RESEARCH ARTICLE

Drain Use in Bilateral Carpal Tunnel Release: A Randomized Clinical Trial on Efficacy and Patient Satisfaction

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Abstract

Objectives: This study aimed to evaluate the efficacy of drain use and its impact on clinical outcomes and patient satisfaction in bilateral carpal tunnel release (CTR).

Methods: In a randomized clinical trial conducted in 2022, 41 patients (82 hands) with moderate to severe bilateral carpal tunnel syndrome (CTS) underwent open carpal tunnel release (CTR). For each patient, one hand was randomly assigned to receive a Penrose drain, while the contralateral hand served as the control. The primary outcome was patient satisfaction at 16 weeks postoperatively. Secondary outcomes included pain (VAS), grip strength, wound healing, and pillar pain, which were evaluated at baseline, as well as at 3 days, 3 weeks, and 16 weeks after surgery.

Results: There were no significant differences between groups in wound healing (P=0.85), pain (P=0.48), pulp pinch strength (P=0.73), or pillar pain (P=0.28). However, palmar grip strength demonstrated a significantly greater improvement in the non-drain group compared with the drain group (P=0.028). Patient satisfaction was significantly lower in the drain group (P<0.001), and functional status (BCTQ-FSS) improved to a greater extent in the non-drain group (P<0.001).

Conclusion: The use of drains in bilateral CTR conferred no clinical benefit and was associated with reduced patient satisfaction, the primary outcome of this study, indicating that their routine application is not justified.

Level of evidence: II

Keywords: Bilateral carpal tunnel syndrome, CTR, Patient satisfaction, Penrose drain, Randomized trial

Introduction

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy, with an annual incidence of one to three cases per 1,000 individuals. Its prevalence in the general population is estimated at approximately 50 per 1,000 people.[1] CTS may occur bilaterally, and previous studies have reported bilateral involvement in 59% to 87% of cases.[2] Management strategies for CTS depend on disease severity and range from conservative approaches to surgical intervention.[3] Carpal tunnel release (CTR) is the most frequently performed hand surgery[4,5] and is considered the current gold standard for treating CTS.[6] The primary surgical goal is not only to alleviate symptoms but also to minimize postoperative complications and pain while facilitating a faster recovery of hand function.[7]

Hematoma formation after CTR can complicate the procedure and increase postoperative pain.[8,9] The use of drains, by reducing hematoma, has been suggested to decrease postoperative pain and pillar pain.[10] In orthopedic practice, drains are commonly employed to prevent hematoma and seroma formation, thereby aiming to reduce the risk of infection and other wound-related complications

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such as flap necrosis, compartment syndrome, and nerve compression.[11] Drains have been used in various orthopedic procedures, including total joint replacement,[12] Spinal surgeries and the management of open fractures.[13] However, the role of surgical drains and their effectiveness in reducing wound complications remains a matter of controversy.[14] In CTR specifically, their use is less common, and the evidence supporting their efficacy is limited.[10]

Given the importance of the above considerations and the lack of coherent research directly comparing the therapeutic effects of drain use versus non-use in the surgical management of bilateral carpal tunnel syndrome, this study was designed to evaluate the impact of drain placement in this setting.

Materials and Methods

Study design

This randomized clinical trial was conducted in 2022 at Shahid Sadoughi Hospital, Yazd. The study protocol was approved by the Research Ethics Committee of Shahid Sadoughi University of Medical Sciences (code: IR.SSU.MEDICINE.REC.1402.10) and registered in the Iranian Clinical Trials Registration Center (IRCT20230407057839N1). Before surgery, the hand assigned to receive a drain was determined randomly using the website www.random.org. Patients were informed before surgery that a drain would be placed in one of their hands. A Penrose drain was used.

Selection of patients

After the study objectives and necessary explanations were presented, written informed consent was obtained from all participants. Patients with moderate-to-severe bilateral CTS were eligible if the diagnosis was confirmed through history (e.g., nocturnal numbness), clinical examination (e.g., Tinel's sign), and electrodiagnostic criteria (nerve conduction velocity <40 m/s). Inclusion required failure of non-surgical treatment for at least six months and candidacy for bilateral surgery as determined by a fellowship-trained hand surgeon. Exclusion criteria were age <20 years, inability to comply with follow-up, presence of conditions causing upper limb disability (e.g., rheumatoid arthritis), unwillingness to participate, or prior history of carpal tunnel surgery.

Surgical procedure

Open CTR was performed under general anesthesia by a fellowship-trained hand surgeon. A 3-cm palmar incision was made, and the median nerve was released. A tourniquet was applied (inflated to 250 mmHg) and deflated immediately after decompression. In the drain group, a Penrose drain was inserted and removed after three days in accordance with standard orthopedic protocols to minimize the risk of infection.[14] The skin was closed with 4-0 nylon sutures, and the dressing was maintained for three days.

