Randomized Clinical Trial

A Randomized Double-blind Trial of 5% Dextrose Versus Corticosteroid Hydrodissection for Meralgia Paresthetica

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Background: Ultrasound-guided 5% dextrose (D5W) hydrodissection provides favorable outcomes for treating peripheral entrapment neuropathies; its safety is well recognized. However, clinical evidence regarding the use of D5W hydrodissection for meralgia paresthetica (MP) is limited. Although corticosteroids are the most common injectates, the possible adverse effects are a big concern.

Objective: To compare the efficacy and safety of ultrasound-guided D5W hydrodissection compared to corticosteroid hydrodissection in patients with MP during a 6-month follow-up period.

Study Design: A prospective, randomized double-blind, controlled trial.

Setting: Outpatient clinic at a university hospital.

Methods: A total of 56 patients with MP were randomly allocated to either a D5W or steroid group in a 1:1 ratio. The patients received one session of ultrasound-guided perineural injection therapy of 10 mL D5W or a corticosteroid solution (1 mL compound betamethasone [1 mL: betamethasone sodium phosphate 5 mg and betamethasone dipropionate 2 mg] mixed with 5 mL 2% lidocaine and 4 mL 0.9% saline).

The primary outcomes were Visual Analog Scale (VAS) scores for MP (pain and paresthesia) and global quality of life. The secondary outcomes included self-reported successful clinical response and injection adverse effects. Evaluations were conducted at pretreatment and at one, 3, 4 and 6 months posttreatment.

Results: All patients completed the study. Compared with baseline, both groups exhibited reductions in VAS scores for MP and global quality of life at all follow-up time points, with statistical differences at 3, 4, and 6 months in the D5W group ($P < 0.05$), as well as those at one, 3, and 4 months in the steroid group ($P < 0.05$). The D5W group exhibited greater improvement than the steroid group in VAS scores for MP and global quality of life at 4 and 6 months ($P < 0.05$), and demostrated a more successful clinical response at 6 months ($P < 0.05$). No adverse effects were reported in the D5W group during the study period, while 6 patients in the steroid group reported an adverse effect.

Limitations: A longer follow-up period is necessary; the exact mechanism of D5W is not clear.

Conclusions: Ultrasound-guided perineural injection therapy of D5W is more beneficial than corticosteroid injection for MP at 4 to 6 months posttreatment. Additionally, D5W displays a better safety profile than corticosteroid. Thus, we suggest D5W as a more suitable injectate for patients with MP.

Key words: Meralgia paresthetica, 5% dextrose, lateral femoral cutaneous nerve, hydrodissection, corticosteroid, ultrasound, efficacy, adverse effects

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Meralgia paresthetica (MP) is one of the most common entrapment neuropathies affecting the lower limbs. It is characterized by paresthesia, pain, numbness, and hypersensitivity in the anterolateral aspect of the thigh (1,2). MP is caused by the compression of the lateral femoral cutaneous nerve (LFCN) along its course, most commonly as it exits the pelvis (3,4). Diagnosing MP is usually based on the patient's clinical history and a physical examination, with electrophysiological studies offering limited significance (5). Ultrasound has been proposed as a noteworthy diagnostic method (6), as it not only helps confirm the compression morphologically with specific sonographic characteristics, but also guides a precise injection at the compression site for diagnostic and therapeutic purposes (7).

There is no consensus on the superiority of any treatment. Therefore, a stepwise increase in treatment intensity, from conservative treatment to perineural injection therapy (PIT) and surgical intervention, is advocated (8,9). Surgical intervention provides favorable outcomes, but it has some drawbacks, such as surgical pain, disorders of wound healing, wound infections, scar formation, loss of sensation, and a long recovery time (10,11). Given the anatomical variations and superficial course of the LFCN, PIT under ultrasound guidance is recommended for patients with MP who are nonresponsive to conservative treatment (12-14).

