Comparison of Responsiveness of the Japanese Society for Surgery of the Hand Version of the Carpal Tunnel Syndrome Instrument to Surgical Treatment with DASH, SF-36, and Physical Findings.

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Abstract

Background. The Japanese Society for Surgery of the Hand version of the Carpal Tunnel Syndrome Instrument (CTSI-JSSH), which consists of two parts; one for symptom severity (CTSI-SS) and the other for functional status (CTSI-FS), is a self-administered questionnaire, specifically designed for carpal tunnel syndrome. Responsiveness of the CTSI-JSSH was compared with that of the JSSH version of the Disability of Arm, Shoulder and Hand questionnaire (DASH), the official Japanese version of the 36-Item Short Form Health Survey (SF-36; version1.2), and physical examinations to elucidate the role of the CTSI-JSSH for evaluation of patients with carpal tunnel syndrome.

Methods. Preoperatively, a series of 60 patients with carpal tunnel syndrome completed the CTSI-JSSH, DASH and SF-36. Results of physical examinations including grip strength, pulp pinch, and static two point discrimination of the thumb, index and long fingers were recorded. Three months after carpal tunnel release surgery, the patients were again asked to fill out the same questionnaires and the physical examinations were repeated. The responsiveness of all the instruments was examined by calculating the standardized response mean (SRM) and effect size (ES). Correlation coefficients were calculated between questionnaire change scores and patients' satisfaction scores, and between the CTSI change scores and those of the DASH and SF-36.

Results. The largest responsiveness was observed in the CTSI-SS(SRM/ES:-1.00/-1.08), followed by the CTSI-FS(-0.76/-0.63), the bodily pain subscale of SF-36(SF-36-BP, 0.45/0.55) and the DASH(-0.46/-0.47). Only the change scores of the CTSI-SS had significant correlation with patients' satisfaction ($r=0.34$, $p<0.01$). Absolute value of Spearman's correlation coefficient of more than 0.5 was observed between the change scores of the CTSI-SS and the DASH, the CTSI-SS and the SF-36-BP, the CTSI-FS and the DASH, and the DASH and the SF-36-BP.

Conclusion. The CTSI-JSSH was proven to be more sensitive to clinical changes after carpal tunnel release than the other outcome measures, and should be used to evaluate patients with carpal tunnel

syndrome who speak Japanese as their native language.

Introduction

Although carpal tunnel syndrome is the most common entrapment neuropathy in the human body, operative indication is still not definitely determined, and many procedures, such as traditional open carpal tunnel release, mini-opened release and endoscopic release, are performed based on the surgeon's preference, not on scientific data. It has been recognized that development of disease specific and patient oriented outcome measures is necessary to compare various treatment modalities so that both surgeons and patients can choose the best treatment procedure. Levine et al. developed a self-administered questionnaire, or Carpal Tunnel Syndrome Instrument (CTSI), which is specific to carpal tunnel syndrome and it has been used widely.[1] We developed a Japanese Society for Surgery of the Hand version of the CTSI (CTSI-JSSH) based on guidelines for cross-cultural adaptation processes recommended by Beaton et al.[2] The CTSI-JSSH is written in Japanese and consists of two sections; one assesses pain and paresthesia, or symptom severity (CTSI-SS) and the other assesses functional status (CTSI-FS). It is now available in Charts for Functional Evaluation of the Hand (4th edition).[3] Validity, reliability and responsiveness of the Japanese versions of both the CTSI-SS and CTSI-FS were found to be good.[4]

In this study, responsiveness of the CTSI-JSSH was compared with that of the Japanese Society for Surgery of the Hand version of the Disability of Arm, Shoulder and Hand questionnaire (DASH-JSSH),[5,6] the official Japanese version of the 36-Item Short Form Health Survey (SF-36; version1.2),[7,8] and physical examinations to elucidate the role of the CTSI-JSSH for evaluation of patients with carpal tunnel syndrome.

Materials and methods

We prospectively recruited 65 patients who had been diagnosed with carpal tunnel syndrome and who gave written informed consent. This was a multicenter study and the ethical committee of each institution approved the study protocol. One female patient, who was unable to fill out the forms by herself due to poor eyesight, was not recruited.

