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Scientific/Clinical Article

Short-term clinical outcome of orthosis alone vs combination of orthosis, nerve, and tendon gliding exercises and ultrasound therapy for treatment of carpal tunnel syndrome

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ABSTRACT

Study Design: Prospective randomized study.
Introduction: Carpal tunnel syndrome (CTS) has been described as the most common compression neuropathy. Many modalities exist for conservative treatment. Efficacy of each modality has been described in the literature. However, the effectiveness of combination of these modalities is not well established. The purpose of this study is to assess the short-term clinical outcome of conservative treatment for CTS comparing orthosis alone with combination of orthosis, nerve/tendon gliding exercises, and ultrasound therapy.
Methods: Forty-one patients who presented to Upper Limb Reconstructive and Microsurgery Clinic, University Malaya Medical Centre with CTS and positive electrodiagnostic study were recruited. Fifteen patients had bilateral CTS. Fifty-six wrists were equally randomized to orthosis alone and a combined therapy of orthosis, nerve/tendon gliding exercise, and ultrasound therapy. All patients were required to complete the Boston Carpal Tunnel Questionnaire during the first visit and 2 months after treatment.
Results: Both the orthosis and combined therapy groups showed a significant improvement in symptoms and function after treatment. The mean difference of symptoms in the orthosis group was 0.53; 95% confidence interval [CI]: 0.23-0.83 ($P = .001$) and in the combined therapy group was 0.48; 95% CI: 0.24-0.72 ($P < .001$). Mean difference of function in the orthosis group was 0.59; 95% CI: 0.28-0.91 ($P = .001$) and combined group was 0.69; 95% CI: 0.49-0.89 ($P < .001$). However, there was no significant difference in symptom severity and functional status scores between the groups.
Discussion: Our findings support other findings where orthosis and exercises improved symptom severity and functional status scores, however, there was no significant difference between orthosis alone and combined treatment.
Conclusion: Patients who underwent conservative management for CTS showed improvement in symptoms and function. However, the combination of orthosis, nerve/tendon gliding exercises, and ultrasound therapy did not offer additional benefit compared to orthosis alone.

Introduction

Carpal tunnel syndrome (CTS) has been described as the most common compression neuropathy.[1] Clinical presentations include tingling, pins and needles, numbness, and pain over the median nerve distribution. Physical examination might reveal weakness and atrophy of the thenar muscles associated with sensory loss at radial three and half fingers. Tinel's sign and Phalen's test are frequently positive.[2]

In chronic nerve compression, the initial changes of CTS are breakdown of blood nerve barrier followed by subperineural edema and fibrosis.[3] The aim of conservative management is to reduce the edema and indirectly prevent further irreversible nerve damage. Recent studies had proved the effectiveness of various modalities in the treatment of CTS. For example, orthosis

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application minimized the carpal tunnel pressure and preserved adequate blood supply to the median nerve, subsequently reduced intraneural edema and improved the symptoms of CTS.[4-10] Tendon and nerve gliding exercises are thought to reduce nerve adherence, disperse extra fluids, and increase neural vascularity by optimizing the motion of nerves and tendons in the tunnel.[11-14] Ultrasound therapy could reduce the inflammation of the median nerve and facilitate the recovery from compression neuropathy.[15-17]

In severe CTS, the median nerve configuration was frequently described as "hour-glass" appearance, due to narrowing under the thickened flexor retinaculum with swellings over distal and proximal region.[18] The high compression pressure and swelling may lead to irreversible nerve damage.[3] Early conservative therapy, even in severe CTS, may prevent progression and delay the need for surgery.

Generally, the treatment of CTS is based on the severity of neuropathy. In early stages, conservative management is the treatment of choice.[1] Modalities that have been used to manage CTS include orthotic support, nerve and tendon gliding exercises, laser and ultrasound therapy, and so on.[19] Combined therapy is the treatment incorporating at least 2 of the modalities. Frequently, patients are given a combination of these modalities assuming that the outcome is greater than a single modality because of their different roles in reducing the nerve swelling and inflammation.

However, there is a potential downside to providing a combination of modalities, since this would increase the patients' number and length of visits to hospital. This would increase the financial burden to both patients and the health care system. Therefore, the effectiveness of combined conservative treatment modalities for CTS should be investigated in order to avoid unnecessary wastage of time, energy, and resources.

The purpose of this study is to assess the short-term clinical outcome of conservative treatment for CTS comparing orthosis alone with combination of orthosis, nerve/tendon gliding exercises, and ultrasound therapy.

