Randomized Controlled Trial

Stellate Ganglion Destruction With Alcohol Versus Thermal Ablation for Chronic Post-Mastectomy Pain: A Randomized Trial

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Background: Post-mastectomy pain syndrome (PMPS) is a persistent post-surgical neuropathic pain. Stellate ganglion (SG) block is used for diagnosis, prognosis, and treatment of pain syndrome.

Objectives: We aimed to evaluate the efficacy of SG destruction with alcohol versus thermal ablation for PMPS management.

Study Design: Randomized, double-blind clinical trial.

Setting: National Cancer Institute, Cairo University, Egypt.

Methods: Female patients aged 20-65 years who underwent breast cancer surgery and suffered moderate to severe pain for more than 6 months were categorized equally into 2 groups. SG destruction was with ultrasound (US) guidance and C7 level confirmation by fluoroscopy either by alcohol injection in Group A or thermal ablation with a time of 60 seconds at 80°C repeated twice in Group B. Follow-up was at 1, 4, 8, and 12 weeks.

Results: Visual analog scale (VAS) measurements after 1, 4, 8, and 12 weeks were significantly lower than pre-procedure measurements in both groups (P value < 0.001). There was a significant reduction in VAS score after 4 and 8 weeks in Group A than in Group B (P value = 0.003 and 0.018). Oxycodone and pregabalin consumption after 4 and 8 weeks were significantly lower in Group A than in Group B. Physical health, mental health, and satisfaction scores were comparable. There were no significant complications in both groups.

Limitations: The relatively small sample size and short follow-up period are limitations to our study.

Conclusion: US-guided SG destruction with alcohol was more effective than thermal radiofrequency for managing acute postoperative pain by decreasing pain score, oxycodone, and pregabalin consumption, which were consumed before the block.

Key words: Alcohol, mastectomy, neuropathic pain, stellate ganglion, thermal, pain, radiofrequency, PMP.

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Among female cancers, breast cancer is by far the most prevalent (1). Post-mastectomy pain syndrome (PMPS) is considered a chronic neuropathic pain that extends after the normal healing time and usually arises after surgical management of breast cancer (2). It is a relatively frequent problem with 25% to 60% incidence (3). Neuropathic pain has gained considerable clinical and academic consideration due to the high prevalence and difficulty in treatment, affecting the patient's mood and social function and resulting in an economic burden on the health care system (4).

The stellate ganglion (SG) is a kind of sympathetic ganglion that results from the union of the inferior cervical and first thoracic ganglia. Stellate ganglion block (SGB) has several clinical indications, including di-

agnostic, prognostic, and therapeutic for sympathetic-maintained and neuropathic pain disorders (5).

Preoperative ipsilateral SGB was used to control acute PMPS (6). Also, vasomotor disorders, such as menopause syndrome, have been treated with SGB (7). This technique has been developed to treat the pain and swelling caused by lymphedema, often associated with PMPS (8). SGB has proven efficacy in managing PMPS (9,10).

However, there are several critical neurovascular structures close to the glottis, including the vertebral and subclavian arteries, as well as pleura, recurrent laryngeal, and phrenic nerves, and C8-T1 anterior divisions, making SGB a potentially hazardous procedure (11).

Steroids, local anesthetics (LA), chemical neurolytics (such as ethanol and phenol), and pulsed and thermal radiofrequency (RF) treatment are common approaches in SGB (5,12). Since repeated blocks are often necessary for individuals with a limited effective duration, it has been suggested that radiofrequency ablation (RFA) might cause permanent damage to the nerves (i.e., heat-induced neurolysis) and is predicted to have a longer sustained impact (5,13).

Compared to surgical neurolysis, RF sympatholytic has the advantages of being more effective over the long term, being safer, allowing for more accurate localization, and having a lower risk of complications. Some of RFA's inefficacy may stem from the SG segment being outside the ablation zone (5).

Chemical neurolysis might help reduce spasticity by inhibiting the stretch reflex chain, particularly when spasticity is mostly related to certain muscle areas (14). Ethanol (35 to 90%) is also a strong neurolytic drug used for pain management, although its application is limited. Few studies have been published on alcohol usage for peripheral nerve blocks to manage postoperative pain (15).

To our knowledge, no previous controlled randomized trials were performed to compare different SG destruction methods in managing PMPS. Hence, this study evaluated the efficacy of SG destruction with alcohol versus thermal ablation for PMPS management.

