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A Randomized Trial of Diagnostic Ultrasound to Improve Outcomes in Focal Neuropathies

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Abstract

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Introduction—Neuromuscular ultrasound is valid, reliable, and accurate, but it is not known if combining it with electrodiagnostic studies leads to better outcomes in individuals with focal neuropathies.

Methods—120 individuals with focal neuropathy based on history, examination, and electrodiagnosis were enrolled. All underwent neuromuscular ultrasound and were randomized to either have their ultrasound results sent to the referring physician or not. Outcomes were assessed at 6 months by evaluators blinded to group assignment.

Results—The Overall Disability Sum Score and 7 of 8 domains of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) showed more improvement in the “report sent” group, though only the general health perception domain was significant ($P = 0.005$).

Conclusions—Most 6-month outcomes did not reach statistical significance between the 2 groups. However, the “report sent” group had trends toward better outcomes with significance reached in the general health perception domain of the SF-36.

Keywords

Ultrasound; Nerve; Carpal Tunnel Syndrome; Ulnar Neuropathy at the Elbow; Outcomes

Introduction

The term “focal neuropathy” refers to a heterogeneous group of conditions in which a single nerve is damaged at a single site. The most common focal neuropathies are idiopathic median mononeuropathy at the wrist [carpal tunnel syndrome (CTS)] and ulnar mononeuropathy at the elbow, but other focal neuropathies include ulnar mononeuropathy at the wrist, fibular mononeuropathy at the knee, and a variety of other mononeuropathies resulting from trauma, masses, and anatomic anomalies.^{1–3} Focal neuropathies are common and costly; CTS alone affects 2.7% of the adult population, is the second-most common indication for workers’ compensation filings, and results in total healthcare costs exceeding \$1 billion annually in the United States.^{4–8}

Treatment of focal neuropathies varies, from rest to physical therapy to surgical intervention, and optimizing treatment begins by first establishing an accurate and refined diagnosis. For half a century, nerve conduction studies and electromyography (EMG), guided by a detailed history and physical examination, have served as the mainstay to confirm the presence of a focal neuropathy.⁹ Additionally, these electrodiagnostic tests allow clinicians to localize and grade the severity of the mononeuropathy. However, electrodiagnosis also forces clinicians to make inferences based upon assumed anatomy and does not provide an anatomic evaluation of the nerve itself or surrounding structures. To fill this void, high-resolution ultrasound has emerged over the past 2 decades as an effective imaging modality to depict peripheral nerves and muscles in a variety of neuromuscular conditions.^{10,11}

Many case reports and series have suggested that neuromuscular ultrasound improves diagnostic accuracy in focal neuropathies, which in turn leads to different treatment decisions, and ultimately results in better outcomes, but this has not been tested systemically

in a prospective manner.^{12–14} This randomized clinical trial was therefore designed to determine if individuals with focal neuropathies diagnosed by a combination of electrodiagnostic studies and neuromuscular ultrasound have better outcomes at 6 months compared to individuals assessed with traditional electrodiagnostic studies alone.

Methods

Prior to initiation of this trial, approval was granted by the Institutional Review Board of Wake Forest School of Medicine (WFSM), and it was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT01394822). Potential participants were recruited from the Diagnostic Neurology Laboratory at Wake Forest School of Medicine. Individuals referred from the Departments of Orthopaedic Surgery & Rehabilitation and Plastic & Reconstructive Surgery at WFSM were invited to participate if their history, examination, and electrodiagnostic testing were all consistent with a focal neuropathy. All surgeons with peripheral nerve expertise in these departments were involved in the study and are authors of this paper (ZJL, AJD, ERW, CJT, JAM, LAK, and GGP), which was part of the study design to prevent the surgeon from disclosing the patient group assignment. Enrollment started in October 2011 and continued until August 2013, when a total of 120 participants were enrolled. Each participant provided written informed consent prior to enrollment.

