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Original Article

Effectiveness of Ultrasound-Guided Median Nerve Methylprednisolone Hydrodissection Vs. Open Surgery in Treatment of Carpal Tunnel Syndrome: A Parallel-Group, Single-Blinded, Randomized Clinical Trial

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Background: Carpal tunnel syndrome (CTS) represents one of the most prevalent entrapment neuropathies affecting the upper extremity. Over the past decade, ultrasound-guided hydrodissection has emerged as a promising, minimally invasive technique for the management of entrapment neuropathies. However, comparing the clinical efficacy of ultrasound-guided hydrodissection against traditional open surgical release remains challenging, as current literature provides conflicting or limited data. This clinical trial sought to compare the functional and clinical outcomes of ultrasound-guided hydrodissection utilizing methylprednisolone versus standard open surgical release in patients diagnosed with moderate-to-severe CTS.

Materials and Methods: In this randomized, parallel-group, single-blinded clinical trial, 46 patients (aged 20–65 years) were recruited and randomly allocated in a 1:1 ratio to either the hydrodissection group (injection of methylprednisolone; n=23) or the open surgery group (n=23). The primary outcome measures were the functional status and symptom severity scores of the Boston Carpal Tunnel Questionnaire (BCTQ), assessed at baseline, one month, and three months post-intervention. Statistical analysis was performed using an intention-to-treat approach, employing mixed-model analysis of covariance (ANCOVA) adjusted for baseline scores.

Results: Forty-four patients (mean age 48±10.3 years) successfully completed the study protocol. Following adjustment for baseline outcomes, the mixed-model ANCOVA demonstrated no statistically significant Group ×\times× Time interaction for either the BCTQ severity (F=1.006F =1.006F=1.006; P=0.330P = 0.330P=0.330; ηp2=0.056\eta_p^2 = 0.056ηp2 =0.056) or functional (F=0.856, F=0.856, F=0.856, P=0.368, P=0.368, P=0.368, ηp2=0.048\eta_p^2 = 0.048, ηp2=0.048) scales. Both cohorts experienced comparable improvements in symptom severity (one month: 0.1\Delta 0.1, 95% CI: −0.4 to 0.6; three months: 0.4\Delta 0.4, 95% CI: −0.25 to 1.05) and functional status (one month: 0.25\Delta 0.25, 95% CI: −0.3 to 0.8; three months: 0.5\Delta 0.5, 95% CI: −0.2 to 1.2).

Conclusion: This clinical trial demonstrates that, in the short term, ultrasound-guided methylprednisolone hydrodissection is as effective as open surgical release for the management of moderate-to-severe CTS. While these findings suggest that hydrodissection may serve as a

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viable minimally invasive alternative, further longitudinal studies with extended follow-up periods are essential to confirm the long-term durability of these outcomes.

Keywords Carpal Tunnel Syndrome, CTS, surgery, methylprednisolone, ultrasound-guided hydrodissection, corticosteroid

Introduction

Carpal tunnel syndrome (CTS) is a frequently encountered neuropathy of the upper extremity, representing a common reason for patients to seek medical consultation (1). The prevalence of CTS in the United States general population is estimated at approximately 3.8%, with incidence rates nearly twice as high in women as in men (2). Furthermore, a systematic review involving 14,525 participants estimated the prevalence of CTS in Iran to range from 1.82% to 64.6%, with an overall pooled prevalence of 17.53% (95% CI: 13.74–21.31%) (3).

Clinical symptoms of CTS include pain, numbness along the distribution of the median nerve, paranesthesia, diminished grip strength, and muscular weakness (4). Whilst the precise etiology remains multifactorial, high-pressure compression of the median nerve, progressive ischemia, and mechanical entrapment are considered primary pathophysiological mechanisms (5). Treatment strategies for CTS vary significantly according to disease severity, spanning a spectrum from conservative to surgical interventions. Although the differences in clinical outcomes between conservative and surgical management are often narrower than previously anticipated, current evidence suggests that conservative interventions are effective in the majority of mild-to-moderate cases; conversely, they are frequently insufficient for the management of severe CTS (6). Consequently, surgical decompression remains the standard of care for patients with severe CTS or those who fail to demonstrate an adequate response to conservative management (7). There is, therefore, a pressing clinical need to evaluate novel, minimally invasive conservative interventions for moderate-to-severe CTS.