Methods

Patients who were diagnosed with CTS based on clinical examination and electrodiagnostic criteria[20] were recruited. Demographic data (age, gender, dominant hand, occupation, underlying medical illness, and symptom duration) were collected on the first clinic visit. The Boston Carpal Tunnel Questionnaire (BCTQ) was used as the primary outcome measure. The study had been approved by the Medical Research Ethics Committee of University Malaya Medical Centre (MREC ID NO 20161-1985). All patients gave informed written consent before participation in the study.

Procedure

Sixty-two patients were clinically diagnosed with CTS between May 2016 and April 2017 during their first visit to the Upper Limb Reconstructive and Microsurgery Clinic, University Malaya Medical Centre. All patients were new referrals from primary care clinics. Patients with thenar muscle weakness or wasting, previous surgery or trauma to the wrist, wrist deformity, cervical radiculopathy, inflammatory joint disease, other peripheral neuropathies, any treatment of CTS received within 3 months of recruitment, and CTS related to pregnancy and diabetes were excluded.

Thus, 59 eligible patients were randomly allocated to the orthosis group and the combined therapy group (orthosis, nerve/tendon gliding exercises, and ultrasound therapy) (Fig. 1). Randomization sequence was created by Microsoft Excel with a 1:1 allocation using random block sizes of 4. Patients were allocated

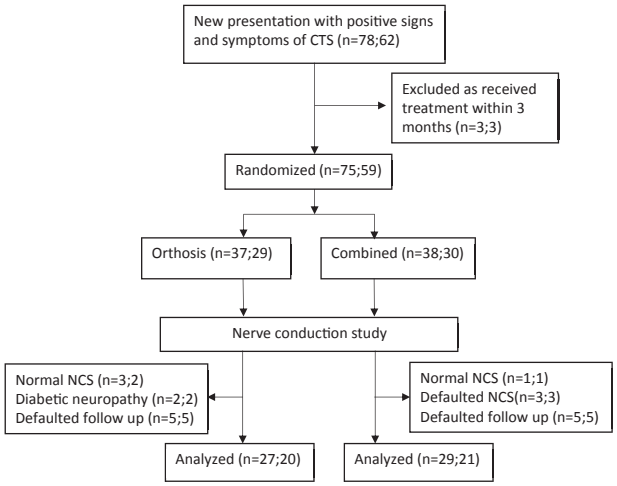

Fig. 1. Flow chart of the study. n = number of wrists; number of patients. CTS = carpal tunnel syndrome; NCS = nerve conduction study.

their treatment group according to the sequence generated by the program. In cases of bilateral CTS, the patients were allocated to the next block of 4, and both wrists involved received the same treatment. Both patients and investigator were aware of the treatment group chosen.

Demographic questionnaire and the BCTQ were self-administered. A brief explanation was given, and patients were left alone in a room to answer the questionnaire. Two questionnaires were given to patients who had bilateral CTS. Subsequently, they were educated on their treatment of choice and the importance of compliance. Adherence of daily orthosis use and exercise performance was self-reported on recording logs. Appointments of nerve conduction study (NCS) were given.

Patients with normal NCS were eventually excluded from our study. Randomization and treatment were started before NCS as we anticipated delay in performing NCS in our center. The numbers of patients with normal study were almost equal in both groups. Thus, the diagnosis of CTS after electrodiagnostic study was by chance in both groups. Ten patients (5 from each group) defaulted follow-up as 4 patients opted for second opinion at different center, 2 opted for traditional medication, 2 had transportation problems, and 2 were uncontactable. Two patients had diabetic neuropathy and 3 patients refused NCS and were also excluded.

Finally, 41 patients with 56 wrists were followed up at 2 months, and BCTQ assessments were repeated immediately after removal of orthosis.

Electrodiagnostic studies

Nerve conduction studies (NCSs) were performed within 1 month of recruitment. This was carried out with Synergy Electromyography Machine (Natus Neurology Incorporated, Middleton, Wisconsin, USA) according to the laboratory's standard protocol.[21] Orthodromic digit to wrist sensory studies and palm to wrist mixed nerve studies were performed on the median and ulnar nerves bilaterally. Motor NCS of the median and ulnar nerves were also performed. NCS results were compared to our laboratory's normal values. CTS was diagnosed if there was evidence of slowing of the median nerve across the carpal tunnel namely median sensory nerve conduction velocity was less than 40 m/s when the ulnar sensory nerve conduction velocity was normal, median distal motor latency (DML) more than 4.5 ms and/or median versus ulnar

palm to wrist mixed nerve conduction velocity difference was more than 10 m/s.