Diagnosis of a Focal Mononeuropathy

As part of routine clinical practice, all patients referred to the Diagnostic Neurology Laboratory at WFSM are evaluated by a neurologist certified by the American Board of Psychiatry and Neurology and with either added certification in Clinical Neurophysiology, Neuromuscular Medicine, or both (authors MSC, JBC, NB, VB, and FOW), and electrodiagnostic tests are planned based on the clinical presentation. During the 22 months this study was conducted, after completing the electrodiagnostic testing the neurologist decided if the patient met criteria for the diagnosis of a focal mononeuropathy and then considered them for enrollment in this trial. For the diagnosis of CTS and ulnar neuropathy at the elbow, the most common focal neuropathies, patients had to meet the diagnostic criteria established by the American Association of Neuromuscular and Electrodiagnostic Medicine, and for all others a clear diagnosis of focal neuropathy, based on clinical and electrodiagnostic information (focal conduction velocity slowing and/or consistent EMG pattern), was required.^{15,16} If they met the criteria they were asked if they would like to participate in the study. For those that enrolled, the neurologist in the laboratory created an electrodiagnostic report to send the referring surgeon. A second neurologist (MSC) and study team (JMB and HD) then obtained consent, performed the ultrasound study, and conducted the baseline data collection. The initial neurologist was not informed of the ultrasound study results, and if MSC was the initial neurologist the electrodiagnostic report was created prior to the ultrasound and collection of baseline study data.

Neuromuscular Ultrasound

All ultrasound studies were performed with a Biosound MyLab 25 device (Esaote Group, Genoa, Italy) with an 18 MHz linear array transducer. Scanning was performed by an ultrasonographer with more than 2 years of neuromuscular ultrasound experience (JMB or

MSC) and interpreted by a physician with more than 10 years of neuromuscular ultrasound experience (MSC). The initial diagnosis guided the ultrasonographic examination, and affected nerves were visualized in at least 2 planes at the site of suspected nerve involvement and typically at an unaffected site for comparison. Parameters assessed included cross-sectional area (often at both the site of interest and an unaffected comparison site) and subjective measurements of echogenicity, echotexture, mobility, and vascularity. Surrounding structures, such as tendons, bones, ligaments, muscles, and vessels were also imaged at the site of suspected nerve involvement.

After the ultrasonographic examination a final diagnosis was established, and a report was created. After each ultrasound study a random number generator was used to determine if the actual report was sent to the referring physician, or if he would receive a report stating the patient was in the study and randomized to not have his or her ultrasound information disseminated (termed the “no information report”). The actual or “no information” report was combined electronically with the electrodiagnostic report, and the combined report was sent to the referring surgeon. A protocol was established to allow the neurologist interpreting the ultrasound to break the blind if a potentially life-threatening condition was identified during the ultrasound and the patient was randomized to not have the report sent, though this did not occur during the study. Additionally, a protocol was established to allow the referring surgeon to obtain the ultrasound results if the surgeon felt it was absolutely crucial to patient care (keeping in mind that theory of clinical equipoise), and the blind was broken twice for this reason during this study (once for recurrent CTS and once for a brachial plexopathy). None of the study personnel conducting the baseline or follow-up evaluations knew the results of the randomization process, so the study participant and data collectors were double-blinded as to the group assignment of the participants. The 2 groups are referred to throughout the rest of this study as the “report sent” and “not sent” groups.

Data Collection

Information was obtained from participants at baseline, 1 month by telephone, and 3 and 6 month follow-up visits. At baseline, the following were recorded: age, gender, height, weight, race, medical comorbidities, diagnosis prior to ultrasound, ultrasound results, diagnosis after ultrasound, Inflammatory Neuropathy Cause and Treatment (INCAT) Group Overall Disability Sum Score (ODSS), Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), strength testing of a muscle innervated by the affected nerve as measured qualitatively by the Medical Research Council (MRC) scale and hand-held dynamometry (abductor pollicis brevis for CTS and first dorsal interosseous for ulnar neuropathy at the elbow as example muscles), sensation testing distal to the affected nerve with pinprick and quantitative tuning fork, and overall satisfaction with the medical care on a 5-point Likert scale.^{17–23}

A 1-month follow-up telephone call determined if participants had any additional diagnostic testing, if they had been informed of a treatment plan by their referring physician, and overall satisfaction with their medical care. During the 3 month study follow-up visit, the following were collected: updated treatment plan, ODSS, SF-36, strength and sensation testing as performed at baseline, and overall satisfaction with medical care. This information

was also collected at the final study visit 6 months after baseline, and additionally a final diagnosis and simple self-assessment (improved, worsened, or unchanged) were collected. Some participants were unable to return to clinic at 3 and/or 6 months, so they were interviewed by telephone at the appropriate intervals, and strength and sensory testing were not performed.