Methods

This randomized, double-blind clinical trial included 70 female patients aged 20-65 years who underwent surgery for breast cancer suffering from moderate to severe pain (visual analog scale [VAS] $\geq$ 4) for more than 6 months and less than 2 years that was described as a refractory and neuropathic pain characterized by the grading system for neuropathic pain (GSNP), with a score of 3 or 4.

The study was conducted from January 2023 to July 2023 following approval of the ethics committee of the National Cancer Institute, Cairo University, Egypt, and registration with clinical trial.gov (ID: NCT05771103). All patients had given signed consent.

Patients were not eligible if they refused to participate in the study or had recent myocardial infarction, systemic anticoagulation, coagulopathy, pre-existing counter lateral nerve palsy, glaucoma, local and systemic sepsis, local anatomical distortion, cardiac conduction block, or psychiatric illness.

The cases were randomized parallelly using sealed opaque envelopes and a random list created by a computer. Cases were categorized equally into 2 groups. SG destruction was with ultrasound (US) guidance and C7 level confirmation by fluoroscopy either by alcohol injection in Group A or thermal ablation with a time of 60 seconds at 80ºC repeated twice in Group B. Participants and outcome assessors were blinded for grouping.

The medical history, physical examination, and routine laboratory analysis, including international normalized ratio (INR), were recorded for all participants. Patients were instructed to evaluate their pain severity via VAS, which varies from 0 (no pain) to 10 (incredible pain), with satisfaction scores of 0 dissatisfied and 10 very satisfied. Patients were told not to speak or swallow during the surgery but to communicate with their nonoperating hands.

Diagnostic stellate ganglion block was performed before at a pain clinic, and only patients who had pain relief were referred to us for therapeutic stellate ganglion block.

Every patient had an intravenous (IV) 18-gauge cannula in the operating room. Oxygen (3 L/min) through a nasal cannula was used. Dexmedetomidine 0.5 ug/kg IV infusion over 10 minutes and fentanyl 1 ug/Kg were used for conscious-alert sedation. All patients were monitored by electrocardiography, noninvasive blood pressure, pulse oximetry, and temperature probe.

Technique of Stellate Ganglion Block

Patients were supine with their heads slightly rotated to the opposite side and a small pillow under their shoulders. After aseptic preparation of the skin with 10% betadine (povidone-iodine) solution, a high-frequency linear transducer (6-13 MHz) of US machine (Sonosite® M. Turbo) was placed at the level of C6 (Fig. 1). The trans-

ducer was placed with little pressure between the carotid artery and the trachea in a para-tracheal approach. A 25-gauge, 3.5-inch needle was placed paratracheal, with the needle staying in plane to the US beam towards the middle of the longus coli muscle (LCM) (Fig. 2). C6-C7 level was identified under fluoroscopic posterior-anterior (PA) guidance (identification of C7 level is by the nearby T1-transverse process ballooning) (Fig. 3). The injection's target was the US images showing the needle tip puncturing the prevertebral fascia in the LCM (Fig. 4). After negative aspiration, the procedure was continued according to the assigned groups, Group A, to avoid spreading along the carotid sheath. The treatment began with the needle tip being positioned anteromedial to the LCM and deeply into the prevertebral fascia. The needle was kept just under the surface of the fascia surrounding the LCM to avoid injecting into the muscle itself. The right fascial plane was identified using portable US guidance, allowing the injectate to be spread caudally and reach the SG at the C7-T1 level. As a result, a smaller amount of injection produced a more permanent sympathetic block. We