Diagnosis of carpal tunnel syndrome was made based on clinical history and physical examinations, such as Phalen's test, Tinel sign at the carpal tunnel, sensory disturbance over the median nerve distribution area, and nerve conduction velocities measured across the wrist. Based on nerve conduction studies, the severity of preoperative carpal tunnel syndrome was determined as mild, moderate, severe, or extremely severe.[9]

Preoperatively, the patients were asked to fill out the CTSI-JSSH, DASH, and SF-36. Pain severity was assessed using the visual analog scale (VAS). Results of physical examinations including grip strength, pulp pinch, static two point discrimination (s-2PD) of the thumb, index and long fingers were recorded. Forty-three patients underwent endoscopic carpal tunnel release surgery and 22 underwent open carpal tunnel release. Six patients had bilateral surgeries on the same day. O ne patient had diabetes, 2 were receiving hemodialysis, 2 had post distal radial fractures and 1 had a ganglion in the carpal tunnel. Six patients had release of the A1 pulley or synovectomy for trigger digit, and 2 patients had tendon transfer to restore thumb opposition, followed by three weeks immobilization of the wrist and thumb. Since the prime purpose of this study was to assess responsiveness of CTSI-JSSH, not to report the result of carpal tunnel release surgery, those 2 patients who had tendon transfer were included.

Three months after surgery, the patients were again asked to fill out the same questionnaires and the physical examinations were repeated. This time each patient rated his or her satisfaction with the surgery into four categories: very satisfied, satisfied, neither satisfied nor unsatisfied, unsatisfied.

Grip strength was measured using a Jamar dynamometer (Sammons Preston Rolyan, IL, USA) or a Smedley's hand dynamometer (Igarashi Ikakougyou Co., Ltd. Tokyo) and pinch strength was measured using a Jamar pinch meter (Sammons Preston Rolyan) or a Pinch gauge (Fuji Seiko Co., Ltd. Nagoya). They were measured three times each, and the average was used for analysis.

The values of s-2PD of the thumb, index, and long fingers were summed and the average was used for analysis.

The patients rated their degree of pain using a VAS range from 0 to 10 (0; no pain, 10; the most severe pain ever experienced).
The responsiveness of all the instruments was examined by calculating the standardized response mean (SRM; mean change/SD) and effect size (ES; mean change/SD of baseline value). SRM greater than 0.8 indicated large change, 0.5 indicated moderate change and less than 0.2 indicated small change. Correlation coefficients were calculated between questionnaire change scores and patients' satisfaction scores, and between the CTSI change scores and those of the DASH and SF-36.
All statistical analyses were conducted using Statistical Package for Social Science (SPSS) version 14.0J software. As some of the instrument values were not normally distributed, correlations between the instruments and patients' satisfaction were assessed using a nonparametric test (Spearmen's correlation). Statistical significance was set at $p < 0.05$.

Results

Five patients were excluded from the study because their second data acquisition was done more than 15 weeks after surgery, leaving 60 patients eligible for analysis. There were 11 males and 49 females. Their ages ranged from 21 to 86 years old, and the average was 60 years old. The duration of the symptoms before their first visit to the hospital ranged from 2 months to 360 months, and the average was 60 months. Preoperative severity of the disease determined by nerve conduction studies was as follows; normal: 1, mild: 0, moderate: 9, severe: 40, extremely severe: 9, not available: 1. All the surgeries were correctly performed because complete release of the transverse carpal ligament was confirmed intraoperatively and no postoperative complications such as infection, nerve/tendon injuries or aggravation of numbness were noted. Nine patients developed trigger digit within 3 months after surgery.
The average pre and postoperative values of each instrument, and SRM and ES are summarized in Tables 1 and 2. Significant improvement was observed in the CTSI-SS, the CTSI-FS, the DASH,

the bodily pain subscale of SF-36 (SF-36-BP), VAS, and s-2PD ($p<0.01$). Grip strength decreased significantly after 3 months postoperatively ($p<0.05$). The largest responsiveness was observed in the CTSI-SS (SRM/ES:-1.00/-1.08), followed by the CTSI-FS (-0.76/-0.63), the SF-36-BP (0.45/0.55) and the DASH (-0.46/-0.47). Only the change scores of the CTSI-SS had significant correlation with patients' satisfaction ($r=0.34$, $p<0.01$). (Table 3)

Absolute value of Spearman's correlation coefficient of more than 0.5 was observed between the change scores of the CTSI-SS and the DASH, the CTSI-SS and the SF-36-BP, the CTSI-FS and the DASH, and the DASH and the SF-36-BP. (Table 3)

Sixteen patients had worse scores in the DASH or CTSI-SS at 3 months after surgery. Eight patients had worse scores in the DASH while the CTSI-SS was improved. Six patients had worsening of both the DASH and the CTSI-SS, and 2 patients had only the CTSI-SS worsening. Although statistical analysis was not performed due to the small sample size, the patients with worsening of the DASH score tended to have a long duration of symptoms, severe stage of the disease, and development of trigger digit, as well as pain over and around the wound.

