

Prospective Study of Outcome of Nocturnal Wrist Splint versus Local Steroid Injection in Mild and Moderate Carpal Tunnel Syndrome

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Abstract

Carpal tunnel syndrome, a common entrapment neuropathy involving median nerve at the wrist is characterized by pain and paresthesia of hands and in severe cases numbness and weakness of thenar muscles. Non-surgical methods have a role in management of mild and moderate cases of CTS. Common options include nocturnal wrist splint and local steroid injection. We could not come across any Indian studies comparing these two methods. This prospective observational study conducted at Government medical college Ernakulam aimed at comparing these two modalities of treatment in mild and moderate cases of idiopathic CTS in patients older than 18 years of age. Patients were allowed to take informed decision to choose either nocturnal wrist splint or ultrasound guided local injection of 40 mg of triamcinolone. They were followed up with BCTQ clinical severity score and functional status score (primary outcome) as well as peak latency and distal latency in NCS (secondary outcome) at 6 weeks and 6 months. Difference between BCTQ score, peak latency and distal latency at 6 weeks and at 6 months from the baseline between the splint and steroid group was compared using Mann Whitney U test. A patient preference for nocturnal wrist splint was noticed in this study mainly because of its non-invasive nature. Both the wrist splint and steroid group showed improvement in BCTQ clinical severity score and functional status score and NCS parameters at 6 weeks and 6 months. There was a greater improvement in the steroid group at 6 weeks. However, the initial advantage seen with steroids when compared to wrist splint declined to non-significant levels at 6 months. This study shows that local steroid injection produced an earlier relief of symptoms which continued at 6 months follow up. Nocturnal wrist splint though lagged behind steroids at 6 weeks follow up in terms of relief of symptoms, there was no significant difference between the two groups at 6 months follow up.

Keywords: Carpal tunnel syndrome, Wrist splint, Local steroid, BCTQ score.

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Introduction

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy encountered in neurology clinical practice. It is caused by compression of the median nerve across the carpal tunnel at the wrist. (1) Symptoms include pain and paresthesia in the hand which may be nocturnal or exacerbated by activities. In severe cases there may be negative symptoms like wasting and weakness of thenar muscles and numbness. Symptoms may be bilateral in 50 % or more of the patients. (2) This affects the quality of life with limitation of daily activities and reduction of work capacity.

Diagnosis is made through evaluation of symptoms, clinical examination and Nerve conduction study (NCS) (3). Treatment options include surgical decompression and nonsurgical (conservative) treatment. Among the nonsurgical methods, systematic reviews have confirmed the short term effectiveness of local steroid injection (LSI) at wrist (4) and nocturnal wrist splint (NWS). (5)

Studies comparing these two nonsurgical methods of wrist splint and local steroid injection are few and many have methodological flaws. INSTINCTS trial published in 2018 (6) compared these two methods and they found that LSI was associated with more improvement at 6 weeks. However the difference between the two methods declined at 6 months when compared to 6 weeks. This study was conducted at primary health level, the severity and follow up assessment was not guided by NCS and the LSI was given blindly. Another recent trial by Vinícius et al comparing these two methods of conservative treatment (7) found both to be effective for short term and that LSI was superior. This study however included electro physiologically severe CTS cases also and also used blinded LSI. Also the

changes in NCS were not assessed on follow up. In both these trials, patients were randomized to receive either of the treatment. We could not come across any Indian study in this regard.

In our trial we were interested to see the patient's choice when offered these two proven modes of treatment. In addition to symptom severity scoring we followed up the patients with NCS to see whether it matches the changes in symptoms.

Methods

Study design and participants

We did a prospective observational study at Government Medical College, Ernakulam. This study received clearance from institutional ethical committee. Participants were recruited from those attending the neurology outpatient clinic with symptoms suggestive of CTS. Those patients with idiopathic CTS, aged 18 years or more and CTS classified as mild or moderate based on NCS were included in the study after obtaining informed consent. Patients were excluded if they had history of previous treatment for CTS other than analgesics, history of significant local trauma or any contraindication for local steroid injection like past history of drug allergy, local infection, anticoagulation therapy or bleeding diathesis.

Procedure

Patients were allowed to take informed decision regarding the modality of treatment as NWS or LSI. The reason for choosing the treatment modality was noted down during interview by open questioning. 40 mg of triamcinolone injection was given after applying lignocaine gel. LSI was given under ultrasound guidance with the help of a radiologist of our institute. For those who chose NWS, illustration was given by the

principal investigator regarding how to wear the splint keeping the wrist at neutral position and they were asked to wear the nocturnal splint throughout the follow up period. No other medications were given for CTS during the study period.