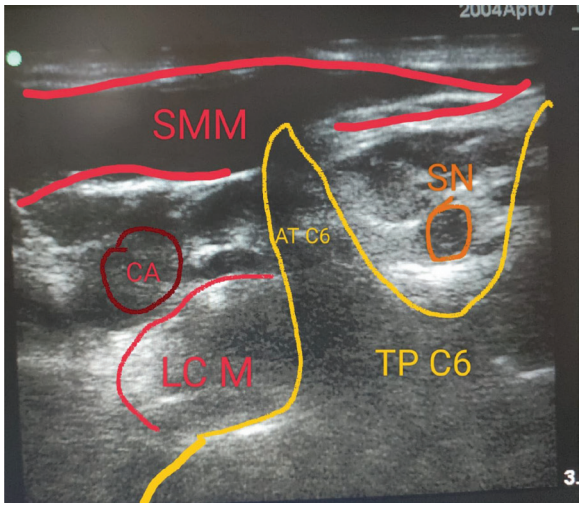

Fig. 1. *US at the level of C6.*

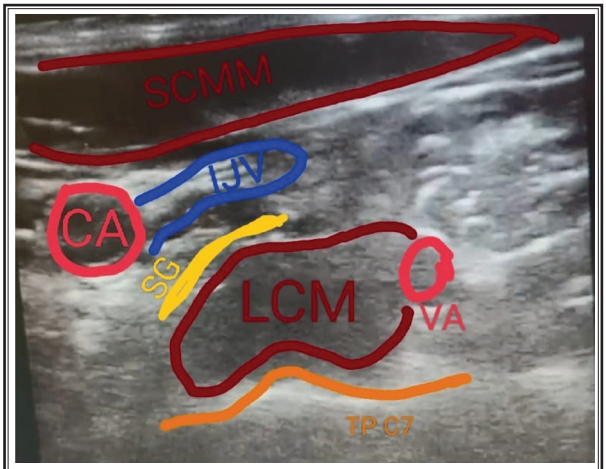

Fig. 2. *US at the level of C7.*

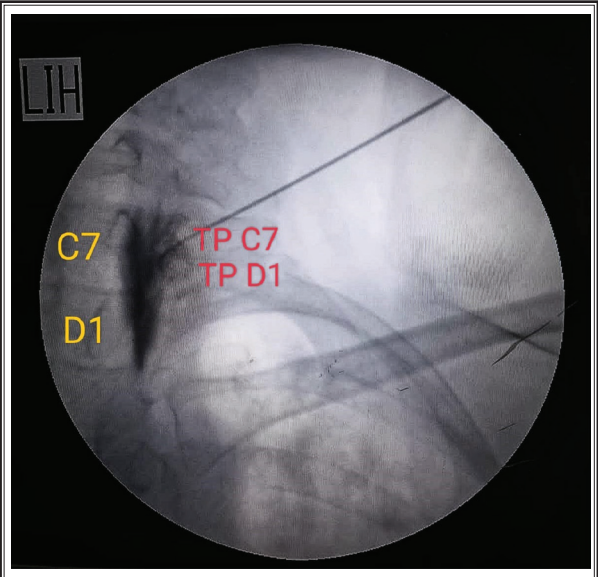

Fig. 3. *Fluoroscopic identification of LCM.*

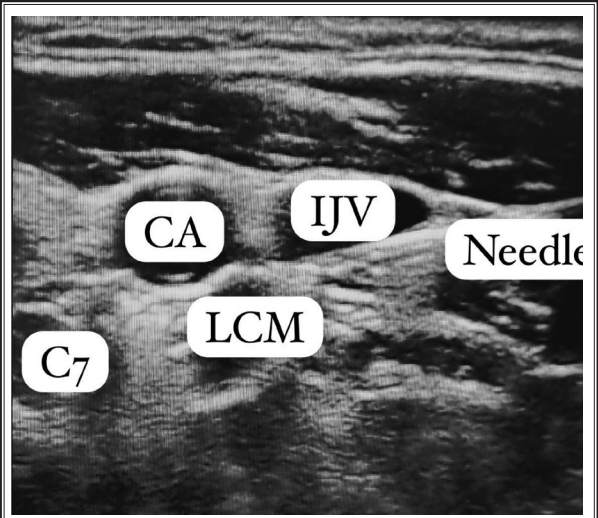

Fig. 4. *US-guided stellate ganglion block.*

began by injecting a 2 mL 1% lidocaine solution. The next step of the process was injecting 1.5 mL of 50% ethanol for a lasting effect. Alcohol ink deep to fascia superficial to LC muscle, in group B, the RF thermal neurolysis was performed at 80ºC for 60 seconds, twice to be 0.5 cm apart.

Positive cases of PMPS are grade 3 (probable) or 4 (definite). Patients who developed PMPS were treated with pregabalin (Lyrica®, Pfizer, Egypt) 75 mg and followed the degree of improvement and the side effects toleration. If the patient still had PMPS, we either increased the dose of pregabalin up to 300 mg BID or added oxycodone for VAS from 1 to 4 (16). VAS score, oxycodone, and pregabalin consumption measurements were assessed at 1, 4, 8, and 12 weeks. Also, quality of life by SF-36 (physical and mental health) and satisfaction score were assessed. We also recorded any perioperative complications (LA toxicity, pneumonia, and arterial puncture).