Discussion

Responsiveness of the CTSI-SS and the CTSI-FS was found to be larger than the DASH, the subscales of SF-36, VAS and physical findings, at 3 months after surgery. This was consistent with the previous reports.[10-12] Gay et al. found the CTSI was most sensitive to clinical changes after carpal tunnel release (ES/SRM:1.77/1.66), followed by the DASH (1.01/1.13), the SF-36-BP(0.57/0.52) and the role-physical subscale of SF-36 (0.39/0.39).[11] Greenslade et al. reported that SRM of the CTSI-SS, the CTSI-FS and the DASH were 1.07, 0.62 and 0.66, respectively at 3 months after open carpal tunnel release.[12] Atroshi et al. reported good response of the CTSI-SS of 1.4-1.9, the CTS-FS of 0.8-1.1, and the SF-36 of 1.0 at 3 months after ECTR.[10]

Although the CTSI is sensitive to clinical changes after carpal tunnel

release, more generic instruments such as the DASH or the SF-36 may also be useful if relative impact of carpal tunnel syndrome on the entire upper extremities or the body is evaluated. Patients with carpal tunnel syndrome scored low in the SF-36, but at three months after surgery, only bodily pain improved significantly. It is unclear whether carpal tunnel release really affected the patients' general health status within 3-month follow-ups.

Carpal tunnel release surgery does not always relieve the symptoms completely and soon. After surgery, patients experienced pain over the wound or the stumps of the transverse carpal ligament, and it could last for several months.[13] During the three months after surgery, numbness in the contralateral side of the hand could be aggravated and trigger digit could also develop. Furthermore, the patients with extremely severe stage of the disease, especially with diabetes, might not feel significant improvement of numbness in a short follow-up period. These factors may explain the fact that grip strength decreased and pinch strength did not improve after surgery, and also the DASH and the CTSI-FS were not as sensitive as the CTSI-SS even though surgery was correctly done. The DASH and the CTSI-FS are affected more by functional changes, while the CTSI-SS is affected by paresthesia or pain, or both, which can improve soon after surgery.

Although statistically not compared, SRM or ES of the CTSI in our patients was smaller than that found by previous investigators.[6,10-13] Only Greenslade et al reported almost comparable data to ours.[11] There are a few factors that should be considered before comparing directly.

Some reports did not show any information regarding duration of the symptoms or severity of the disease or other coexisting disease, and our study population had severer stages of the disease as determined by nerve conduction studies, longer duration of the symptoms or older age than the other studies. [10,11,14,15] Simply comparing the SRM or ES among the studies should be done with caution, and other outcome measures should also be included to ensure adequate comparison of the procedures.[13]

In conclusion, the CTSI-JSSH version was proven to be more

sensitive to clinical changes after carpal tunnel release than the other outcome measures, and should be used to evaluate patients with carpal tunnel syndrome who speak Japanese as their native language.

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Table 1 Responsiveness of each instrument

	Preoperative		Postoperative		Postoperative-Preoperative			Responsiveness	
Instrument (N)	**MEAN**	**SD**	**MEAN**	**SD**	**MEAN**	**MEDIAN**	**SD**	**SRM**	**ES**
CTSI-SS(60)* **	2.59	0.72	1.81	0.67	-0.77	-0.80	0.78	-1.00	-1.08
CTSI-FS(59) **	2.28	0.87	1.71	0.64	-0.55	-0.50	0.72	-0.76	-0.63
DASH-DS(55)* **	33.3	19.6	23.8	18.5	-9.14	-9.17	19.7	-0.46	-0.47
SF-36-PF(60)	72.2	24.1	71.8	26.6	-0.43	0	22.8	-0.02	-0.02
SF-36-RP(58)	54.0	41.0	56.8	42.3	2.44	0	41.9	0.06	0.06
SF-36-BP(60)* **	46.3	22.2	58.4	24.1	12.1	11.5	27.2	0.45	0.55
SF-36-GH(59)	57.5	18.3	59.1	16.3	1.57	0	15.0	0.10	0.09
SF-36-VT(59)	56.3	21.3	60.2	22.6	4.07	5	21.7	0.19	0.19
SF-36-SF(60)	77.9	24.4	82.9	21.5	5.00	0	21.1	0.24	0.20
SF-36-RE(56)	66.1	42.9	63.2	42.2	-2.98	0	46.4	-0.06	-0.07
SF-36-MH(58)	67.4	18.8	70.1	19.8	2.98	4	19.7	0.15	0.16
VAS(57)*	3.3	3.1	2.3	2.4	-1.0	-0.5	3.6	-0.29	-0.34

