SCIENTIFIC ARTICLE

The Six-Item CTS Symptoms Scale and Palmar Pain Scale in Carpal Tunnel Syndrome

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Purpose To evaluate measurement properties of 2 brief outcome measures for carpal tunnel syndrome: the 6-item carpal tunnel symptoms scale (CTS-6) and the 2-item palmar pain scale (measuring severity of pain in the scar/palm and pain-related activity limitation). Our hypothesis was that the CTS-6 is responsive to change in symptoms after surgical treatment and the pain scale is a valid measure of surgery-related pain.

Methods This study followed 447 consecutive patients with carpal tunnel syndrome undergoing open release; 308 completed the CTS-6 and the Disabilities of the Arm, Shoulder, and Hand–short form (QuickDASH) before surgery and the CTS-6, QuickDASH, palmar pain scale, and 2 items regarding global rating of change and treatment satisfaction once after surgery (range, 2–13 mo). The mean scores for the CTS-6 (range, 1–5) and QuickDASH and palmar pain scales (range, 0–100) were calculated (lower score is better). Responsiveness was assessed with the effect size (ES). We estimated the CTS-6 score change indicating minimal clinically important difference based on scores for patients with moderate self-rated improvement.

Results The mean baseline CTS-6 score was 3.16, mean change after surgery was −1.54 (95% confidence interval [CI], −1.65 to −1.44), and ES was 2.0. The ES was large (2.5) in patients with the largest self-rated improvement and decreased with lower self-rated improvement. A score change of 0.9 indicated a minimal clinically important difference. The mean change in QuickDASH score was −25.4 (95% CI, −27.8 to −23.0), and ES was 1.25. The mean palmar pain score for patients with time since surgery of less than 3 months was 38.5, at 3 to 6 months was 35.4, and greater than 6 months was 19.5; the mean score was significantly higher among patients with lower satisfaction.

Conclusions The CTS-6 is highly responsive to change in symptoms, and the palmar pain scale is a valid measure of surgery-related pain. These brief scales can be appropriate primary and secondary outcomes measures in clinical trials studying carpal tunnel syndrome. *(J Hand Surg 2011;36A:788–794.*

Type of study/level of evidence Diagnostic I.

Key words Carpal tunnel syndrome, CTS-6 symptoms scale, patient-reported outcomes, carpal tunnel release, QuickDASH.

STUDIES THAT EVALUATE treatment effects in carpal tunnel syndrome (CTS) increasingly use patient-reported symptoms and disability as primary outcome measures. The 11-item symptom severity and 8-item functional status scales, introduced in 1993[1] and later translated to other languages[2–5] have been used in several clinical trials.[6–8] However, these scales were initially developed without examining their item struc-

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ture with, for example, factor analysis. We recently investigated the symptom severity and functional status scales using modern measurement methodology in a stepwise process that resulted in removal of 4 items that did not fit well in the symptom severity scale and merging of 2 other items in that scale.[9] We developed the 6-item CTS symptoms scale as a brief outcome measure of symptoms in CTS (Appendix 1).[9] (Appendix 1 is available on the *Journal's* Web site at www.jhandsurg.org.) The 6-item CTS symptoms scale is shorter than the 11-item symptom severity scale not only because of fewer items but also because of a different layout (the 6 items share horizontal item response choices). The 6-item CTS symptoms scale demonstrated good internal consistency, test-retest reliability, and validity compared with the 11-item symptom severity scale and did not exhibit differential item functioning with regard to gender (none of the items performed differently in women than men).[9] The 6-item CTS symptoms scale can improve the efficiency of outcome measurement in CTS but it needs to be evaluated with regard to responsiveness.

After carpal tunnel release, pain in the scar or proximal palm is common but varies in severity and duration.[6,7,10] Several endoscopic or small-incision surgical techniques were introduced, with the main proposed benefit being decreased surgery-related morbidity.[10] Consequently, measurement of postoperative pain that is mainly related to the surgery itself would be important in assessing the effectiveness of such techniques in that respect. We developed a 2-item palmar pain scale (Appendix 2) (Appendix 2 is available on the *Journal's* Web site at www.jhandsurg.org) and used it as a specific measure of surgery-related pain after carpal tunnel release.[7] The scale has not been evaluated in a large cohort.

The purpose of this study was to evaluate measurement properties of 2 brief outcomes measures for CTS: the 6-item CTS symptoms scale (CTS-6) and the 2-item palmar pain scale. Our hypothesis was the CTS-6 is responsive to change in symptoms after surgical treatment and the palmar pain scale is a valid measure of surgery-related pain.

MATERIALS AND METHODS

Study sample

This study enrolled all adult patients with primary CTS planned for open carpal tunnel release at 1 orthopedic department over 15 months beginning January 2008. The examining surgeon established the diagnosis through history, physical examination, and, if required, nerve conduction tests. All patients had failed treatment with wrist splinting. After surgery a soft dressing was applied and patients were given oral and written instructions on postoperative exercises and gradual return to activities. Therapy was not routinely prescribed.

Measures and follow-up

The patients completed a questionnaire consisting of the CTS-6 and the Disabilities of the Arm, Shoulder, and Hand–short form (QuickDASH) in the preoperative area on the day of surgery. A follow-up questionnaire consisting of the CTS-6, QuickDASH, palmar pain scale, and 2 separate items concerning global rating of change in hand status after surgery and treatment satisfaction, respectively, was sent by mail to all patients. A reminder was sent when necessary. To evaluate responsiveness over a longer period, the follow-up questionnaire was mailed at a time ranging from 10 to 52 weeks postoperatively by a research assistant who had no knowledge of the patients' medical data except for the date of surgery. Each patient completed the follow-up questionnaire only once. We chose the follow-up times based on findings from a randomized trial of carpal tunnel release showing that major improvement in the baseline CTS symptom severity scores occurred by 6 weeks postoperatively, with only small additional improvement observed at 12 and 52 weeks, whereas postoperative pain gradually decreased up to 1 year.[7] Two other randomized trials have shown near-normal mean CTS symptom severity score at 12 weeks postoperatively.[11,12] Consequently, a responsive measure of CTS symptoms should be able to detect change in CTS symptoms measured before surgery and at 10 to 52 weeks after surgery, and a measure of postoperative pain should be able to detect differences in pain severity measured at different time intervals during this postoperative period.

Six-item CTS symptoms scale: This scale consists of 6 items that inquire about severity and frequency of night and daytime numbness and tingling and pain (Appendix 1). The CTS-6 was scored with conventional scoring (similar to that used for the 11-item symptom severity scale); each item was scored on a scale of 1 (no symptom) to 5 (most severe symptom). For each patient, a CTS-6 score was calculated as the mean of the items answered by the patient, with only 1 missing item response allowed, and would thus range from 1 (best) to 5 (worst).

QuickDASH: This scale is an 11-item measure of upper extremity–related disability and has previously been studied in patients with CTS.[13] The QuickDASH score may range from 0 (no disability) to 100 (most severe disability).