In recent decades, corticosteroids have been the most commonly used injectates for treating MP (15-18). However, the efficacy of corticosteroid injection for peripheral entrapment neuropathies has been reported to be unsustainable (19). Additionally, corticosteroids are associated with several adverse effects, including skin thinning, soft tissue atrophy, vasomotor symptoms, gastrointestinal reactions, menstrual irregularities, edema, and hyperglycemia (20,21).

Recently, ultrasound-guided 5% dextrose (D5W) hydrodissection (HD) has been proposed as a treatment for peripheral entrapment neuropathies in some high-quality clinical trials (22-24). Moreover, D5W has similar osmolarity as normal saline and is considered harmless to peripheral nerves (25). D5W HD may be an effective treatment for MP (26); however, its use for MP has only been reported in a case report with limited clinical significance.

Despite the frequent use of corticosteroids and D5W for peripheral entrapment neuropathies, there are few studies clarifying the comparative efficacy of these 2 injectates for MP. In our clinical practice, D5W has longer therapeutic effectiveness and a more favorable safety profile than corticosteroids. Therefore, this study aimed to compare the 6-month efficacy and adverse effects of D5W and corticosteroid PIT under ultrasound guidance for treating MP.

Methods

Study Design

This prospective, double-blind, randomized controlled study was conducted at an outpatient clinic of the Department of Ultrasound at a university hospital. It has the approval of the local ethics review board (2024PHB019-001), and is officially registered at ClinicalTrials.gov (NCT06251882). All enrolled patients provided written, informed consent. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

From February 2022 through June 2023, a total of 60 consecutive patients with MP who presented at our clinic were eligible; 56 of them were enrolled in the study. They were randomized to either the D5W group or steroid group in a 1:1 ratio using computer-generated random numbers method.

If MP was bilateral, only the more affected side was recorded for analysis. The patients were administered one session of ultrasound-guided PIT of 10 mL of D5W or a corticosteroid solution (one mL compound betamethasone [1 mL: betamethasone sodium phosphate 5 mg and betamethasone dipropionate 2 mg] mixed with 5 mL 2% lidocaine and 4 mL 0.9% saline).

All included patients were 18-80 years old. They had at least 3 months of typical clinical symptoms of MP. MP was clinically diagnosed by 2 neurologists: one had 15 years of experience and the other and 11 years of experience. All patients underwent high-resolution ultrasound to confirm that the LFCN was compressed as it exited the pelvis (7) and that there was no evidence of other specific musculoskeletal system diseases (e.g., thigh muscle atrophy, symptoms radiating from the spine, reflex deficits, or paresis). In addition, all patients were refractory to conservative treatment for MP.

Exclusion criteria were: MP secondary to trauma, surgery, or occupying lesions of the LFCN; pregnancy; concurrent rheumatic immune diseases, hypothyroidism, or diabetes mellitus; a known history of lidocaine

or corticosteroids allergies; L2-L3 radiculopathy; or a history of local injection or surgery for MP.

Ultrasound-guided Evaluation and Treatment

Ultrasound evaluations were performed by a senior radiologist with 20 years of experience in musculoskeletal ultrasound using the Aplio i800 ultrasound unit (Canon Medical Systems, Corporation) with an 18 MHz linear array transducer.

LFCN-specific ultrasound was performed as previously described (27). Each patient was placed supine on the table. The intermuscular space between the sartorius and the tensor fasciae latae was used as an initial sonographic landmark. Multiple sweeps were conducted proximally and distally to confirm the course of the nerve in the transverse plane. The nerve's longitudinal axis was also assessed for confirmation. Then, the transducer was moved toward the painful iliac region where the nerve exits the pelvis. Abnormal sonographic characteristics of the LFCN were identified, including an enlarged cross-section of the LFCN, intraneural vascularity, an abrupt caliber change, and indistinct perineurium (7).

The treatment procedures were performed by the same radiologist, who was independent from the patient allocation. The patients were positioned consistently, with their hips appropriately externally rotated to better expose the compressed nerve. The transducer was placed in the transverse plane over the compression site of the LFCN. The clinician then systematically moved the transducer medially or laterally for easier needle access.