ABBREVIATIONS: CTSI-JSSH-SS, the Symptom Severity scale of the Japanese Society for Surgery of the Hand Version of Carpal Tunnel Syndrome Instrument (CTSI-JSSH); **CTSI-JSSH-FS,** the Functional Status scale of CTSI-JSSH; **DASH-JSSH,** the Disability/Symptom scale of Japanese version of DASH; **SF-36-PF,** Physical functioning subscale of the 36-Item Short-Form Health Survey (SF-36); **SF-36-RP,** Role-physical subscale of SF-36; **SF-36-BP,** Bodily pain subscale of SF-36; **SF-36-GH,** General health subscale of SF-36; **SF-36-VT,** Vitality subscale of SF-36; **SF-36-SF,** Social functioning subscale of SF-36; **SF-36-RE,** Role-emotional subscale of SF-36; **SF-36-MH,** Mental health subscale of SF-36; **VAS [0-10],** Visual analog scale for pain [0-10 scale].

*: Significant difference between preoperative and postoperative median value ($p<0.05$)

**: Significant difference between preoperative and postoperative median value ($p<0.01$)

***: Significant difference between preoperative and postoperative median value ($p<0.001$)

Table 2　Responsiveness of grip strength, pinch strength and s-2PD

	Preoperative		Postoperative		Postoperative-Preoperative			Responsiveness	
Instrument (N)	**MEAN**	**SD**	**MEAN**	**SD**	**MEAN**	**MEDIAN**	**SD**	**SRM**	**ES**
Grip strength(66)*	16.38	9.37	14.81	7.29	-1.57	-1.17	6.04	-0.26	-0.17
Pinch(66)	5.52	2.55	5.65	2.72	0.13	-0.13	1.42	0.09	0.05
s-2PD(59)**	8.45	4.18	7.09	3.31	-1.40	-0.67	3.25	-0.43	-0.33

s-2PD; static two point discrimination

*: Significant difference between preoperative and postoperative median value ($p<0.05$)

**: Significant difference between preoperative and postoperative median value ($p<0.01$)

Table 3　Correlation of change scores of each instrument

Instrument scale (N)	Correlation with			
	CTSI-SS	**CTSI-FS**	**DASH**	**Satisfaction (58)**
CTSI-SS (60)	—	—	—	0.337**
CTSI-FS (59)	0.467**	—	—	0.175
DASH (55)	**0.665****	**0.641****	—	0.196
SF-36-PF (60)	-0.318*	-0.371**	-0.485**	-0.236
SF-36-RP (58)	-0.358**	-0.291*	-0.410**	0.051
SF-36-BP (60)	**-0.580****	-0.397**	**-0.621****	-0.254
SF-36-GH (59)	-0.318*	-0.145	-0.292*	-0.252
SF-36-VT (59)	-0.412**	-0.421**	-0.392**	-0.188
SF-36-SF (60)	-0.186	-0.350**	-0.324*	-0.028
SF-36-RE (56)	-0.437**	-0.264	-0.420**	-0.06
SF-36-MH (58)	-0.267*	-0.474**	-0.449**	-0.102
VAS (57)	-0.355**	-0.186	-0.393**	-0.108
Grip strength (66)	-0.181	0.064	-0.142	0.002
Pinch (66)	-0.183	-0.147	-0.056	-0.174
s-2PD (60)	0.003	0.013	0.026	-0.03

*: $p<0.05$, **: $p<0.01$, Spearman's correlation(r_s)

Bold: significant correlation; when $p<0.05$ and $|r_s|>0.5$

Instrument scale (N)	Correlation with Grip strength	Correlation with Pinch
Grip strength (66)	—	—
Pinch (66)	0.345**	—
s-2PD (60)	0.001	-0.204

*: $p<0.05$, **: $p<0.01$, Spearman's correlation(r_s)