Prospective Study

Effect of Ultrasound-Guided Partial Release of the Transverse Carpal Ligament with a Needle in Patients with Refractory Carpal Tunnel Syndrome

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Background: Neuropathic pain in the hands due to carpal tunnel syndrome (CTS) disturbs sleep and affects the quality of life.

Objectives: We evaluated the effect of ultrasound (US)-guided partial release of the transverse carpal ligament (TCL) using an 18-G needle in patients with refractory CTS.

Study Design: A prospective outcome study.

Setting: The outpatient clinic of a single academic medical center.

Methods: This study was prospectively conducted. A total of 155 consecutive patients (191 wrists) with refractory chronic CTS (M:F = 28:127; age = 54.7 ± 9.6 years; pain duration = 50.3 ± 36.3 weeks) were enrolled and underwent US-guided partial release of the TCL using a needle. The pain severity was measured using the Numeric Rating Scale (NRS) at 3 and 6 months after the treatment. Successful treatment outcomes were defined as more than 50% reduction in the NRS score at 6 months after the treatment compared with the score at pre-treatment and NRS score < 3 at 6 months after the treatment without any surgical intervention.

Results: There were 3 dropouts, and 188 wrists were included in the study. No side effects were reported. A total of 162 wrists (86.2%) showed successful treatment outcomes at 6 months after TCL release. Of the 26 wrists which had unsuccessful treatment outcomes, 6 received surgical treatment. The NRS scores at 3- and 6-month post-treatment were significantly reduced: the average NRS scores were 7.1 ± 0.6 at baseline, 1.9 ± 1.7 at 3 months after the treatment, and 1.7 ± 1.7 at 6 months after the treatment.

Limitations: We conducted our study without a control or a placebo group.

Conclusion: We believe that US-guided partial release of the TCL using a needle can be an effective and safe technique for treating chronic refractory pain due to CTS. It can potentially be attempted before surgical treatment.

Key words: Ultrasound, release, carpal tunnel syndrome, needle, chronic pain, transverse carpal ligament

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Carpal tunnel syndrome (CTS) is one of the most common peripheral entrapment neuropathies (1). It is caused by compression of the median nerve by the transverse carpal ligament (TCL), which results in neuropathic pain, numbness, tingling, and weakness of the hands (2). In particular, neuropathic pain in the hands due to CTS disturbs sleep and affects the quality of life (3). For the management of this pain, conservative treatment is initially attempted before surgical interventions. Conservative treatment includes administration of oral medications, exercise, acupuncture, steroid injections, and pulsed

radiofrequency therapy (4-6). However, these conservative treatments are effective mainly during the early stages of CTS (7).

If neuropathic pain caused by CTS is refractory to these conservative treatments, surgical interventions, such as open carpal tunnel release, are considered. The goal of surgery is to divide the flexor retinaculum to decompress the median nerve at the wrist level (8). However, surgical treatment can result in various adverse effects, such as nerve injury, hypertrophic scarring, dysesthesia, reduced grip power, neuroma, and joint stiffness (9). To minimize these complications, minimally invasive carpal tunnel release procedures using endoscopy or under the guidance of ultrasound (US) were developed (10,11). However, the endoscopic procedure has a limitation in that the field of view to directly visualize the median nerve is relatively small. Moreover, the previously developed US-guided techniques use a knife with or without a hook to release the TCL, which might cause damage to the nerve, vessels, or tendon (12-14). Additionally, a skin incision is needed for inserting the knife.

For a less invasive procedure for carpal tunnel release, we conducted the partial release of TCL using a needle under the guidance of US in a patient with refractory CTS and evaluated its effectiveness and safety.