Statistics

During initial design of the study, it was decided that the change in ODSS score, from baseline to 6 months, would be the primary outcome measure. *A priori* defined secondary outcomes measures included SF-36 domain and component scores, MRC and hand-held dynamometry strength testing, INCAT Sensory Sum Score (SSS) and quantitative tuning fork sensory testing, and participant satisfaction with care, all with 6-month results compared to baseline.²⁴ Additionally, participants' overall assessment of their condition at 6 months was also an *a priori* defined secondary outcome. The ODSS was used to calculate sample size, with an assumed standard deviation of 1.0 in both groups, alpha of 0.05, and power of 80%. These assumed values indicated that 128 total participants were needed to determine a 1.0 difference in the ODSS between the groups.

Descriptive statistics were generated that included means and standard deviations for continuous variables and percentages and frequencies for discrete variables. Baseline characteristics were compared between the "report sent" and "not sent" groups using multivariate logistic regression, with the following variables in each model: age, gender, body mass index (BMI), race, presence of diabetes, diagnosis pre-ultrasound, change in diagnosis, and surgery at any time as pre-specified covariates, with group assignment as the dependent variable. The change in each outcome variable was compared from baseline to 6 months, and multivariate repeated measures models were created to assess for differences between the 2 groups. The models only included participants with baseline and 6-month data points (data from the 3 month assessment were not in the model). Two subgroup analyses were performed using only those without CTS and only those for whom the diagnosis was changed after ultrasound, with each subgroup being pre-specified during study design. For 2 specific participants the referring surgeons asked that the blind be broken during the study, as the surgeon thought it was critical to patient care, and this option had been built into the study design. The primary model, as well as the subgroup models, were assessed with these 2 individuals in the "not sent" group (intention to treat assignment), the "report sent" group (what actually occurred), and without the individuals in the models. A significance level of 0.05 was pre-specified, and the *a priori* decision was made not to use a Bonferroni correction, as a pre-specified primary outcome had been designated, other tests were exploratory, and the parameters lacked independence.²⁵ For all 6-month changes that were statistically significant or approached significance ($P < 0.07$), Cohen effect sizes were calculated by determining the difference between the 2 groups and dividing it by the baseline standard deviation for the specific measure. Effect sizes of 0.20 to 0.49 were considered small, 0.50 to 0.79 moderate, and > 0.80 large.²⁶ CONSORT 2010 guidelines for the reporting of randomized clinical trials were followed.²⁷

Results

A total of 125 participants were approached regarding enrollment, 120 enrolled in the study (5 declined to participate), and 100 completed the 6 month data collection (26 by telephone). Sixty-two were randomized to have their ultrasound report sent to the referring surgeon ("report sent" group) and 58 were randomized to the "not sent" group (Figure 1). There were no significant differences between the 2 groups at baseline with regards to age, gender, BMI, race, presence of diabetes, referring physician, diagnostic physician, or diagnosis (Table 1). Fifty-one of the "report sent" group and 49 of the "not sent" group provided 6 month data, so there was no significant difference in follow-up rates between the groups. After undergoing neuromuscular ultrasound, the baseline diagnosis (which had been established after the history, examination, and electrodiagnostic testing) was changed or refined by the examining neurologist in 27.5% of participants, and this did not differ between the "report sent" (30.6%) and "not sent" (24.1%) groups ($P = 0.425$). The percentage of participants undergoing surgery did not differ between the groups; 29.0% of the "report sent" group and 31.0% of the "not sent" group underwent surgery for their mononeuropathy at some point during the 6 months of follow-up ($P = 0.811$).