Ultrasound-guided hydrodissection has recently emerged as a promising therapeutic modality for entrapment neuropathies (8). Hydrodissection is a minimally invasive procedure involving the injection of fluid into anatomical spaces to facilitate the disruption of perineural adhesions and dissections (9). By specifically targeting the sub-synovial space, this technique may improve CTS-related symptoms by releasing adhesions surrounding the median nerve (10). Evers *et al.* demonstrated a notable decrease in the gliding resistance of the median nerve within the carpal tunnel following hydrodissection (11). Injectates typically utilized in clinical practice include platelet-rich plasma, 5% dextrose, and normal saline (12-13). Furthermore, given that local corticosteroid injections are established as a standard treatment for CTS, recent investigations have begun to explore the clinical effectiveness of hydrodissection combined with corticosteroids (13). However, due to the limited number of studies investigating the efficacy of corticosteroid-based hydrodissection, significant uncertainty remains regarding its relative superiority over other therapeutic interventions (14-15). Notably, no previous study has directly compared the clinical efficacy of ultrasound-guided hydrodissection against open surgical release in patients with CTS (16). Considering that traditional surgery may be associated with complications-including extensive scarring, prolonged recovery, and potential iatrogenic somatosensory impairment-this clinical trial aimed to compare the functional and clinical effects of ultrasound-guided hydrodissection utilizing methylprednisolone versus traditional open surgery for the treatment of moderate-to-severe CTS (17).

Materials and methods

This study was conducted as a randomized, single-blinded, parallel-group clinical trial involving patients diagnosed with carpal tunnel syndrome (CTS). Participants aged 20 to 65 years were recruited from the clinic of Rohani Hospital, affiliated with the Babol University of Medical Sciences, between July 2020 and January 2022. The diagnosis of CTS was confirmed by a board-certified neurosurgeon (A.Z.) based on clinical

physical examination findings and electromyography/ nerve conduction studies (EMG-NCS).

The exclusion criteria were as follows: a history of diabetes mellitus, hypothyroidism, proximal median nerve entrapment, chronic renal failure, rheumatoid arthritis, cervical radiculopathy, polyneuropathy, or thoracic outlet syndrome; corticosteroid injection to the affected wrist within the preceding six months; prior surgical intervention to the wrist; distal radius fracture on the ipsilateral side; pregnancy or lactation; consistent use of non-steroidal anti-inflammatory drugs (NSAIDs) or systemic corticosteroids; and an inability or refusal to provide informed consent.

The study protocol received formal approval from the Ethics Committee of the Babol University of Medical Sciences (Reference: IR.MUBABOL.HRI.REC. 1398. 372) and was conducted in strict accordance with the ethical principles outlined in the Declaration of Helsinki (revised in Brazil, 2013). The trial was prospectively registered with the Iranian Registry of Clinical Trials on June 2020 (Registration number: IRCT20200629047948N1). All participants were provided with a comprehensive explanation of the study design, and written informed consent was obtained prior to enrolment.

Randomization and blinding

Patients were randomly assigned in a 1:1 ratio to either the open surgery or ultrasound-guided hydrodissection group. Allocation was performed using block randomization to ensure an equal distribution of participants across both treatment arms. A pre-generated sequence of six blocks (AABB, ABAB, ABBA, BBAA, BABA, and BAAB) was utilized to maintain the 1:1 ratio.

The randomization sequence was generated by an independent research staff member who had no role in patient recruitment, clinical data collection, or data entry. To ensure concealment of allocation, this sequence remained inaccessible to the clinical team until the moment of participant enrolment.

To maintain blinding, the investigators responsible for assessing baseline data, as well as those monitoring post-interventional clinical outcomes and potential complications, remained blinded to the treatment assignment throughout the study duration. Due to the inherent nature of the interventions (i.e., surgical versus injection-based), full blinding of the participants and the performing clinicians was not feasible; however, the use of independent outcome assessors effectively mitigated potential bias in the evaluation of clinical results.

Interventions

Patients assigned to the surgical cohort underwent a standard open carpal tunnel release. Under local anesthesia, a 2.5 cm longitudinal incision was performed 1.5 cm distal to the wrist crease, oriented towards the fourth digit. Following the incision and careful retraction of subcutaneous adipose tissue and the palmar aponeurosis, the distal margin of the transverse carpal ligament (TCL) was identified. The TCL was then released under direct visualization, with a longitudinal incision extending from the distal to the proximal border, thereby achieving complete decompression of the median nerve.