Under rigorous sterile conditions, a 22G needle on a 10 mL syringe was introduced from the lateral side via an in-plane approach to target the LFCN at the compression site. The clinician used a one-person technique, with one hand holding the syringe and the other hand the transducer. During the insertion, the needle tip was continuously visualized. When the needle tip was adjacent to the nerve, approximately 3 mL of 1% lidocaine was injected to achieve perineural spread. Once local anesthesia was achieved, HD was performed at the superior (5 mL) and inferior (5 mL) area of the LFCN using a total of 10 mL D5W or corticosteroid solution via the same approach (Fig. 1).

Any other therapy (oral medication, physical therapy, acupuncture, etc.) was prohibited during the study period. A research assistant regularly followed up with the study patients to find out whether any other therapy was received.

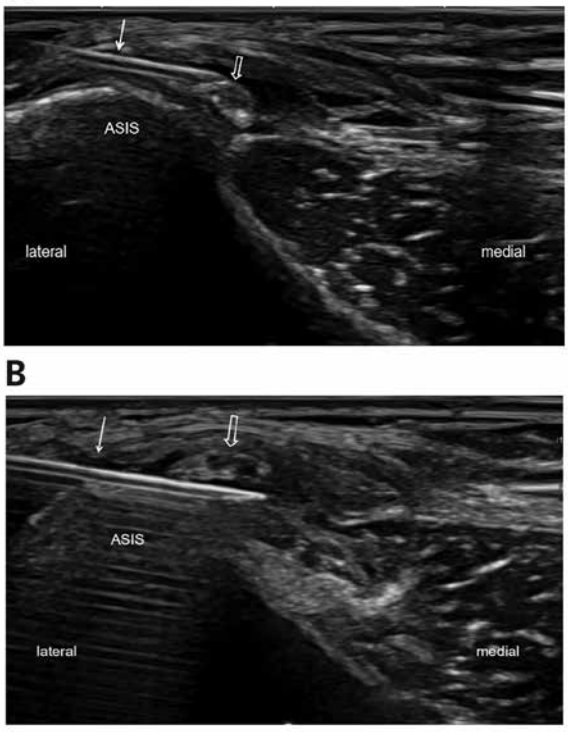

Fig. 1. *A) Ultrasound-guided injection at the inferior area of the nerve. B) Ultrasound-guided injection at the superior area of the nerve.*
ASIS, anterior superior iliac spine; arrow: needle; empty arrow: lateral femoral cutaneous nerve.

Outcome Measurements

An independent investigator conducted all outcome measurements at baseline and one, 3, 4, and 6 months posttreatment.

Primary Outcomes

Visual Analog Scale

The intensity of MP symptoms (pain and paresthesia) was evaluated using a 10-point Visual Analog Scale (VAS), with scores ranging from 0 (no symptoms) to 10 (intolerable symptoms). Higher scores indicated more severe symptoms (18).

VAS Scores for Global Quality of Life

The influence of MP on patient global quality of life was evaluated on a 10-point VAS, with scores ranging from 0 (no influence) to 10 (intolerable influence). Higher scores indicated more severe influence (18).

Secondary Outcomes

Successful Clinical Response

The overall improvement in each patient's condition was assessed based on the patient's subjective impression of the therapeutic effect regarding symptom relief (excellent > 70%; good 50%-70%; fair 30%-49%; no change < 30%; and worsened when symptoms became worse post-PIT). Excellent or good symptom relief was categorized as a successful clinical response (22).

Adverse Effects

The possible adverse effects of injections were recorded, including local pain, allergies, menstrual disorders, gastrointestinal symptoms, agitation, skin thinning, soft tissue atrophy, vasomotor symptoms, edema, hyperglycemia, and other relevant manifestations (20,21).