A variety of parameters were evaluated at 6 months and compared to baseline using repeated measures analyses in models with the following covariates: age, gender, BMI, race, presence of diabetes, pre-ultrasound diagnosis, change in diagnosis, and surgical intervention. Greater improvement 6 months after diagnosis was seen in the "report sent" group compared to the "not sent" group in the ODSS ($P = 0.166$), 7 of the 8 SF-36 domains, both of the SF-36 summary scores, MRC score ($P = 0.056$), tuning fork score ($P = 0.134$), and patient satisfaction ($P = 0.273$), though the only improvement that was significantly greater in the "report sent" group was the general health perception domain of the SF-36 ($P = 0.005$). The emotional role domain of the SF-36 ($P = 0.731$), hand-held dynamometry ($P = 0.808$), and SSS ($P = 0.576$) showed less improvement in the "report sent" group than the "not sent" group, but none of these differences were significant. Tables 2 and 3 and Figures 2 and 3 demonstrate these findings. Pre-determined sub-group analyses, including only those without CTS, only those with a change in diagnosis following ultrasound, and analyses with the 2 participants in whom the blind was broken in the "report sent" group or not including them in the analyses, did not result in meaningful changes in these results.

Effect sizes were calculated for outcomes that reached or approached statistical significance ($P < 0.07$). For the general health perception domain, effect size was 0.40, for physical component summary score it was 0.34, and for MRC it was 0.41.

At 6 months after diagnostic testing the participants were also asked to self-assess their condition with the options of "improved," "worsened," or "unchanged." In 69.2% of the "report sent" group they rated themselves as "improved," whereas 54.9% of the "not sent" group rated themselves as "improved" ($P = 0.325$). In the subgroup analyses of only those without CTS, the difference was significant when the 2 patients in whom the blind was broken were included in the "report sent" group and when they were not included. When these individuals were included in the "report sent" group, 69.2% of this group rated as "improved" compared to only 30.8% of the "not sent" group ($P = 0.037$), and when these 2

individuals were not included, the “report sent” group rated “improved” in 66.7% compared to 30.8% in the “not sent” group ($P = 0.0497$). The self-assessment data are contained in Table 4.

Example Cases

For those who do not conduct neuromuscular ultrasound, the benefit of the test is often best illustrated through cases. Therefore, 2 specific patients from this study will be described briefly to illustrate the potential benefit of neuromuscular ultrasound. Participant 79 suffered a left humerus fracture, which was treated with internal plating. The humerus healed well, but he had persistent weakness in the left arm. History, examination, and electrodiagnostic testing were consistent with severe median and radial mononeuropathies proximal to the antecubital fossa. Ultrasound showed discrete enlargement of both nerves 2–3 cm proximal to the antecubital fossa, with both nerves surrounded by extensive scar tissue. The radial nerve was visualized superficial to the metal plate over the humerus. He was randomized to have his report sent, and based on the findings he underwent neurolysis of both nerves 2–3 cm proximal to the antecubital fossa. At 6-month follow-up he reported improvement in strength and sensation, self-assessed as “improved,” and rated as “extremely satisfied.” In this case, ultrasound provided precise localization of the focal neuropathy and identified scar tissue, which guided surgical intervention. Participant 110 had a fall at work and developed chronic right shoulder pain and mild scapular winging. History, examination, and electrodiagnostic testing were consistent with a chronic right long thoracic mononeuropathy. Ultrasound showed normal size and echogenicity of the right brachial plexus and long thoracic nerve, without evidence of nerve discontinuity. He was randomized to the “not sent” group. He was taken to surgery for exploration of the brachial plexus and long thoracic nerve, and post-operatively at 6-month follow-up he reported more weakness and pain, and rated himself as “worsened.” Since the ultrasound showed no anatomic abnormalities of the long thoracic nerve and brachial plexus, it is possible that if this report was available, the surgeon may not have proceeded with exploratory surgery.