The primary outcome was the change in VAS pre-procedure and 1, 4, 8, and 12 weeks after the block. The secondary outcome was patient satisfaction and the analgesic concomitant medications pre-procedure and 1, 4, 8, and 12 weeks after the block.

Sample Size

The sample size calculation was done by G. power 3.1.9.2 (Universitat Kiel, Germany) based on 0.05 α error and 95% power of the study to determine a 20% decrease in VAS score with Group A (SG destruction with alcohol) than in Group B (SG destruction with thermal ablation) (mean 4.57 and SD 0.64 according to a previous study (5)). Five cases were added to each group to overcome dropouts. Therefore, 35 patients were allocated to each group.

Statistical Analysis

SPSS v26 (IBM Inc., Armonk, NY) was used for the statistical analysis. Mean ± SD was used to express the quantitative data using the unpaired Student's t test. Median and interquartile range (IQR) was used to express quantitative nonparametric data using the Mann-Whitney test between the 2 groups and the Friedmann test for repeated measures within the same group. Frequency (%) was used to express qualitative variables using the Chi-square test. A 2-tailed *P* value < 0.05 was considered statistically significant.

Results

Ninety-six individuals were initially screened for inclusion in the trial; 17 were not eligible, and 9 declined to participate. The remaining patients were randomized equally into 2 groups (35 each). Statistical analyses were performed on all allocated participants (Fig. 5).

Patient characteristics and GSNP were comparable between groups (Table 1).

VAS measurements were significantly lower after 1, 4, 8, and 12 weeks than pre-procedure in both groups (*P* value < 0.001). VAS measurements were significantly lower after 4 weeks and 8 weeks in Group A than in Group B (*P* value = 0.003 and 0.018), and were insignificantly different pre-procedure, after one week, and 12 weeks between both groups (Table 2).

Oxycodone and pregabalin consumption measurements were significantly lower after 4 weeks and 8 weeks in Group A than in Group B (*P* value < 0.05) and were insignificantly varied at pre-procedure, after one week, and 12 weeks between both groups (Table 2).

The quality of life by SF-36 (physical and mental health) and satisfaction scores were insignificantly different between both groups (Table 3). No significant complications (LA toxicity, pneumonia, and arterial puncture) were encountered in both groups.

Discussion

The sympathetic nervous system has been linked to several pain syndromes, and LA targeting the sympathetic ganglia provides advantages for treating sympathetically mediated pain (17).

According to Kuntz's research, the brachial plexus receives nerves from the T2 and T3 sympathetic ganglia as they bypass the stellate ganglion (18). A sympathetic nerve block can alleviate pain through multiple mechanisms, including the interruption of afferent nociceptive fibers that accompany autonomic nerves. A second mechanism is the disruption of reflex control systems, which alters the peripheral or central sensory processing (19).

When the response to nerve blocks is temporary, and rehabilitation is ineffective, spinal cord or peripheral nerve stimulation (20) and destructive interventions (such as surgical, radiofrequency sympathectomy, or chemical techniques) are used (21).

SG neurolysis treats nociceptive and neuropathic pain caused by malignancies (the thoracic viscera, upper limb, and head/neck), iatrogenic plexopathy, and PMPS (22,23).

In acute pain after mastectomy, Aghamohamadi et al (6) showed that preoperative ipsilateral SGB using bupivacaine significantly reduced the pain score

and had a significant analgesic-sparing effect.

Also in treating PMPS, Abbas et al (9) reported the efficacy and safety of fluoroscopic SGB using 0.25% bupivacaine in decreasing mean VAS score and opioid consumption.

To our knowledge, this is one of the earliest studies comparing SG destruction's efficacy with alcohol versus thermal ablation for PMPS management.

This study showed that SG destruction, either by alcohol or thermal ablation, significantly lowered pain scores in all measurements compared to pre-procedure. There was a significant reduction in VAS score, oxycodone, and pregabalin consumption after 4 and 8 weeks in group A than in group B. Physical health, mental health, and satisfaction scores were comparable between groups.