Sample Size

The G*Power 3.1.9.2 (Heinrich Heine University) was utilized to calculate the sample size (28). A preliminary power analysis was conducted using an independent t test to compare the intergroup differences in changes in VAS scores between baseline and 6 months posttreatment. A large effect size was used due to the absence of preliminary data; the results suggest that at least 22 patients per group are required to achieve sufficient power ($[1 - \beta] = 0.80$, $\alpha = 0.05$, effect size= 0.85).

Statistical Analyses

Statistical analyses were performed by IBM SPSS Statistics 26.0 (IBM Corporation). $P < 0.05$ was considered statistically significant (2-tailed). Continuous data are presented as median (interquartile range) or mean ± SD, as appropriate. Categorical data aw presented as numbers (%). Continuous data were compared by the Mann-Whitney U test or independent t test (between groups), and the Friedman test followed by the post hoc Bonferroni test (within the group). Categorical data were compared by the χ^2 test or Fisher's exact test.

Results

All patients completed the study, as shown in the flow chart (Fig. 2). There were no statistically significant differences regarding clinical and demographic characteristics between the 2 groups at baseline (Table 1).

Compared with baseline, both groups had reductions in VAS scores for MP pain and paresthesia and global quality of life at all follow-up time points, with statistical differences at 3, 4, and 6 months in the D5W group ($P < 0.05$), and at one, 3, and 4 months in the steroid group ($P < 0.05$). The steroid group had more reductions in VAS scores for MP pain and paresthesia and global quality of life than D5W group at one and 3 months, with a statistical difference at one month ($P < 0.05$). The D5W group had more significant reductions in VAS scores than the steroid group at 4 months and 6 months ($P < 0.05$) (Table 2; Fig. 3).

A total of 46.4% (13/28) vs 64.3% (18/28), 64.3% (18/28) vs 64.3% (18/28), 78.6% (22/28) vs 53.6% (15/28), and 85.7% (24/28) vs 50.0% (14/28) of patients had a successful clinical response at one, 3, 4, and 6 months in the D5W group and the steroid group, respectively ($P = 0.282$, 1.000, 0.089, 0.004, respectively).

Six incidences of adverse effects were reported in the steroid group, including 3 incidences of vasomotor symptoms, one incidence of local pain, and 2 incidences of menstrual disorders. No patient in the D5W group experienced an injection-related adverse effect.

Discussion

This is the first prospective, double-blind, randomized controlled study comparing the efficacy of ultrasound-guided PIT of D5W or corticosteroid for treating MP. Although the steroid group exhibited larger reductions in VAS scores at the initial postinjection month, the efficacy started to decline from the first month onward. On the contrary, the efficacy of D5W continued to improve from one to 6 months, while the efficacy of the corticosteroid declined and was not statistically significant at 6 months. These findings support the short-term effect of corticosteroid injection, and the superiority of D5W compared with steroid in the midterm.

Several characteristics make D5W suitable for PIT, including that it has similar osmolality with normal saline and causes less pain than other injectates, as well as its well-recognized safety for peripheral nerves (25). Although the exact mechanism of D5W is unclear, it is speculated that D5W results in the downregulation of receptor potential vanilloid receptor-1, subsequently blocking calcitonin gene-related peptide and substance P, which contribute to neuropathic pain and inflammation (29).

HD mechanically releases the compressed nerve from adhesive connective tissue, improving nerve conduction and reversing ischemic damage (30). Recently, a new hypothesis has been proposed by Li, et al (22) who reported long-term efficacy over 1-3 years for patients

with carpal tunnel syndrome after PIT of 10 mL D5W. As such, long-term efficacy cannot be simply explained by pharmacological and mechanical effects. They hypothesized that D5W may contribute to subsequent nerve regeneration (22). Further studies are required to validate this hypothesis.