Patients in the hydrodissection cohort received an ultrasound-guided perineural injection. The procedure was performed using a high-frequency linear R15 probe and the SonoAce R7 system (Samsung Medison, Seoul, South Korea). The median nerve was identified via ultrasonography, tracing its course from the distal forearm to the carpal tunnel, deep to the common flexor tendons (CFT).

Using an in-plane approach, a needle was advanced under direct sonographic visualization from the ulnar side of the wrist, passing beneath the CFT to reach the median nerve. To facilitate hydrodissection, 10 mL of an injectable solution-comprising 20 mg of bupivacaine (Exir), 40 mg of methylprednisolone (Exir), and 3–5 mL of normal saline-was administered to isolate the median nerve from the surrounding flexor tendons and the ligamentous floor of the canal. The needle tip was used to perform multiple passes at the level of the CFT to ensure the distribution of the therapeutic mixture. Post-procedure, manual pressure was applied to the entry site for 3–5 minutes to ensure hemostasis prior to patient transfer to the recovery unit.

Outcome

The primary clinical outcome was the assessment of symptom severity and functional status, measured using the Boston Carpal Tunnel Syndrome Questionnaire (BCTQ). This validated instrument comprises two distinct subscales: the Symptom Severity Scale (SSS) and the Functional Status Scale (FSS). Participants completed the

BCTQ at baseline (pre-intervention), and at follow-up assessments at 1 month and 3 months post-intervention.

Each item on the questionnaire is scored on a Likert scale ranging from 1 (no symptoms/no difficulty) to 5 (most severe symptoms/most severe functional impairment). The mean score for each subscale is calculated, with higher scores indicating greater symptom severity or more significant functional disability.

To interpret clinical significance, we utilised the threshold proposed by Kleermaeker et al., defining a minimal clinically important difference (MCID) as a change of at least 30% from baseline, rather than relying on a fixed absolute score reduction.

Sample size calculation

Sample size calculation was performed using G*Power software (version 3.1; Heinrich Heine University Düsseldorf, Germany), based on the effect sizes reported in previous studies by Gurcay et al. (21) and Guo et al. (22). Adopting a two-sided significance level (α\alphaα) of 0.050.050.05 and a power (1−β1-\beta1−β) of 0.800.800.80, the analysis indicated that a minimum of 16 participants per group were required. To account for an anticipated attrition rate of 20%, the sample size was increased to 20 participants per study arm, resulting in a total enrolment of 40 patients.

Statistical analysis

Data analysis was performed according to the intention-to-treat (ITT) principle, with participants analyzed in the groups to which they were originally randomized. Continuous variables are expressed as mean ± standard deviation (SD), and categorical variables as frequency (percentage). Baseline characteristics between the two groups were compared using the independent samples t-test for continuous data and the χ2\chi^2χ2 test for categorical data.

To evaluate between-group differences in BCTQ scores over the three time points (baseline, 1 month, and 3 months), a repeated-measures analysis of covariance (ANCOVA) was employed. The model included time as the within-subject factor and group as the between-subject factor, with baseline BCTQ scores included as a covariate to account for potential initial variations.

To determine the magnitude of effect, partial eta squared (ηp2\eta_p^2ηp2) was calculated for significant findings, as this metric is preferred for ANOVA-based models (23). Effect sizes were interpreted according to established conventions: 0.010.010.01 (small), 0.060.060.06 (medium), and 0.140.140.14 (large). In instances where significant differences were observed, *post hoc* comparisons were conducted using independent samples t-tests or χ2\chi^2χ2 tests with appropriate adjustments for multiple comparisons. All statistical analyses were conducted using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, N.Y., USA), with statistical significance defined as a two-sided P<0.05P < 0.05P<0.05.

Results

Participant Flow and Baseline Characteristics

A total of 102 patients were screened for eligibility. Of these, 49 did not meet the inclusion criteria, and 7 declined to participate. Consequently, 46 patients were randomised. Two participants were subsequently excluded from the analysis: one withdrew before the intervention, and one was lost to follow-up. Thus, 44 patients (22 per group) completed the study and were included in the final analysis (Figure 1, 2). Baseline characteristics were well-balanced between the surgery and hydrodissection groups, with no statistically significant differences observed across all variables (Table 1). No treatment-related adverse events were reported in either cohort.