Evaluations

Baseline assessments included pain using the visual analogue scale (VAS), pulp pinch strength, palmar grip strength, and the Boston Carpal Tunnel Questionnaire (BCTQ) for each hand. On postoperative day 3, wound healing and pain were evaluated by the orthopedic surgeon using the Southampton score for surgical site infections and the VAS. At the 3-week follow-up, VAS, pulp pinch strength, palmar grip strength, pillar pain, and the BCTQ were assessed for both hands. At the 16-week follow-up, in addition to these measures, patient satisfaction was also evaluated. The primary outcome of this study was patient satisfaction.

The visual analogue scale was scored by patients from zero to ten.

Pillar pain was assessed using the table test. In this test, the patient places both hands on the edge of a table and bears weight through the hands while keeping the elbows extended. Discomfort or pain in the thenar or hypothenar region was then evaluated.[15] The test was considered positive if the patient reported discomfort or pain in the thenar or hypothenar eminences while bearing weight in this position.

Statistical analysis

The Boston questionnaire consists of two scales. The Symptom Severity Scale (SSS) consists of 11 questions and assesses the severity, frequency, timing, and type of symptoms. The Functional Status Scale (FSS) also includes eight questions that evaluate how this syndrome affects daily life.[16]

Data were analyzed using SPSS software (version 26; IBM Corp., Armonk, NY, USA). The required sample size of 70 hands (35 per group) was calculated using G*Power software, based on detecting a moderate effect size (0.5) in patient satisfaction (primary outcome), with a power of 80% and a significance level of $\alpha = 0.05$. This sample size was considered adequate for patient-centered outcomes. Quantitative variables were analyzed using paired-sample and independent-sample t-tests, and P values were reported accordingly.

Results

A total of 41 patients (82 hands) were included in the final statistical analysis, with 41 hands assigned to the drain group and 41 hands to the non-drain group. The demographic characteristics of the patients are presented in [Table 1].

On postoperative day 3, wound assessment revealed normal healing in 10 hands, erythema with signs of inflammation in 23 hands, and clear or bloody discharge in 8 hands in the drain group. In the non-drain group, normal healing was observed in 8 hands, erythema with signs of inflammation in 25 hands, and clear or bloody discharge in 8 hands. No statistically significant difference was found between the two groups (P = 0.85).

The mean VAS score in the drain group decreased from 7.29 ± 1.45 at baseline to 3.34 ± 1.54 at 16 weeks postoperatively. In the non-drain group, the mean VAS score decreased from 7.32 ± 1.75 to 3.02 ± 1.58 over the same period. Within-group analysis revealed a significant reduction in pain from baseline to 16 weeks in both groups (P < 0.001 for each). However, no significant difference was found between the two groups (P=0.48).

Table 1. The results of demographic indicators in patients with bilateral CTR				
Variable	**Mean**	**SD**	**Min**	**Max**
Age (year)	50.21	10.4	29	70
Variable		**Frequency**		**Percentage**
Sex	Male	4		9.8
	Female	37		90.2
	Total	41		100

Pillar pain was assessed at weeks 3 and 16, with no significant difference in its resolution between the drain and non-drain groups [Table 2].

The mean pulp pinch strength in the drain group increased from 11.80 ± 3.85 kg at baseline to 13.80 ± 5.40 kg at 16 weeks postoperatively. In the non-drain group, the mean pulp pinch strength increased from 11.43 ± 3.62 kg to 13.83 ± 5.60 kg over the same period. Within-group analysis demonstrated significant improvements in both groups from baseline to 16 weeks. However, no significant differences were observed between groups at any time point [Table 3].

Table 2. The results of comparing Pillar Pain after CTR in the studied patients				
Pillar pain	**Drain**		**Without Drain**	
	Frequency	**Percentage**	**Frequency**	**Percentage**
3rd week after surgery	21	46.7	24	53.3
16th week after surgery	21	55.3	17	44.7
P-value		***0.287***		

Table 3. Comparison results of Pulp Pinch (kg), Palmar Grip (kg), SSS, and FSS in the studied patients						
		Drain		**Without Drain**		**P-Value**
		Mean	**SD**	**Mean**	**SD**	
Pulp Pinch (kg)	*Before surgery*	11.8	3.85	11.43	3.62	0.957
	Three weeks after surgery	11.37	4.28	11.65	4.77	0.570
	16 weeks after surgery	13.80	5.40	13.83	5.60	0.734
	The difference between before and after surgery	2	3.68	2.4	4.02	0.383
	P-Value		***0.0001***		***0.0001***	
Palmar Grip (kg)	*Before surgery*	14.10	5.74	15.12	5.49	0.738
	Three weeks after surgery	14.66	5.91	14.59	5.55	0.930
	16 weeks after surgery	16.74	7	16.82	7.43	0.672
	The difference between before and after surgery	2.64	4.42	1.69	5.91	0.028
	P-Value		***0.0001***		***0.0001***	
SSS	*Before surgery*	44.32	2.46	43.23	2.46	0.536
	Three weeks after surgery	29.54	2.13	30.18	2.83	0.135
	16 weeks after surgery	25.37	1.97	21.33	2.56	0.058
	The difference between before and after surgery	18.95	3.47	21.90	3.32	0.860
	P-Value		***0.0001***		***0.0001***	
FSS	*Before surgery*	23.05	2.67	25.63	2.27	0.060
	Three weeks after surgery	20.66	1.67	24.10	2.34	0.051
	16 weeks after surgery	19.32	2.82	17.27	2.02	0.056
	The difference between before and after surgery	3.73	3.45	8.35	2.86	0.0001
	P-Value		***0.0001***		***0.0001***	