Ultrasound-guided PIT of a corticosteroid combined with an anesthetic is the most commonly used treatment for MP. Despite this treatment's widespread use, there is no consensus regarding the dosage, times, or efficacy duration in the literature. Palamar, et al (15) and Kilic, et al (16) reported that one session of a 3 mL solution resulted in significant pain relief (> 50%) at one-month follow-up. Taglifico, et al (18) reported that 2 sessions of a 3 mL resolution resulted in complete recovery of symptoms at 2-month follow-up. Klauser, et al (17) reported that an average of 2.25 sessions of a 10 mL solution resulted in complete symptom relief in 15 out of 20 patients at 12-months postinjection. A systematic review by Jawaid, et al (19) reported that the efficacy of a corticosteroid injection did not extend beyond one month compared to a control group.

The discrepancy regarding the duration of therapeutic effect in these studies may arise from differences in injectate times, methods, symptom severity, and patient selection. In our study, the significant efficacy did not extend to 6 months, and the efficacy started to deteriorate from the first month onward. Thus, our findings indicate that the clinical benefit of a single corticosteroid injection for MP was short-lived.

In our study, the patients in the steroid group experienced greater symptom relief than those in the D5W group at one month. This was probably because corticosteroid exerted its anti-inflammatory function in the initial month, which was stronger than the antineurogenic inflammation function provided by D5W. However, the pathology of MP is chronic and slow in nature; in general, it is an ischemia-reperfusion degenerative neuropathy (31). Therefore, the clinical benefit declined as the inflammation decreased in the steroid group. Although HD might still play a role after the first month, the significant effect would not be sustained.

In contrast, the beneficial effect of D5W continued to improve, reaching significant intergroup differences in symptom relief (D5W > steroid), at 4 to 6 months postinjection. This may also support the hypothesis that D5W may contribute to nerve regeneration through some unknown mechanism. Although the improvement during the first month was not that prominent in the D5W group, this was probably because one month was not enough for nerve regeneration to occur. This hypothesis can be practically confirmed after reviewing the study by Wu, et al (32) who concluded that there

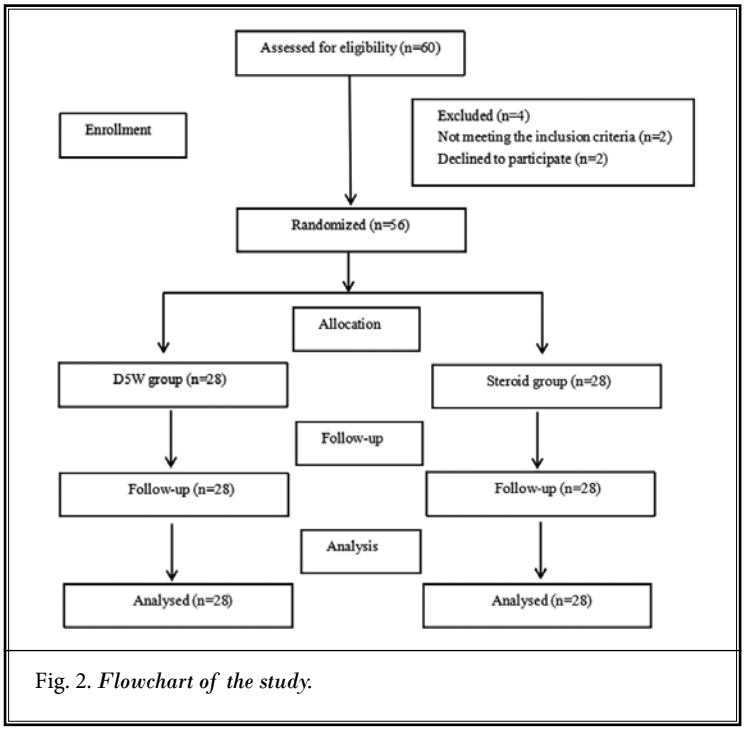

Fig. 2. *Flowchart of the study.*

Table 1. *Baseline demographic and clinical characteristics in both groups.*

Variables	D5W Group (n = 28)	Steroid Group (n = 28)	[a]*P* value
Age (years)	48.1 ± 2.6	43.0 ± 2.1	0.131
Gender (men/ women)	12/16	14/14	0.789
Body height (cm) Body weight (kg)	168.2 ± 1.0 71.4 ± 2.0	165.2 ± 1.4 70.3 ± 2.4	0.097 0.725
Duration (mos)	15.2 ± 2.5	14.9 ± 3.8	0.947
Lesion site (left/right)	16/12	13/15	0.593
VAS for MP	7.2 ± 0.2	6.9 ± 0.3	0.362
VAS for global quality of life	5.5 ± 0.4	5.2 ± 0.6	0.693