Discussion

This is the first randomized controlled trial designed to determine if diagnostic neuromuscular ultrasound can lead to improved outcomes in patients with focal neuropathies. Of the 17 outcome measures selected, the “report sent” group had better 6-month results than the “not sent” group for 14 of the measures, though statistical significance was only reached for the general health perception domain of the SF-36 ($P = 0.005$) and participant self-assessment ($P = 0.037$, only in subgroup of those without CTS). The SF-36 physical component summary score ($P = 0.053$) and MRC strength assessment ($P = 0.056$) approached statistical significance, and it is also notable that for 7 of the outcome measures the “report sent” group improved at 6 months while the “not sent” group worsened, though these divergent outcomes did not always reach statistical significance (Figures 2 and 3). The pre-specified primary outcome measure, the ODSS, did not show a significant difference between the 2 groups. It is possible that the ODSS, as well as other outcome measures, did not reach statistical significance because of the sample size. During study planning, power calculations indicated that 128 individuals would be needed to detect

a difference in the ODSS change at 6 months between the two groups, but because of slow recruitment and attrition, only 120 individuals were enrolled and 100 studied at both baseline and 6 months. It is possible, though certainly not guaranteed, that a larger sample size would have resulted in more of the trends that favored the “report sent” group reaching statistical significance.

There are other limitations, most of which were identified during study design, that may have affected the results of this study. First, there is not an ideal outcome measure for focal neuropathies, since these conditions affect arms and legs in a variety of patterns. The ODSS was chosen as the primary outcome measure because it is validated, reliable, responsive, assesses the arms and legs, and has been used in a variety of neuropathies.^{17,28} However, the ODSS was originally designed to evaluate outcomes in inflammatory neuropathies, so it had not previously been used to evaluate a myriad of focal mononeuropathies. Given this early-identified limitation, other measures were also selected to assess a variety of general, strength, and sensory-specific outcomes, though these are also limited in that they have not been explored thoroughly for the evaluation of a variety of different focal neuropathies. The second limitation is that most of the focal neuropathies in this study were CTS, and only 1 participant in the study had a lower extremity focal neuropathy. It is expected that imaging may be more helpful for focal neuropathies at non-entrapment sites, as these neuropathies are more likely the result of anatomic anomalies or trauma²⁹ (although it is also helpful in precisely localizing and identifying anatomic anomalies at entrapment sites). For this reason, those without CTS were analyzed separately, and there was a large difference in favorable self-assessments by the “report sent” group compared to the “not sent” group (69.2% vs. 30.8%, $P = 0.037$). Third, only 1 experienced ultrasonographer performed the neuromuscular ultrasound examinations in this study, which may limit the generalizability of these results. However, it should be noted that ultrasonographers of varying experience have similar accuracy in nerve and muscle measurements,³⁰ and the current study did not require advanced neuromuscular ultrasound techniques or skills. Fourth, a Bonferroni correction was not applied, and if the most strict correction had been used ($0.05/17$ outcome measures = 0.003) then none of the tests would have been statistically significant. As described previously, during study design it was decided a Bonferroni correction should not be applied because a pre-specified primary outcome had been designated, other tests were exploratory, and the parameters lacked independence.²⁵ Finally, it is possible that in some cases the participants may have been able to determine group assignment if they were very perceptive when interacting with the referring surgeon, though all referring surgeons were aware of the study design and need to maintain the blind. In addition, study results were not available to patients in the electronic medical record. We are unaware of the blind being broken (except in the 2 cases in which it was broken by study protocol at the request of the referring surgeon), and therefore it is very unlikely this would have introduced a large bias in either direction. The study design, in which all participants received neuromuscular ultrasound yet only half had their results sent to the referring physician, was specifically created to help maintain the blind. In future studies, the participants could be asked to guess their group assignment at the end of the study as a means of assessing the effectiveness of the blinding.