Methods

Patients

A prospective study was performed at a single pain clinic. A total of 155 consecutive patients with CTS (M:F = 28:127; age = 54.7 ± 9.6 years; pain duration = 50.3 ± 36.3 weeks) were recruited and underwent partial release of the TCL using an 18-G needle under the guidance of US from January 2011 to December 2020. Thirty-six patients had a bilateral manifestation of CTS. Therefore, 191 wrists were treated in total. The inclusion criteria were as follows: 1) Diagnosed with CTS according to the following criteria: ① paresthesia or dysesthesia with a weak and clumsy hand, which is exacerbated by repeated wrist use or falling asleep and relieved after postural adjustment or hand shaking; ② numbness due to sensory impairment in the median nerve innervated territory; ③ thenar muscle weakness and/or atrophy; and ④ positive Phalen's test ± Tinel's sign. CTS was diagnosed if patients fulfilled criteria ① and at least one of the remaining criteria (15-17); 2) ≥ 3-month history of neuropathic pain in the affected hand due to CTS; 3) unsatisfactory response to US-guided steroid injection near the median nerve in the affected wrist and oral pain medications (non-steroidal anti-inflammatory drug and/or tramadol hydrochloride/acetaminophen); and 4) pain score of at least 4 on the Numeric Rating Scale (NRS, which has a range of 0-10, with 0 indicating no pain and 10 indicating the worst imaginable pain) for the affected hand. We excluded patients with a history of wrist surgery, carpal fracture, or foreign bodies such as tumors and cysts in the wrist. The institutional review board of Yeungnam University Hospital approved the study, and all patients signed an informed consent form.

Procedures

All procedures were performed by the same clinician (SHL) (Fig. 1). Each patient was placed in a supine position on a bed with the shoulder mildly abducted and the elbow fully extended. The patient's hand was positioned palm-up, and the wrist was supported on the back with a towel to extend it. Initially, US-guided hydrodissection was performed between the TCL and median nerve using a mixed solution with 1 mL of 2% mepivacaine, 2 mL of 50% dextrose, 1 mL of normal saline, and 1 mL of dexamethasone palmitate. To release the TCL, an 18-G needle was used and using a needleholder, the needle tip was bent in the opposite direction to the needle bevel. The 18-G needle was connected to an empty 5 mL Luer lock syringe. With a transverse scan through the carpal tunnel, the key anatomic structures, including the superficial palmar branch of the radial artery, ulnar artery, and palmar cutaneous branch of the median nerve, were visualized. For TCL release, the needle along with the US probe (12 MHz linear probe, Venue 40 unit: GE Healthcare, Milwaukee, WI) was used to transverse-obliquely approach the hamate and pisiform bones from the radial side of the wrist. Local anesthesia was applied to the superficial area of the TCL and subcutaneous tissues, and the 18-G needle was advanced under US guidance using the in-plane technique. Thereafter, digging, lifting, swinging, turning, and rotating were performed to tear the superficial layer of TCL and release it. The TCL was considered to be adequately released when the needle passed easily through the ligament. The procedure was conducted once for each patient.

Outcome Assessments

All outcome assessments were performed by a single investigator. Pain intensity was measured using the NRS. The average monthly pain intensity for

each patient was assessed before the treatment and 3 and 6 months after the TCL release. Successful treatment outcomes were defined as 1) > 50% pain reduction in pain intensity from baseline value at 6 months after the treatment, 2) NRS score < 3 at 6-months post-treatment, and 3) surgical treatment was not required.