Data were presented as mean ± SD or number (%);
VAS, Visual Analog Scale;
[a]*P* obtained from independent t test, χ^2 test , or Fisher's exact test;
$P < 0.05$ is considered statistically significant.

Table 2. *Pre- and posttreatment Visual Analog Scale scores in both groups.*

	D5W Group (n = 28)	Mean Difference (95% CI)	[a]*P* Value	Steroid Group (n = 28)	Mean Difference (95% CI)	[a]*P* Value	Intergroup Difference (95% CI)	[b]*P* Value
VAS scores for meralgia paresthetica								
Baseline	7.2 ± 0.2	-	-	6.9 ± 0.3	-	-	-	0.362
Month one	4.8 ± 0.2	-2.4 (-2.6 to -2.4)	0.180	1.6 ± 0.2	-5.3 (-5.6 to -4.9)	< 0.001	3.2 (2.7 to 3.7)	< 0.001
Month 3	3.2 ± 0.2	-4.0 (-4.3 to -3.7)	< 0.001	2.7 ± 0.3	-4.2 (-4.7 to -3.7)	< 0.001	0.5 (-0.4 to 0.9)	0.140
Month 4	2.3 ± 0.2	-4.9 (-5.2 to -4.5)	< 0.001	3.5 ± 0.3	-3.3 (-3.8 to-2.8)	< 0.001	-1.2 (-1.9 to -0.5)	0.001
Month 6	1.9 ± 0.2	-5.3 (-5.6 to -5.0)	< 0.001	4.2±0.3	-2.6 (-3.1 to -2.1)	0.068	-2.4 (-3.1 to -1.6)	< 0.001
VAS scores for global quality of life								
Baseline	5.5 ± 0.4	-	-	5.2 ± 0.6	-	-	-	0.693
Month one	2.8 ± 0.2	-2.7 (-3.3 to -2.1)	0.060	1.4 ± 0.3	-3.8 (-4.5 to -3.0)	< 0.001	1.4 (0.7 to 2.1)	< 0.001
Month 3	1.9 ± 0.2	-3.5 (-4.2 to -2.8)	< 0.001	1.8 ± 0.2	-3.3 (-4.1 to -2.5)	< 0.001	0.0 (-0.6 to 0.6)	0.906
Month 4	1.2 ± 0.2	-4.3 (-5.5 to -4.0)	< 0.001	2.9 ± 0.3	-2.3 (-3.0 to -1.5)	0.003	-1.7 (-2.5 to -1.0)	< 0.001
Month 6	0.8 ± 0.2	-4.7 (-5.4 to -4.0)	< 0.001	3.5 ± 0.4	-1.7 (-2.4 to -1.0)	0.251	-2.7 (-3.5 to -1.9)	< 0.001

Data are presented as mean ±SE;
VAS, Visual Analog Scale;
[a]*P* value obtained from Friedman test with subsequent post-hoc Bonferroni test;
[b]Independent t test (change from baseline [mean difference] between groups);
$P < 0.05$ is considered statistically significant.