Using outcome measures designed for polyneuropathies (ODSS, SSS), non-specified neuromuscular conditions (MRC, quantitative tuning fork), or general health (SF-36) also make it somewhat challenging to interpret the clinical meaningfulness of the changes in outcomes. For this reason, effect sizes were calculated for the outcomes that met or approached clinical significance; namely the general health perception domain and physical component summary scores of the SF-36 and the MRC testing. Responsiveness of the SF-36 has been assessed in a variety of conditions, including polyneuropathies, but not in focal neuropathies. In a previous study of individuals who developed diabetic complications, including polyneuropathy, SF-36 effect sizes ranged between 0.02 and 0.66, similar to the effect sizes in this study (0.34 and 0.40).³¹ Additionally, a detailed study to determine the minimum clinically important difference in individuals with chronic inflammatory demyelinating polyneuropathy examined both the SF-36 physical component and MRC scores. Using a variety of methods, they suggest a minimum important change ranging from 4.14 to 8.87 for the physical component score and from 2.00 to 3.60 for the MRC.³² Applied to our data, this would indicate that the physical component change (3.53) was close to the minimum clinically important difference, and the MRC change (0.64) did not reach the cut-off.

In 1991 Fryback and Thornbury proposed a hierarchical model, with 6 levels, for evaluating the efficacy of a diagnostic test.³³ Unfortunately, most imaging modalities currently used in routine clinical practice do not meet all 6 proposed levels. Neuromuscular ultrasound has been evaluated for nearly 2 decades, and previous studies have met the first 4 levels, demonstrating that it is valid and reliable, accurate, changes diagnosis, and changes treatment plan.^{11,13,14,30,34} This study again demonstrated that the diagnosis is changed or refined in about one-fourth (27.5%) of patients undergoing neuromuscular ultrasound after electrodiagnostic testing, which is very similar to the previous results obtained by Padua et al (25%).¹³ Additionally, this study fulfilled the fifth level of the hierarchical model by demonstrating that neuromuscular ultrasound leads to improved patient outcomes. The sixth and final level of the model is to demonstrate that the imaging modality is cost-effective, which has not yet been confirmed. However, it should be noted that ultrasound study of an extremity is a relatively inexpensive test, so it is certainly possible that future cost-benefit analyses may favor neuromuscular ultrasound.

In the future, similar prospective, outcome-based studies of neuromuscular ultrasound would be informative. Alterations that may provide even more relevant information might include a larger sample size (at least 150 participants), more effective incentives to encourage complete follow-up through 6 months, and focused recruitment to include more participants with lower extremity focal neuropathies. In addition, cost-benefit analyses would be particularly informative and may allow for neuromuscular ultrasound testing to fulfill the sixth and final level in the hierarchical model of an efficacy diagnostic imaging test.

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Abbreviations

BMI	Body mass index
CTS	Carpal tunnel syndrome
EMG	Electromyography
HHD	Hand-held dynamometry
INCAT	Inflammatory Neuropathy Cause and Treatment
LE	Lower extremity
MRC	Medical Research Council
NA	Not applicable
ODSS	Overall Disability Sum Score
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
SSS	Sensory sum score
STD	Standard deviation
UE	Upper extremity
WFSM	Wake Forest School of Medicine

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Figure 1.
A CONSORT 2010 flow diagram details the randomization and follow-up that occurred in the trial.

Figure 2.

The change in 6 different parameters, from baseline to 6 months later, is depicted in this figure. Absolute values are used so that positive numbers indicate improvement in each parameter (specifically, the ODSS and INCAT ratings are changed so that more positive values indicate improvement). HHD = hand-held dynamometry; INCAT = Inflammatory Neuropathy Cause and Treatment; MRC = Medical Research Council; ODSS = Overall Disability Sum Score.

Figure 3.

The change from baseline to 6 months after diagnosis in the 8 domains and 2 component scales of the SF-36. * $P < 0.05$.

Table 1

Baseline Demographics.

Characteristic	Overall N=120	Report Sent N=62	Not Sent N=58	P-value*
Mean Age (STD)	53.1 (14.1)	52.1 (14.7)	54.2 (13.4)	0.414
Female Gender (%)	70 (58.3)	38 (61.3)	32 (55.2)	0.497
Mean BMI (STD)	32.1 (8.4)	33.2 (8.6)	30.9 (8.1)	0.126
Non-Caucasian Race (%)	22 (18.3)	12 (19.4)	10 (17.2)	0.817
Diabetic (%)	28 (23.3)	18 (29.0)	10 (17.2)	0.138
Referring Physician	NA	NA	NA	0.491
Diagnostic Physician	NA	NA	NA	0.292
Diagnosis Pre-ultrasound	NA	NA	NA	0.727
-Carpal Tunnel Syndrome (%)	89 (74.2)	47 (75.8)	42 (72.4)	
-Ulnar Neuropathy at Elbow (%)	9 (7.5)	4 (6.5)	5 (8.6)	
-Other UE Neuropathy (%)	21 (17.5)	10 (16.1)	11 (19.0)	
-LE Neuropathy (%)	1 (0.8)	1 (1.6)	0 (0.0)	