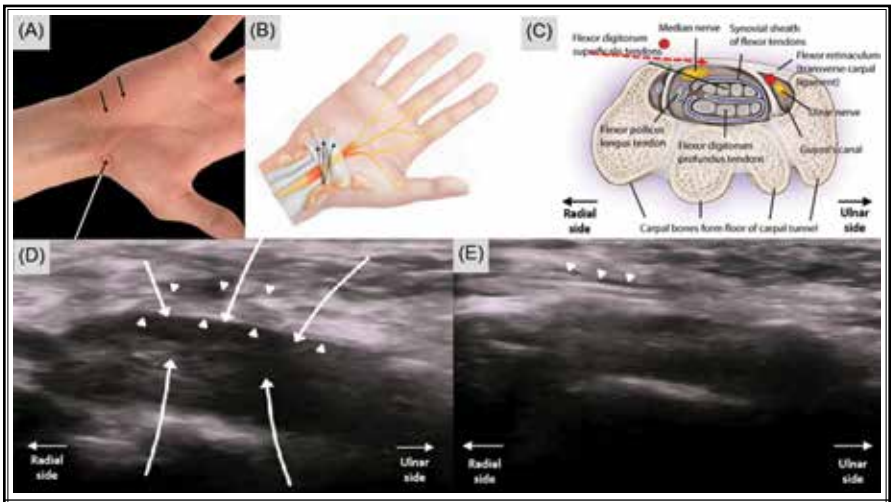

Fig. 1. *Ultrasound (US)-guided partial release of the transverse carpal ligament (TCL) with an 18-G needle*
(A) The needle entry point and direction: The hook of the hamate and the pisiform are approached transverse-obliquely with the needle from the radial side of the wrist (the arrow on the radial side: needle entry point; 2 arrows on the ulnar side: the hook of the hamate and the pisiform). (B) The direction (arrows) of needle insertion for TCL release is shown. (C) An illustrated image of needle insertion is depicted. The needle is inserted under the superficial palmar branch of the radial artery (red circle on the radial side: superficial palmar branch of the radial artery; red circle on the ulnar side: ulnar artery; arrow: the direction of needle insertion). (D) Transverse US scan through the carpal tunnel (arrows: median nerve; arrowheads: TCL) is shown. (E) Needle release of the superficial layer of TCL with digging, lifting, swinging, turning, and rotating is performed (arrowheads: needle)

Statistical Analysis

Data were analyzed using SPSS software, version 24.0 (IBM Corporation, Armonk, NY). The changes in NRS scores were evaluated using a repeated measure one-factor analysis. When a patient received surgical treatment, we placed the NRS score after surgical treatment into the pre-treatment NRS score. Multiple comparisons were obtained following a contrast using the Bonferroni correction. The level of statistical significance was set at $P < 0.05$.

Results

There were 3 dropouts in our study. No adverse effects, such as hematoma, injection, nerve injury, or tendon rupture were observed after TCL release. The reasons for dropouts were unknown as the patients did not visit our clinic and could not be contacted. All 3 patients had unilateral CTS. Therefore, 188 wrists were included in the final analysis. A total of 162 wrists (86.2%) showed successful treatment outcomes at 6 months after TCL release. Of the 26 wrists where treatment was not successful, 6 underwent surgical treatment.

The average NRS scores were 7.1 ± 0.6 at baseline, 1.9 ± 1.7 at 3 months after TCL release, and 1.7 ± 1.7 at 6 months after TCL release. The NRS scores were significantly decreased at 3 and 6 months after the treatment when compared with the pre-treatment scores ($P < 0.001$).

Discussion

In this study, we evaluated the effectiveness of partial release of the TCL using a needle under the guidance of US in patients with chronic pain due to CTS, which was refractory to US-guided steroid injection near the median nerve and oral pain medication. In total, 86% of patients showed successful outcomes after the TCL release procedure (> 50% reduction in pain intensity from baseline value and NRS score < 3 at 6-months post-treatment).

Generally, conservative treatment is performed before surgical treatment for pain due to the invasiveness and expensiveness of the latter (2,3). Likewise, for the treatment of CTS, conservative treatment is initially attempted. Steroid injection near the median nerve is one of the most commonly used conservative treatment methods; however, its effectiveness was reported to be sustained only for a short term (< 1 month) in many systematic reviews and clinical trials (18-20). This indicates that reduction of chemical inflammation around the median nerve is not sufficient for a good therapeutic outcome for CTS. Therefore, mechanical decompression of the compressed median nerve by TCL release is essential for the effective treatment of CTS. Several types of thin hook knives have been cre-

ated and used for minimally invasive surgical release of the TCL, and these procedures are performed under US guidance to protect the critical surrounding structures (12-14). However, it is technically demanding, and a clinician needs substantial training to safely apply it. In this study, we attempted to release TCL using a needle. Even if the surrounding structures are punctured by a needle, this would be less injurious than that with a hooked knife. Therefore, the release of the TCL with a needle can be easily and safely applied to patients with CTS.