Severity of CTS was graded based on electrodiagnostic test results.[22] Mild CTS was defined as abnormal sensory studies or palm to wrists studies only; moderate CTS was abnormal sensory studies with prolonged median DML; and severe CTS was when median sensory nerve action potential was absent with prolonged median DML.

Orthosis

All orthoses were fashioned and applied on the palmar surface (Fig. 2) by a trained occupational therapist in the neutral position of the affected wrist. They were made with thermoplastic material fastened with Velcro and Beta pile straps. Patients were required to wear the orthosis strictly for 8 weeks. They were allowed to remove them for an hour each day. Adjustments of orthoses were done accordingly if patients felt discomfort.

Physiotherapy

Standardized nerve gliding and tendon gliding exercises were demonstrated and supervised by the investigator. For median nerve gliding, 2 exercises were adopted based on biomechanical study by Coppieters.[12] For the first exercise, wrist extension (loading) and finger flexion (unloading) was alternated with wrist flexion (unloading) and finger extension (loading). The second exercise consisted of elbow flexion (unloading) and wrist extension (loading) alternating with elbow extension (loading) and wrist flexion (unloading).

For tendon gliding exercise, we used the Wehbe and Hunter technique.[14] This involved 5 movements of the fingers. It began in full extension followed by full flexion of the fingers. The third position was to extend distal interphalangeal joints (DIPJs), whereas the metacarpophalangeal joints (MCPJs) and proximal interphalangeal joints (PIPJs) were kept in full flexion. Subsequently, all the PIPJs were extended, whereas the MCPJs were in flexion and DIPJs maintained in extension (table top). Finally, all MCPJs were extended, and all PIPJs and DIPJs were flexed fully (hook). Ten repetitions of both the nerve and tendon gliding exercises were performed per session. Patients were required to complete 10 sessions per day. They were required to fill up the compliance chart after each session.

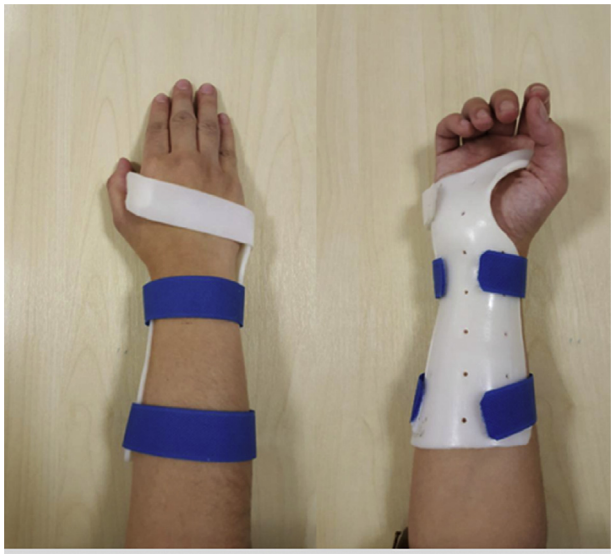

Fig. 2. Orthosis over palmar aspect of right wrist.

Ultrasound therapy

Patients were referred to a dedicated physiotherapist. Ultrasound therapy was commenced once a week for 8 weeks, and each session consisted of 5 minutes of therapy. The ultrasound machine was set at a frequency of 1 MHz, intensity of 1.0 W/cm^2 and pulsed mode of 1:4.[15,17] A transducer of 5 cm^2 in size and aquasonic gel couplant was used. The transducer was placed over the affected wrist, focusing on the carpal tunnel area, ranging from wrist crease to palmar region. A stroking method was used with a sonation area of approximately 5 $\times$ 5 cm^2.[15,17] The machine was calibrated, and the output was adjusted regularly with a simple underwater balance.[15,17]

Sample size

A priori sample size was estimated based on 2 means of matched pairs. Based on a previous study,[9] the mean (standard deviation) for baseline within orthosis group was 2.0 (0.4). We obtained effect size of 0.6 and considering 5% marginal error and 80% of power of study, a statistical power analysis indicated that a minimal sample size of 22 subjects was needed in each group. The sample size calculation was performed using G*Power Software (3.1.10).