Baseline data of participants were collected at the entry point of the study. All patients were followed up at 6 weeks and later at 6 months. At baseline and at each follow up, patients were assessed with Boston Carpal Tunnel Questionnaire (BCTQ) clinical severity and functional status scoring (available online) and NCS. BCTQ questionnaire examines symptoms and functional disability of CTS in the past 2 weeks. Severity scale questionnaire has 11 items and scores range from 11 to 55. Functional status scale questionnaire has 8 items with scores ranging from 8 to 40. For those who required it, the questionnaire and scoring options were explained in the native language by the principal investigator.

Outcome

BCTQ clinical severity score and functional status score at 6 weeks and 6 months was kept as the primary outcome. Changes in peak latency and distal latency as measured in NCS at 6 weeks and 6 months, failure of treatment or any adverse incidents related to treatment were considered in the secondary outcome. Failure of conservative treatment was considered when there is requirement of surgery due to worsening or non-remission or significant relapse of symptoms.

Statistical analysis

Data was coded and entered in MS excel worksheet and was analyzed using the SPSS statistical package version 22. Qualitative data was summarized using frequency and percentage. Quantitative data was summarized using mean and standard deviation. Difference between BCTQ score, peak latency and distal latency at 6 weeks and at 6 months from the baseline between the splint and steroid group was compared using Mann Whitney

U test. Significance level was fixed at a p value <0.05.

Results

86 patients with CTS were screened for the study in a span of 9 months from March 2022 -December 2022 of which 38 patients were included in the study after applying the inclusion and exclusion criteria and after obtaining informed written consent. Females constituted the majority (76.3%). Age group ranged from 24 years to 65 years (mean 43.95 ± 9.61). 22 patients (57.9%) opted for splint and 16 patients (42.1%) opted for local steroid injection. The reasons cited for preferring wrist splint included fear of injection and fear of 'accidental injury to nerve' despite the reassurance of it being ultrasound guided, when compared to noninvasive nature of wrist splint. For those who chose steroid, the main reason was that it is a onetime treatment.

Five patients were lost for follow up at 6 weeks and two more patients were lost for follow up at 6 months. When contacted over phone, they reported good remission of their symptoms which they cited as the reason for default in follow up. They were considered while calculating the failure rate and the two people who were lost to follow up after 6 week were included in the 6 week data analysis.

Table 1 depicts the comparison between baseline data of the splint and steroid groups. There was no significant difference in the baseline parameters of the two groups.

6 weeks follow up

BCTQ severity score, functional status, peak latency and distal latency, all showed a significant improvement from baseline (mean difference of BCTQ severity scale was 6.58 ± 5.35 , 95% CI 4.68 -8.473, $p < 0.05$, mean difference of BCTQ functional status score was 4.91 ± 3.28 (95% CI 3.75 - 6.07), $p < 0.05$,

mean difference of peak latency was 0.54 ± 0.63 , 95 % confidence interval 0.31-0.76, $p < 0.05$, mean difference of distal latency was 0.60 ± 0.71 , 95 % confidence interval 0.35 -0.85, $p < 0.05$). There were no serious complications observed related to the treatment. Three patients reported lightening of skin at the injection site at 6 weeks follow up.

Between wrist splint and steroid group, the decline in BCTQ severity scoring showed a significant difference favoring local steroid injection (mean difference in splint group was 4.47, mean difference in steroid group was 8.81, $p = 0.017$) as evidenced by Mann Whitney U test. A similar result was seen in BCTQ functional status scoring (mean difference in splint group was 3.76; mean difference in steroid group was 6.13, $p = 0.037$). There was no significant difference between these two groups in peak latency and distal latency. One patient with wrist splint was referred for surgery at 6 weeks as there was no relief of symptoms, BCTQ scoring remained the same and there was increase in peak latency and distal latency.

The failure rate for conservative method was 0.03 % at 6 weeks (0.04 % of splint group and 0% of steroid group).

6 months follow up

A significant improvement in all outcome measures was seen at 6 months also.

BCTQ severity scoring showed a mean difference of 7.23 (95 % CI 5.38 -9.09, $P <$

0.05). BCTQ Functional scoring showed a mean difference of 5.07 (95 % CI 3.74 -6.4, $p < 0.05$). Peak latency showed mean difference of 0.78 with 95 % CI between 0.46-1.10, $p < 0.05$. Distal latency showed mean difference of 0.92 with 95 % CI 0.57-1.26, $p < 0.05$.

Comparison between splint and steroid group showed that the difference between two groups seen at 6 weeks in BCTQ severity scale and functional status scale has declined to non significant levels at 6 months (BCTQ severity scale mean difference in splint group was 6.87 and that of steroid group was 7.6, $p = 0.7$, BCTQ functional status mean difference in splint group was 5.0, steroid group was 5.13, $p = 0.9$). There was no significant difference between the groups in peak latency and distal latency.