Symptom Severity and Functional Status

Adjusting for baseline values, a mixed-model ANCOVA revealed a significant main effect of time on the Symptom Severity Scale (SSS) and Functional Status Scale (FSS) scores ($F=29.76$, P <0.001; ηp2=0.70\eta_p^2=0.70ηp2=0.70). However, there was no significant group × time interaction ($F=1.01$, $P = 0.33$; ηp2=0.06\eta_p^2=0.06ηp2=0.06), indicating that both interventions resulted in comparable improvements in symptom severity and functional status at 1 and 3 months post-intervention (Table 2). Further analysis confirmed that neither sex ($F=0.02$, $P = 0.99$; ηp2<0.01\eta_p^2 < 0.01ηp2<0.01) nor age ($F=0.74$, $P = 0.73$; ηp2=0.08\eta_p^2=0.08ηp2=0.08) had a statistically significant impact on these outcomes.

Changes in Function

When evaluating the Symptom Severity Scale (SSS) of the BCTQ, the mixed-model ANCOVA, adjusted for baseline scores, similarly demonstrated a significant main effect of time ($F=29.17$, P <0.001; ηp2=0. 70\eta_p^2=0. 70ηp2=0.70). However, the group × time interaction

remained non-significant (F=0.86, *P* = 0.37; ηp2=0.05\eta_p^2=0.05ηp2=0.05). These results indicate that both surgical and hydrodissection cohorts achieved comparable improvements in symptom severity at the 1-month (Δ 0.25; 95% CI, -0.30 to 0.80) and 3-month (Δ 0.50; 95% CI, -0.20 to 1.20) follow-up assessments (Table 2).

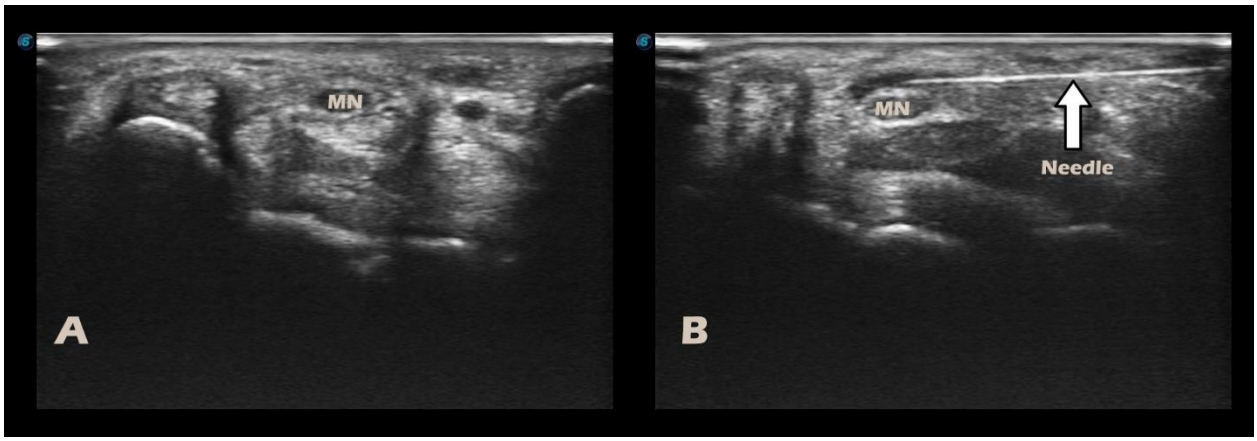

Fig 1. Ultrasound-guided median nerve hydrodissection with methylprednisolone. A: Before the procedure; B: During the procedure; MN: median nerve.