Statistical analysis

All data were analyzed by an independent statistician. Demographic data and baseline BCTQ scores of the orthosis and combined therapy groups were compared with independent *t*-tests and chi-square tests. The outcome of both intervention groups was analyzed using repeated-measures analysis. Difference in BCTQ including symptom severity score and functional status score within each group (orthosis and combined therapy) were calculated independently before and after intervention. Subsequently, the mean difference in BCTQ (symptom severity and functional status scores) before and after intervention were compared between the orthosis and combined therapy groups. All data analysis was performed using SPSS 23.0.

Results

The demographic data and preintervention characteristics between the orthosis and combined therapy groups were comparable (Table 1).

A total of 41 patients with 56 wrists participated in our study. In the orthosis group, there were 20 patients. Seven patients had bilateral CTS, and 13 were unilateral (9 right, 4 left). In the combined therapy group, there were 21 patients with 8 bilateral CTS and 13 unilateral (5 right, 8 left).

All patients completed the adherence log. No adverse effects were found, and the exercise program did not require revised.

The comparison of mean difference of the symptom severity and functional status scores (BCTQ) before and after intervention for each group independently is summarized in Table 2. There was a significant difference in BCTQ in both symptom severity and functional status scores between before and after intervention in both groups, respectively. Thus, there was significant improvement in symptoms and function after 2 months of intervention in both groups independently. However, comparison of mean difference of BCTQ score before and after intervention between the 2 groups showed no significant difference. Therefore, there was no improvement in symptom severity or functional status scores between the groups (Table 3).

Table 1
Demographic data and preintervention status of patients in orthosis and combined therapy groups

Characteristics	Intervention of wrist[a]; *n* or mean (SD)		Significance, *P*
	Orthosis (27)	Combined therapy (29)	
Age	56.6 (13.9)	50.41 (9.92)	.06
Gender			.70
Male	4	3	
Female	23	26	
Dominant hand			.48
Right	26	29	
Left	1	0	
Wrist involved			.30
Right	16	13	
Left	11	16	
Patients with number of wrist involved			>.99
Single	13	13	
Both	7	8	
NCS			.13
Mild	3	9	
Moderate	10	11	
Severe	14	9	
Duration of symptoms in months	15.7 (15.5)	18.9 (19.7)	.51
BCTQ			
SSS	2.26 (0.8)	2.11 (0.6)	.45
FSS	2.05 (0.9)	2.18 (0.8)	.59

SD = standard deviation; NCS = nerve conduction study; BCTQ = Boston Carpal Tunnel Questionnaire; SSS = Symptom Severity Score; FSS = Functional Status Score.
[a] Total number of patients in orthosis = 20, combined therapy = 21.

Discussion

Generally, in mild and moderate CTS, we opt for noninvasive treatment as first line and subsequently, plan for surgery if that treatment fails.[23] Patients are subjected to multiple combinations of conservative treatment assuming that the modalities have synergistic effects.[24] Theoretically, each modality which functioned differently in improving the symptoms and function would collectively improve the outcome in combination. Although each conservative modality had been observed to be effective in treating CTS independently, there were limited studies available comparing outcome of single vs multiple therapies.[4-13,15]

Combination therapy is time consuming and is not likely to be cost-ineffective, if it does not improve outcomes above that achieved by use of an orthotic. Each therapy session and orthosis application and adjustment increases cost. Multiple visits to hospital also increase patient burden in terms of time. In addition, patients need to take leave from their job in order to attend therapy, increasing the costs to patients and to their employers.

Table 2
Comparison of mean symptom severity and functional status scores between preintervention and postintervention within each group independently

BCTQ[a]	Preintervention	Postintervention	Mean difference (95% CI)	Significance, *P*
Orthosis (*n* = 27)				
SSS	2.26 (0.8)	1.72 (0.7)	0.53 (0.23-0.83)	.001
FSS	2.05 (0.9)	1.45 (0.4)	0.59 (0.28-0.91)	.001
Combined therapy (*n* = 29)				
SSS	2.11(0.6)	1.63 (0.7)	0.48 (0.24-0.72)	<.001
FSS	2.18 (0.8)	1.48 (0.5)	0.69 (0.49-0.89)	<.001

BCTQ = Boston Carpal Tunnel Questionnaire; CI = confidence interval; SSS = Symptom Severity Score; FSS = Functional Status Score.
[a] Total number of patients in orthosis = 20, combined therapy = 21.