Two patients both of the steroid group were referred for surgery at 6 months. Of them one had relapse of symptoms after experiencing an interim complete remission and the other patient had worsening of symptoms when compared to 6 weeks follow up. The failure rate (requirement for surgery) for the conservative method was 0.06 % at 6 months (0.13 % in steroid group and 0.05 % in wrist splint group). 3 patients of the steroid group (0.2%) had mild worsening of the BCTQ scoring and NCS values at 6 months and they were advised additional wrist splint.

Table 1: Baseline data

Characteristic	Splint, n=22 (57.9%)	Steroid, n=16 (42.1%)	P value
Age (years)	44.27 \pm 9.74	43.5 \pm 9.74	0.81
Female, n (%)	16 (72.7%)	13 (81.2%)	0.54
BCTQ SS (mean)	18.95 \pm 5.09	21.44 \pm 5.23	0.15
BCTQ FS (mean)	13.41 \pm 3.49	14.88 \pm 3.09	0.18
PL (mean)	4.69 \pm 0.98	4.78 \pm 0.97	0.79
DL (mean)	4.75 \pm 1.16	4.93 \pm 1.07	0.63

*BCTQ SS -Boston Carpal Tunnel Questionnaire Symptom Severity score

BCTQ FS -Boston Carpal Tunnel Questionnaire Functional Status score

PL-Peak Latency

DL-Distal Latency

Table 2: Outcome at 6 weeks and 6 months

Characteristic	Splint (SD)	Steroid (SD)	P value
Mean BCTQ SS score difference			
At 6 weeks	4.47(\pm 3.60)	8.81(\pm 6.07)	0.017
At 6months	6.86(3.9)	7.6(\pm 5.97)	0.69
Mean BCTQ FS score difference			
At 6 weeks	3.76(\pm 2.75)	6.13(\pm 3.44)	0.037
At 6months	5.0(3.38)	5.13(\pm 3.85)	0.92
Mean PL difference			
At 6 weeks	0.44(\pm 0.57)	0.63(\pm 0.68)	0.38
At 6months	0.77(0.80)	0.79(\pm 0.94)	0.95
Mean DL			
At 6 weeks	0.51(\pm 0.83)	0.70(\pm 0.55)	0.45
At 6 months	0.87(\pm 0.99)	0.97(\pm 0.91)	0.76

Discussion

In this study we observed a patient preference for nocturnal wrist splint, mainly because of the noninvasive nature of this method.

At 6 weeks, there was greater improvement in the steroid group in comparison to wrist splint group in terms of BCTQ severity scale and BCTQ functional status scale which was statistically significant. At 6 months, both the groups continued to show statistically significant improvement. However the initial advantage seen in the steroid group in comparison to splint group diminished to non-significant levels at 6 months. 0.19% (3/16) patients of the steroid group reported lightening of the skin at the injection site. There was no incidence of any adverse effects in the wrist splint group.

The failure rate (requirement for surgery) for the conservative method was 0.03 % at 6 weeks (0.04 % of splint group and 0% of steroid group) and 0.06 % at 6 months (0.13 % in steroid group and 0.05 % in wrist splint group). 3 patients of the steroid group (0.2%) had mild worsening of the BCTQ scoring and NCS values at 6 months and they were advised additional wrist splint. Even though the failure rate requiring surgery was more in splint group at 6 weeks and in steroid group at 6 months (surgery

rate as well as need for add on therapy), we could not assess the statistical significance of this as the numbers were very less.

The long term outcome of patients treated with nonsurgical methods has a major implication while explaining the prognosis to patients. Also the role of add on therapy in averting a surgery needs to be explored. Based on the results of this study as well as that the previous studies with similar results (6, 7) we propose that combining steroid and wrist splint earlier during treatment, may result in rapid and longer lasting benefits. We plan to follow up the participants further on, to study their outcome at 1 year including that of three patients who had been given add on therapy at 6 months.

We had assessed NCS also on follow up and found that the NCS parameters improved or worsened in parallel to BCTQ scoring. This may help as an additional tool for follow up of CTS patients.

The choice of steroid (methylprednisolone, triamcinolone, and hydrocortisone) and its dose varies among different studies and each of these options has found their efficacy in respective studies. We used triamcinolone as it had uninterrupted supply in our pharmacy.

Ultrasound guided approach has been used in this study for giving steroid injection. There are conflicting results about comparison between the landmark guided (blind) and ultrasound guided. (8, 9, 10). We noted that the immediate complications were nil with ultrasound guided method.

Conclusion

Our study suggests that local corticosteroids injection produced a rapid remission of symptoms and their effect continued at 6 months follow up. In comparison, wrist splint though lagged behind steroid at 6 weeks produced an equitable improvement at 6 months. This information may be practically converted to combining steroid and wrist splint at the outset which may provide an early and longer lasting improvement. However studies with a longer follow up and those which included third group of add on or dual therapy would bring out more information about the long term outcome of these nonsurgical methods of CTS treatment.

Limitations

The limitations of our study include smaller sample size and non-blinded non-randomized nature of the study.

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