Smoot B, Laverty D. Tampa Scale for Kinesiophobia Short Form and Lower Extremity Specific Limitations. *74th Annual Meeting of the American Society for Surgery of the Hand.* September 5-7, 2019, Las Vegas NV, USA
14. Haidar LA, **Kortlever JTP**, Ring D. Comparing Elbow Pathophysiology in Throwers Choosing Ligament Reconstruction to Those Who Do Not. *American Shoulder and Elbow Surgeons Annual Meeting*. October 16-19, 2019, New York NY, USA
15. Kim E, **Kortlever JTP**, Gonzalez AI, Dale J, Ring D, Reichel LM. Incidental Distal Biceps Tendinopathy on Magnetic Resonance Imaging. *American Shoulder and Elbow Surgeons Annual Meeting*. October 16-19, 2019, New York NY, USA
16. Kleiss IIM, **Kortlever JTP**, Ring D, Vagner GA, Reichel LM. A Randomized Controlled Trial of Decision Aids for Upper Extremity Conditions. *American Academy of Orthopaedic Surgeons Annual Meeting.* March 24-28, 2020, Orlando FL, USA
17. Kleiss IIM, **Kortlever JTP**, Ring D, Vagner GA, Reichel LM. Fatehi A. A Randomized Controlled Trial of Decision Aids for Upper Extremity Conditions. *Healthcare Communication Virtual Research Forum of the Academy of Communication in Healthcare.* June 27-28, 2020, Austin TX, USA
18. Lemmers M, Versluijs Y, **Kortlever JTP**, Gonzalez AI, Ring D. Misperception of Disease Onset in People with Gradual Onset Disease of the Upper Extremity. *75th Annual Meeting of the American Society for Surgery of the Hand.* October 1-3, 2020, San Antonio TX, USA
19. Kim E, **Kortlever JTP**, Gonzalez AI, Reichel LM, Ring D. Prevalence of Incidental Biceps Tendinopathy on MRI. *75th Annual Meeting of the American Society for Surgery of the Hand.* October 1-3, 2020, San Antonio TX, USA
20. O'Connor CM, **Kortlever JTP**, Ring D. Misinformation in Patient Handouts about Upper Extremity Illness. *75th Annual Meeting of the American Society for Surgery of the Hand.* October 1-3, 2020, San Antonio TX, USA
21. O'Connor CM, **Kortlever JTP**, Vagner GA, Reichel LM, Ring D. Patient and Surgeon Factors Associated with Prosthetic Replacement Rather than Open Reduction and Internal Fixation of a Radial Head Fracture. *75th Annual Meeting of the American Society for Surgery of the Hand.* October 1-3, 2020, San Antonio TX, USA
22. Bakker D, **Kortlever JTP**, Kraan GA, Mathijssen N, Colaris JW, Ring D. Treatment Recommendations for Suspected Scapholunate Ligament Pathology. *FESSH-ON(line)-WEEK 2021 Virtual Congress.* June 16-19, 2021, Virtual

**Equal contributions*

About the Author

Joost Teunis Pieter Kortlever was born on January 31, 1990 in Nieuwegein, The Netherlands. He graduated high school in 2008 and subsequently started medical school at the University of Amsterdam. His goal to become an (orthopedic) surgeon was apparent early on in his career, partly by growing up playing sports, being a handyman, and his interest in anatomy, trauma, and injuries. Halfway through his medical school he completed a five-month scientific internship at Massachusetts General Hospital of Harvard Medical School in Boston. During his time at the Hand & Upper Extremity department he took on his first research projects under the supervision of Prof. Dr. David Ring. He published his first papers and his interest in combining surgery with clinical research was sparked. He went on to finish medical school in 2017 and then started his two-year PhD research fellowship at the department of Surgery and Comprehensive Care of The University of Texas at Austin (under supervision of Prof. Dr. David Ring and of Prof. Dr. Henk Coert and Dr. Arnold Schuurman from Utrecht Medical Center). Inspired by the well-known international research activities in Boston, he helped setup and grow the 'Science Factory 2.0' in Austin. With his help, this has led to a continuous collaboration of research activities between various orthopedic clinics in Austin and the fruitful involvement of both national and international researchers. Among others, his work resulted in numerous peer-reviewed publications, presentations at international conferences, Clinical Orthopaedics and Related Research 'Top-50 Worldwide Reviewer' in 2019, and this PhD thesis. He was the director of research of the Science Of Variation Group (a collaborative effort of a large number of fully trained, practicing, and experienced surgeons to improve the study of variation in interpretation and classification of injuries) from 2017 to 2020. In the two years following his research fellowship he worked as a resident not in training in General Surgery and Orthopedic Surgery. In January 2022, he started his residency at the department of General Surgery of Canisius Wilhelmina Hospital in Nijmegen, The Netherlands. In the summer of 2023, he continued his Orthopedic Surgery residency at Radboud University Medical Center in Nijmegen.