We released only the superficial layer of the TCL as it reduces the risk of injury to the median nerve and tendons underlying the TCL. Furthermore, while attempting to release the whole depth of the TCL, one should be careful to completely cut the deep layer as an incomplete trim causes the remaining ligament to remain tethered to the median nerve, worsening the symptoms of CTS. As observed in our results, although the TCL was released only superficially, it appears to be sufficient to decompress the pressure exerted on the median nerve in patients with CTS. Additionally, before we released the TCL with an 18-G needle, US-guided hydrodissection was conducted between the TCL and median nerve using a solution containing anesthetics and steroids, which allowed us to distinguish the boundary between the median nerve and TCL, making the procedure safe. In addition, Guo et al (21) reported that needle release of the TCL using steroid injections near the median nerve showed better treatment outcomes than those of release of the TCL without injecting steroids.

The average duration between pain onset and needle release was 50 weeks, and all the included patients had chronic pain. Considering these facts, our patients' pain would have reached a plateau state before the procedure. Therefore, the reduction in pain following needle release was not due to natural recovery. Thus, even though we did not compare the effect of our procedure with those of a control or sham procedure, our results provide sufficient evidence of the usefulness of needle partial release of the TCL in patients with refractory CTS.

To date, only one study (Guo et al) has been reported on the effectiveness of needle release of the TCL in patients with CTS. That study recruited 49 patients with CTS (50 wrists) (18). Twenty-five wrists were treated with US-guided 22-G needle release and steroid injections near the median nerve, and 25 wrists with only US-guided needle release of the TCL without steroid injections. They found that the effectiveness of TCL release and steroid injection was excellent or good in 84% of wrists and was better than those of TCL release without steroid injection. Guo et al's study differed from our study in that they released the whole depth of the TCL. Our study showed that even a partial release of the TCL has a sufficient therapeutic effect on CTS.

In clinical practice, surgical treatment is usually considered when conservative treatment fails to control CTS symptoms. Regarding surgical treatment, conventional open, mini-incision, or endoscopic carpal tunnel releases can be applied. Conventional open carpal tunnel release allows direct vision of the ligament and surrounding vital anatomic structures. However, complications related to the incision such as pillar pain, scar tenderness, complex regional pain syndrome, and cosmetic concerns occur frequently (22). Mini-incision carpal tunnel release results in less postoperative pain and a smaller length of scar compared with conventional open carpal tunnel release (23). However, it has the disadvantages of a smaller viewing area and less exposure for examination during the procedure, injury to the median and ulnar nerves, flexor tendon injury, and difficulty in bleeding control. To avoid the disadvantages of conventional open and mini-incision carpal tunnel releases, the endoscopic carpal tunnel release technique was introduced. It reduces incisional discomfort after surgery but requires expensive apparatus, a steep learning curve, and has a higher risk of neurovascular injury (22). Although all these surgical treatment methods result in significant pain reduction and have a high success rate, each surgical method can develop various complications. In contrast, after US-guided partial release of the TCL, there was a high treatment success rate with no significant adverse effects.

Conclusions

In conclusion, we found that partial release of the TCL using an 18-G needle under the guidance of US significantly reduced neuropathic pain at 3 and 6 months after the procedure in patients with CTS refractory to steroid injections and oral pain medications. The rate of successful outcomes at 6 months after the procedure was 86%. After injecting steroids near the median nerve, clinicians often consider surgical treatment as the next intervention. Based on our results, we think that US-guided partial needle release of the TCL is a beneficial treatment option, which can be safely applied before resorting

to surgery. Our study had some limitations. First, we conducted our study without a control or a placebo group. However, in clinical practice, if steroid injection fails to control neuropathic pain due to CTS, clinicians have limited options to control the pain conservatively. Thus, it was challenging to choose an appropriate procedure for the control group, and the recruitment of a sham or placebo group is complicated because of ethical issues. Second, the outcome was not evaluated according to the CTS severity. Third, the electro-diagnostic evidence of CTS at pre- and post-treatment was not evaluated. Fourth, we did not present the physical examination findings. Lastly, long-term follow-up was not conducted. Further studies compensating these limitations are warranted in the future.

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