Table 3
Comparison of mean differences preintervention and postintervention of symptom severity and functional status scores between orthosis and combined therapy groups

BCTQ[a]	Orthosis	Combined therapy	Mean difference (95% CI)	Significance, *P*
SSS	0.53	0.48	0.05 (−0.33 to 0.42)	.80
FSS	0.59	0.69	−0.10 (−0.45 to 0.26)	.59

CI = confidence interval; BCTQ = Boston Carpal Tunnel Questionnaire; SSS = Symptom Severity Score; FSS = Functional Status Score.
[a] Total number of patients in orthosis = 20, combined therapy = 21.

Our study shows that patients from both the orthosis and combined therapy groups significantly improved in symptom severity and functional status scores after treatment. These findings support other findings where orthosis and exercises improved symptom severity and functional status scores.[4]

However, this study did not support our hypothesis that there would be a greater improvement in symptom severity and functional status in the combined therapy group. The results showed no significant difference between the orthosis and combined therapy groups using the BCTQ. This indicated that no additional benefit or synergistic effect was observed from combined therapy. This result supports other findings which showed no significant difference between the orthosis with and without exercises.[4,25] The difference between our study was that ultrasound therapy was included in our combined therapy group, and our treatment duration was longer than 4 weeks.

Baysal et al[24] demonstrated that combined treatment with orthosis, ultrasound therapy, and nerve and gliding exercises was superior to the orthosis and ultrasound therapy combination. Our control group consisted of orthosis alone. The nerve gliding exercise used in both studies were different. Baysal et al used Totten and Hunter[26] as reference, whereas ours was according to Coppieters.[12] The number of repetitions in our exercises was more, 10 instead of 5. In our study, there was no significant difference between groups after 2 months of intervention. The exercises used in the study may be the factor that results in the difference between the studies; however, further study needs to be investigated.

In severe CTS, the role of conservative treatment is limited. Patients with either neurological deficit or severe symptoms affecting daily activities were frequently counseled for surgical decompression. However, patients who refused invasive treatments for certain reasons might still benefit from orthosis for some symptom relief. Orthosis application is still superior to no treatment at all.[7,9] Therefore, orthosis can be considered as beneficial temporarily in patients with severe CTS who are awaiting surgery.

In our study, combination therapy was not superior compared to orthosis alone in early treatment of CTS. This suggests that it may not be necessary to subject patients to multiple therapies, but it supports the uses of an orthotic. Combination therapy may be an option for selective patients. Since there have been conflicting findings about the role of multimodal therapy for CTS, in comparison to the use of an orthotic alone, it may require a synthesis of multiple trials by meta-analysis before a definitive conclusion can be reached.

Limitation of study

Adherence of subjects to exercises and orthosis were important in the study. This was ensured, as patients completed a compliance chart diligently. However, since this was self-reported, we may have overestimated adherence.

The BCTQ assessment in this study was carried out immediately after patients removed their orthosis. For future studies, it would be interesting to know if there was any improvement after the orthosis has been discontinued for a period of time in order to allow the patient to go back to their daily activity and reassess the BCTQ again.

The frequency of ultrasound therapy used was once a week. This was less than described in other studies[24] because of shortage of man power and high volume of patients.

We used hands rather than persons in our analysis, which violates the assumption of independent observations that statistical tests are based on. This may have contributed to our finding.

Finally, both patients and investigator were not blinded as the treatment groups consisted of different modalities. Patients were educated regarding the modalities as this was crucial in ensuring compliance. The choices of treatment groups were also stated in consent form which made blinding impossible.

Conclusion

Patients who underwent conservative management for CTS showed improvement in symptoms and function. However, the combination of orthosis, nerve and tendon gliding exercises, and ultrasound therapy was not superior compared to orthosis alone. Thus, orthosis is sufficient in early treatment of CTS, reducing the cost and time spent.

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1. The study design was
   a. retrospective
   b. RCTs
   c. qualitative
   d. a case series
2. The primary outcome measure was
   a. the Purdue Peg Board
   b. an EMG
   c. the DASH
   d. the Boston Carpal Tunnel Questionnaire
3. All subjects presented with
   a. positive median and ulnar nerve findings
   b. gross atrophy of the thenar eminence
   c. positive electrodiagnostic findings
   d. bilateral CTS
4. The orthotic device
   a. was complex and presented technical challenges in construction
   b. held the wrist in close to neutral and allowed adequate MP flexion
   c. was made of leather
   d. was purchased from a certified orthotist
5. The authors concluded that the wearing of an orthosis alone was just as effective as the additional interventions of nerve gliding and ultrasound
   a. true
   b. false

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