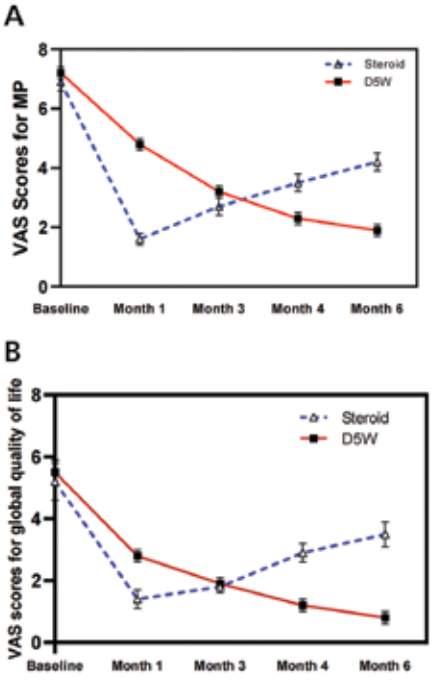

Fig. 3. *A) The Visual Analog Scale scores for meralgia paresthetica in both groups at each time point. B) The Visual Analog Scale scores for global quality of life in both groups at each time point.*

was a sustained symptom relief in patients with carpal tunnel syndrome between 3 to 6 months post-D5W HD, whereas the a control group's efficacy (who received only normal saline) started to decline from the third month onward. Since we adopted the same procedure to eliminate the cofounding effect of HD, the inter-group differences at different time points were due to the different injectates.

Theoretically, there is a cumulative effect of D5W HD (25). Su, et al (26) reported a 35-year-old woman with a 20-year history of MP who had significant symptom relief after 7 sessions of D5W HD during a 6-month follow-up. The authors concluded that D5W HD was beneficial for treating MP, even in an extreme chronic case. Considering the possible adverse effects of steroid injection, we performed a single injection in each group in our study. We believe that repetitive injections may have a more lasting and greater therapeutic effect. Thus, further studies are necessary to precisely evaluate the optimal number of injections.

Compared with corticosteroid injection, D5W has a better safety profile for patients with peripheral entrapment neuropathies. Peters-Veluthamaningal, et al (33) reported that 38.9% (14/36) patients exhibited steroid-flare effects after corticosteroid injections. Van, et al (34) reported that 13.3% (4/30) patients experienced adverse effects, including swollen hand, pain, swelling, and depigmentation at the injection site after

corticosteroid injection. The possible adverse effects of corticosteroid injections limit its clinical use and repetitive injections. Hence, we advocate D5W as a more suitable injectate for patients with MP.

Real-time ultrasound was noteworthy in our study. MP was diagnosed based on typical clinical symptoms, sonographic characteristics, and a positive response after local anesthesia. All patients were successfully anesthetized under ultrasound guidance. Another advantage of ultrasound is that it allows a targeted injection to be performed at the compression site that precisely releases the compressed nerve from surrounding tissues to enhance the efficacy of D5W HD. However, successful use of ultrasound requires technical expertise and extensive ultrasound knowledge of peripheral entrapment neuropathies.

Limitations

Our study has a few limitations. First, the exact mechanism of D5W was not explored. Second, the optimal number of D5W HD sessions was not investigated. Third, the outcomes may be inadequate due to a lack of objective measurements. However, the LFCN is a pure sensory nerve, and pain and sensory disturbances are the most typical characteristics of MP. Furthermore, subjective measurements were considered as the primary outcomes in almost all previous studies. In our study, the intergroup differences were statistically significant. Hence, we believe the results of our study are of clinical significance. Fourth, a longer follow-up duration is necessary to gain a more comprehensive understanding of D5W HD for MP. Lastly, it may be helpful to include a sham treatment group to compare the therapeutic effects of D5W and corticosteroid. Of note, although local anesthetic by itself may provide some benefit, D5W clearly outperformed a corticosteroid/local anesthetic combination.

Conclusions

Ultrasound-guided PIT with D5W provides more favorable outcomes than corticosteroid at 4 to 6 months postinjection. Additionally, D5W displayed a better safety profile than corticosteroid. Hence, we recommend D5W HD as a preferred choice for patients with MP. However, further investigations involving multiple injections and extended treatment durations are required to establish the long-term effectiveness of this treatment.

Author Contributions

XS: Conception, design, and drafting the article; JZ: Conception, design, revising the manuscript critically for important intellectual content; GL: Data acquisition and interpretation; LB: Data analysis; HX: study design and supervision. All authors approved the final version and are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work was appropriately investigated and resolved.

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