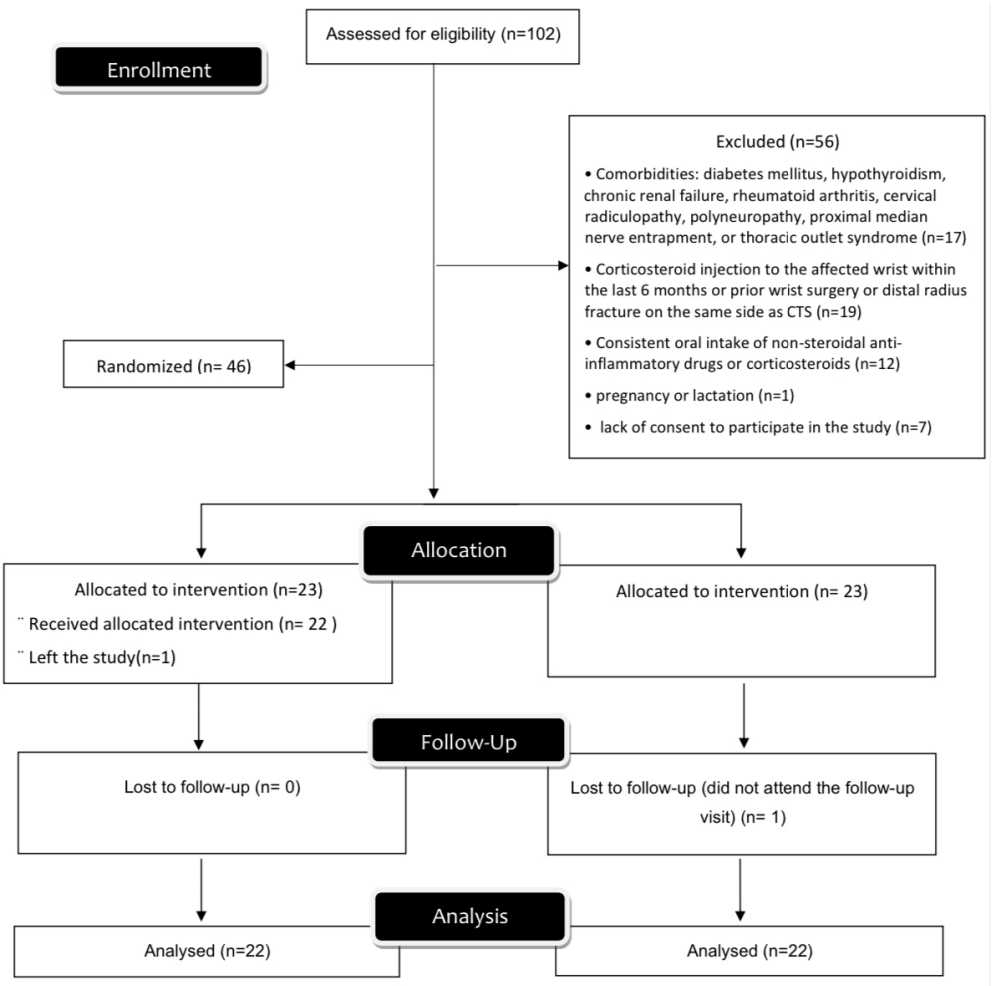

Fig 2. CONSORT flow diagram of the study

Table 1. Baseline characteristics by treatment assignment

		Methylprednisolone injection	Open surgery	p-value
Age (years)		48 ± 11.1	47.9 ± 9.6	0.45
Female, n (%)		72.7	86.4	0.42
BMI (kg/m^2)		29.7 ± 6.2	30.2 ± 5.8	0.47
Severity, n (%)	Moderate	45.5	40.9	0.76
	Severe	54.5	59.1	
CTS side (Right hand), n (%)		54.5	63.6	0.54
Duration of pain (months)		20.6 ± 7.1	22.3 ± 8.8	0.49
BCTQ Severity Score before (1-5)		4.1 ± 0.5	3.9 ± 0.6	0.193
BCTQ Function Score before (1-5)		4.05 ± 0.5	3.95 ± 06	0.553

Values are expressed as mean ± standard deviation; BCTQ: Boston Carpal Tunnel Questionnaire; P-value<0.05 is statistically significant.

Table 2. Primary outcome at baseline and one and three months by randomized treatment assignment

Group	Outcome	Time	Before	1 month	3 months
Methylprednisolone Injection	BCTQ Severity Score (1-5)		4.1 ± 0.5	2.5 ± 1.0	2.25 ± 0.9
	BCTQ Function Score (1-5)		4.05 ± 0.5	2.75 ± 1.0	2.5 ± 1.2
Open surgery	BCTQ Severity Score (1-5)		3.9 ± 0.6	2.4 ± 0.7	1.85 ± 1.0
	BCTQ Function Score (1-5)		3.95 ± 0.6	2.5 ± 0.9	2.0 ± 1.1

Values are expressed as mean ± standard deviation; BCTQ: Boston Carpal Tunnel Questionnaire; P-value<0.05 is statistically significant.