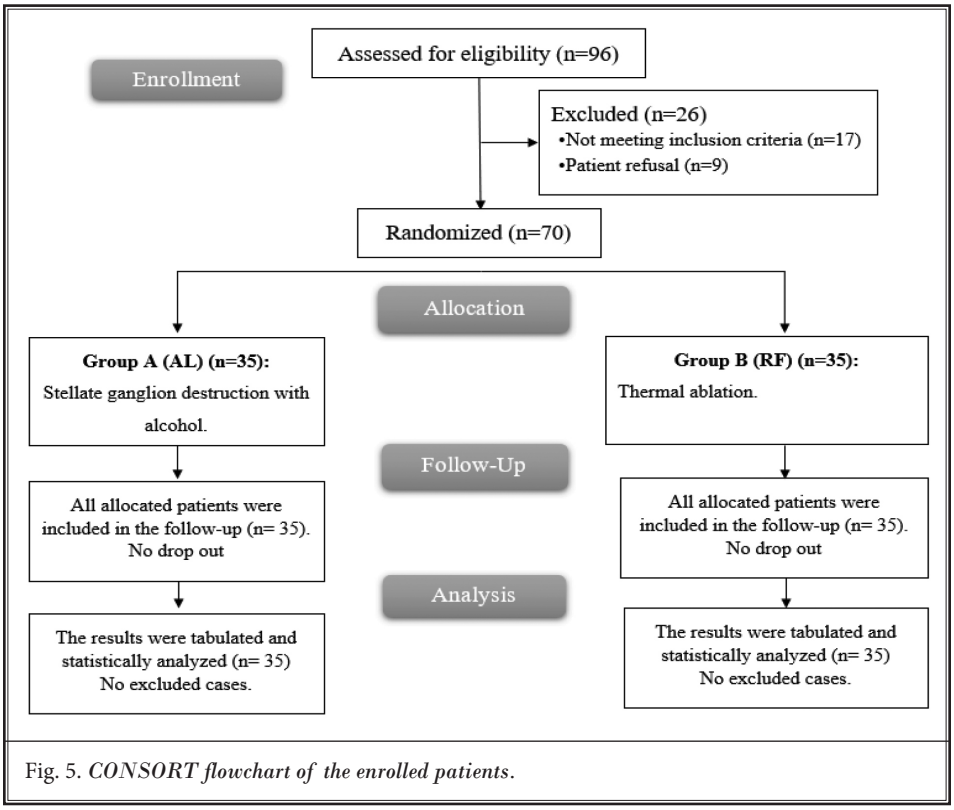

Fig. 5. *CONSORT flowchart of the enrolled patients.*

In numerous clinical procedures, the conception of the prolonged and more potent effect of thermal RF in neuroablation has been extensively adopted. In addition, the delayed reaction time of pulsed RF neuromodulatory mechanism "C-Fos expression and reduced release of substance P in the dorsal horns leading to decreased nociception and hyperalgesia" may be for a period of 4 to 6 weeks (5,25). Consequently, the pulsed RF, frequently used in sensory neuropathy, has a time lag that may not be tolerable in patients with intractable cancer pain (26).

Kastler et al (12) reported relief in 67% of complex regional pain syndrome (CRPS)-type I cases following CT-guided thermal RF treatment of the SG.

Abbas et al (5) demonstrated that using thermal RF for SG destruction in neuropathic PMPS in cancer patients statistically lowered the VAS pain scores, oxycodone, and pregabalin consumption at all post-procedure assessment sites compared to baseline.

However, Van Eijs et al study (24) has reported that SGB radiofrequency treatment is preferred over phenol neurolysis because effects are comparable with lower risk for side effects for a more prolonged lumbar sympathetic block in patients suffering from upper limb CRPS. The difference may be due to the different surgical procedures and different chemicals used (3 mL of 7% phenol contrasted to 1.5 mL of 50% alcohol in our study).