* indicates comparison between “report sent” and “not sent” groups;

LE = lower extremity; NA = not applicable; STD = standard deviation; UE = upper extremity. The “Other UE Neuropathy” group included radial nerve, musculocutaneous nerve, long thoracic nerve, and brachial plexus lesions.

Table 2

Measures at 6 Months Compared to Baseline

Measure	Report Sent			Not Sent			P-value
	N	Mean	STD	N	Mean	STD	
ODSS	51	-0.63	0.98	49	-0.39	0.89	0.166
Strength	39	0.64	1.50	35	-0.03	1.44	0.056
	37	0.18	2.31	36	0.48	3.41	0.808
Sensation	39	-0.46	1.48	35	-0.66	1.49	0.576
	38	0.64	2.20	35	-0.28	2.19	0.134
Satisfaction	51	0.02	0.55	49	-0.18	1.24	0.273

The “mean” columns refer to the mean difference at 6 months compared to baseline. The *P*-values are from repeated measures models that compare the 2 groups, including baseline measure, age, gender, BMI, race, diagnosis pre-ultrasound, change in diagnosis, and surgery at any time as pre-specified covariates. The “satisfaction” row is the change in the Likert rating scale. HHD = hand-held dynamometry; INCAT = Inflammatory Neuropathy Cause and Treatment score; MRC = Medical Research Council strength rating; ODSS = Overall Disability Sum Score; SSS = Sensory Sum Score; STD = standard deviation.

Table 3**SF-36 Outcomes at 6 Months Compared to Baseline**

Measure		Report Sent			Not Sent			P-value
		N	Mean	STD	N	Mean	STD	
SF-36	Physical Functioning	51	2.65	25.44	49	-1.94	24.85	0.137
	Role-Physical	51	13.24	45.10	49	7.65	39.60	0.124
	Pain	51	13.49	27.52	49	9.65	24.72	0.452
	General Health Perceptions	51	3.80	13.31	49	-5.35	14.95	0.005
	Vitality	51	2.55	20.65	49	-2.24	21.07	0.410
	Social Functioning	51	6.86	26.85	49	0.26	29.15	0.147
	Role-Emotional	51	4.58	52.92	49	10.20	50.09	0.731
	Mental Health	51	3.06	17.24	49	-0.73	16.94	0.335
	Physical Component Scale	51	3.53	9.69	49	0.54	9.13	0.053
	Mental Component Scale	51	1.20	11.75	49	0.48	10.36	0.647

The “mean” columns refer to the mean difference at 6 months compared to baseline. The *P*-values are from repeated measures models that compare the 2 groups, including baseline measure, age, gender, BMI, race, diagnosis pre-ultrasound, change in diagnosis, and surgery at any time as pre-specified covariates. SF-36 = Short Form 36; STD = standard deviation.

Table 4

Self-assessment 6 Months after Initial Diagnosis

Measure	Report Sent	Not Sent	P-value
“Improved” by Self-Assessment			
All Participants ¹	69.2%	54.9%	0.325
Only CTS, Intention to treat ²	66.7%	35.7%	0.072
Only CTS, Blind broken in “report sent” ³	69.2%	30.8%	0.037
Only CTS, Blind broken not included ⁴	66.7%	30.8%	0.050

At 6 months participants were asked to rate their condition, in regards to their focal neuropathy, as “improved,” “worsened,” or “unchanged.” This table lists the percentage of participants who rated themselves as “improved” 6 months after diagnostic testing with the following specifics:

¹ = all participants;

² = only those without CTS, intention to treat classification;

³ = only those without CTS, 2 participants with blind broken included in “report sent” group;

⁴ = only those without CTS, 2 participants with blind broken not included.