Consistent with the functional findings, neither sex (F=0.12, *P* = 0.89; ηp2=0.01\eta_p^2=0.01ηp2=0.01) nor age (F=0.70, *P* = 0.77; ηp2=0.02\eta_p^2=0.02ηp2=0.02) exerted a statistically significant influence on symptom progression

Discussion

This clinical trial represents the first prospective comparison of ultrasound-guided methylprednisolone hydrodissection versus open carpal tunnel release for patients diagnosed with carpal tunnel syndrome (CTS). Our findings indicate that both interventions yielded comparable short-term efficacy in improving symptom severity and functional status at one and three months post-procedure, even in patients with moderate to severe CTS.

Previous investigations have explored the utility of ultrasound-guided hydrodissection for CTS (11, 14, 24). Consistent with our results, studies by [Insert citation 11] and [Insert citation 24] demonstrated positive therapeutic effects of nerve hydrodissection. However, the superiority of hydrodissection with corticosteroids over corticosteroid injection alone remains a subject of debate, with some studies suggesting uncertainty (14, 15). While local steroid injections have been established as effective for mild CTS (25) and potentially mild-to-moderate disease (26), their suitability for severe CTS has been questioned. Notably, our trial demonstrated that ultrasound-guided methylprednisolone hydrodissection provided short-term benefits comparable to open surgery, even in the moderate-to-severe CTS population. This aligns with Gurcay et al.'s findings, which reported no significant short-term differences in recovery between local steroid injection and open surgery (21). They proposed local steroid injection as a viable alternative for patients reluctant to undergo surgery (21). Similarly, Celik et al. observed improvements in symptom severity and electrophysiological parameters within the first month for both steroid injection and open surgery, although the surgical group showed a higher recovery rate at three and

six months (27). The consistent functional and severity improvements observed in both groups in our study are also supported by Makhlouf et al.'s research, which highlighted the significant clinical benefits of ultrasound-guided steroid injection in CTS patients (28).

The proposed mechanisms for these positive outcomes include the short-term reduction of pressure on the median nerve, primarily through decreased inflammation both within and distal to the carpal tunnel (29). While the precise effects of nerve hydrodissection are still being elucidated, the injected fluid may facilitate gliding of the entrapped nerve, reduce repetitive compression, and restore normal median nerve motion within the carpal tunnel, thereby improving blood flow and nerve conduction (30, 31). Intriguingly, Wu et al. (32) and others (33) have suggested that the therapeutic benefits of nerve hydrodissection may persist beyond the absorption of the injectate, potentially due to mechanical effects such as improved lubrication or altered biomechanics within the carpal tunnel. Nonetheless, further research is imperative to delineate the long-term efficacy of ultrasound-guided corticosteroid hydrodissection compared to surgical interventions.

We acknowledge the limitations of this study. Firstly, the three-month follow-up period may not be sufficient to capture potential long-term differences between the interventions. Longer follow-up is warranted to ascertain the durability of the benefits observed. Secondly, our assessment relied solely on the BCTQ. While the BCTQ is a well-validated measure, incorporating pain intensity assessments might provide a more comprehensive clinical picture, though we acknowledge that pain is not always the predominant symptom in CTS. Finally, post-intervention electrophysiological studies were not performed. Although some evidence suggests a weak correlation between EMG findings and clinical outcomes in CTS (34), such data could offer additional insights into nerve recovery.

Conclusion

In conclusion, this clinical trial demonstrates that ultrasound-guided methylprednisolone hydrodissection is as effective as open carpal tunnel surgery for achieving short-term improvements in symptom severity and functional status in patients with moderate-to-severe CTS. The optimal treatment strategy may vary individually, underscoring the importance of personalized, patient-centered approaches in managing CTS.

Declarations

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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No funding was received for this study.

Authors' contribution

All authors were participated in the concept and design, analysis and interpretation, data collection, writing the article, critical revision, final approval, statistical analysis, overall responsibility.

Acknowledgments

N/A

Ethics approval and consent to participate

This study was conducted in strict adherence to the ethical principles outlined in the Declaration of Helsinki (revised in Brazil, 2013) and received full approval from the Ethics Committee of Babol University of Medical Sciences (Approval Number: IR.MUBABOL. HRI.REC. 1398.372). The trial protocol was prospectively registered with the Iranian Registry of Clinical Trials (IRCT), an entity recognised by the International Committee of Medical Journal Editors (ICMJE) and the World Health Organization (WHO), on June 29, 2020 (Registration Number: IRCT20200629047948N1). All participants provided written informed consent prior to their enrolment in the study. Where applicable, consent was also obtained from their legal guardian(s).

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