The mean palmar grip strength in the drain group increased from 14.10 ± 5.74 kg at baseline to 16.74 ± 7.00 kg at 16 weeks postoperatively. In the non-drain group, it increased from 15.12 ± 5.49 kg to 16.82 ± 7.43 kg over the same period. Within-group analysis demonstrated significant improvements in both groups from baseline to 16 weeks (P<0.001 for each). Notably, the magnitude of improvement was significantly greater in the non-drain group compared with the drain group (P = 0.028) [Table 3].

The mean Symptom Severity Scale (SSS) and Functional Status Scale (FSS) scores for both groups are presented in [Table 3]. In both groups, symptom severity decreased significantly, and functional status improved significantly over time. However, only the improvement in FSS scores differed significantly between groups, favoring the non-drain group (P<0.001).

As shown in [Table 4], patient satisfaction was significantly lower in the drain group compared with the non-drain group (P<0.001).

Table 4. Comparison of the results of patients' satisfaction with CTR

Satisfaction	Drain		Without Drain	
	Frequency	Percentage	Frequency	Percentage
Poor	4	9.8	2	4.9
Average	4	9.8	13	31.7
Good	27	65.9	10	24.4
Excellent	6	14.6	16	39.0
Total	41	100	41	100
P-value		***0.0001***		

Discussion

In this study, the dominant hand was the right hand in 90.2% of patients and the left hand in 9.8%. The drain was placed in the right hand in 58.5% of patients and in the left hand in 41.5%. Although drain placement was more frequently randomized to the dominant hand, patients may have unconsciously evaluated their overall performance and satisfaction primarily in relation to the dominant hand, potentially influencing the results. The hypothesis that drain placement in the dominant hand might affect satisfaction and functional outcomes could not be tested, as detailed subgroup data distinguishing satisfaction scores by dominant versus non-dominant hand were not available. This represents a limitation of the present study.

The reduced satisfaction in the drain group may be attributed to discomfort caused by the presence of the drain, pain during its removal, and the associated inflammatory reaction. In contrast, no significant differences were observed between the two groups in wound healing, pulp pinch strength, or pillar pain during the four-month follow-up period.

The significant difference in palmar grip strength improvement, favoring the non-drain group (P=0.028), was unexpected. This finding may be explained by reduced local inflammation or discomfort in the non-drain group, potentially facilitating earlier mobilization. Alternatively, it could represent a Type I error due to multiple comparisons. Nevertheless, the clinical significance of the relatively small difference in grip strength (1.69 kg vs. 2.64 kg) remains uncertain and warrants confirmation in larger studies.

The objective variables assessed by the physician did not differ significantly between the two groups. However, patient-reported (subjective) outcomes, such as satisfaction and FSS, were significantly different, which may reflect psychological or physical effects related to the presence of the drain.

The 3-month evaluation reported by Saeed et al. (2024) demonstrated pain improvement in both groups, with and without Penrose drain insertion, whereas pulp pinch strength improved only in the drain group.[17] In contrast, in the present study, pinch strength improved in both groups, with no statistically significant difference between them. Furthermore, unlike Saeed et al., our study specifically evaluated patients with bilateral CTS, allowing for direct comparison between the two hands of each patient.

It is important to note that infection and tissue reactions are potential complications associated with drains, particularly with prolonged use. In our study, however, no complications related to the Penrose drain were observed, which mitigates concerns about its safety profile.

The absence of hematoma in our cohort is consistent with its reported rarity, suggesting that drains do not address a frequent clinical problem in CTR. Instead, our findings underscore patient satisfaction as a key outcome, with the use of drains being associated with significantly lower satisfaction rates (P < 0.001). These results indicate that even in bilateral CTR, where the perceived risk of complications might be higher, routine drain placement is not justified and may adversely affect the patient experience.

This study has certain limitations. Blinding of the examiner and patients, which is an essential aspect of trials of this type, was not feasible because the presence or absence of a drain was visible. Future studies with more extended follow-up periods and larger sample sizes are recommended to validate these findings. A key strength of this study was the inclusion of patients with bilateral CTS, which allowed direct

comparison between the two hands of the same patient, thereby minimizing interindividual variability.

Conclusion

According to the findings of this study, drain placement in bilateral CTR provides no clinical benefit in terms of wound healing, pain, pulp pinch strength, or pillar pain. However, it was associated with reduced patient satisfaction, poorer functional recovery (BCTQ-FSS), and less improvement in palmar grip strength, suggesting that its routine use is not warranted.

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