Forouzanfar et al (13) published a retrospective analysis of thermocoagulation RF treatment of the SG in a diversity of chronic pain syndromes. At the one-

Table 1. *Patient characteristics and GSNP of the studied groups.*

		Group A (n = 35)	Group B (n = 35)	*P* value
Age (years)		50.37 ± 10.13	45.34 ± 11.79	0.060
Weight (kg)		95.94 ± 12.79	91.04 ± 13.91	0.130
ASA physical status	II	18 (51.43%)	16 (45.71%)	0.632
	III	17 (48.57%)	19 (54.29%)	
Side	Right	22 (62.86%)	16 (45.71%)	0.15
	Left	13 (37.14%)	19 (54.29%)	
GSNP		4 (3 - 4)	3 (3 - 4)	0.235

Data are presented as mean ± SD, frequency (%), or median (IRQ). ASA, American Society of Anesthesiologists. GSNP, grading system of neuropathic pain.

year follow-up, they reported complete pain relief in approximately 37.8% of patients, partial pain relief in 41%, and no pain relief in 21.0%. Kastler et al (27) reported significant pain relief following thermal RF SG treatment administered 5 times over 3 years in case of residual ischemic symptoms.

Table 2. *VAS, oxycodone, and pregabalin consumption measurements (mg) of the studied groups.*

	Group A (n = 35)	Group B (n = 35)	*P* value
VAS			
Pre	8 (6 - 9)	8 (7 - 9)	0.689
After 1w	2 (1.5 - 3)	2 (1 - 3)	0.094
After 4w	3 (3 - 5)	2 (2 - 3.5)	0.003*
After 8w	5 (3 - 6)	4 (3 - 5)	0.018*
After 12w	5 (4 - 7)	5 (4 - 7)	0.624
Oxycodone consumption (mg)			
Pre	75.43 ± 12.68	78.86 ± 10.22	0.217
After 1w	45 ± 5	47.57 ± 9.42	0.158
After 4w	47.14 ± 6.67	52.57 ± 11.46	0.018*
After 8w	52 ± 6.77	57.71 ± 12.62	0.021*
After 12w	59.71 ± 9.85	64.86 ± 12.69	0.062
Pregabalin consumption (mg)			
Pre	347.86 ± 49.4	330 ± 64.11	0.196
After 1w	269.29 ± 44.18	251.43 ± 41.98	0.088
After 4w	239.29 ± 48.31	267.86 ± 45.2	0.013*
After 8w	261.43 ± 44.12	284.29 ± 46.21	0.038*
After 12w	321 ± 44.32	300 ± 51.09	0.071

Data are presented as mean ± SD or median (IQR). *: Significant when *P* value ≤ 0.05. VAS, Visual analog scale.

Alcohol administration around the nerve results in the degeneration and absorption of all nerve components, excluding the neurilemma. Denervation and pain alleviation occur over one week. Below 50% concentration, there is no motor impairment, and 100% concentration is linked with the destruction of a mixed somatic nerve's sympathetic, sensory, and motor components, as well as an increased risk of peripheral neuropathy (28). As a result, we selected a concentration in the middle. As absolute alcohol is connected with an increased risk of neuritis, dysesthesias, and injection-related pain, we propose diluting it with an LA to reduce the dangers mentioned above (15). Significant and longer-lasting comfort reported with an alcoholic administration validates its usage in clinical cases without apparent major consequences (15).

Lillemoe et al (29) reported that the average pain ratings in patients with pancreatic cancer were lower significantly at 2, 4, and 6 months of follow-up after chemical splanchnicectomy with alcohol.

Dolly et al (30) showed that there was a significant decrease in VAS score and morphine requirement at all the follow-up intervals till 16 weeks, with statistically significant improvement in quality-of-life scores in carcinoma gall bladder patients receiving 20, 30, and 40 mL of 70% alcohol in celiac plexus block.

In addition, Sayed et al (31) found that the administration of alcohol for chemical neurolysis in splanchnic plexus block was valuable in reducing pain in patients with intra-abdominal malignancy. The physical, mental, and life function scores significantly increased after the intervention.

In our study, there were no significant complica-

Table 3. *Quality of life by SF-36 and satisfaction score measurements of the studied groups.*

			Group A (n = 35)	Group B (n = 35)	*P* value
Quality of Life by SF-36	Physical health	Pre	71.94 ± 18.64	70.37 ± 21.93	0.748
		After 1w	67.11 ± 20.34	69.11 ± 20.34	0.216
		After 4w	65.03 ± 22.76	67.46 ± 23.96	0.665
		After 8w	73.51 ± 15.17	76.03 ± 18.23	0.533
		After 12w	74.86 ± 23.61	77.74 ± 18.72	0.573
	Mental health	Pre	69.49 ± 18.77	71.97 ± 17.22	0.566
		After 1w	69.83 ± 19.1	74.23 ± 21.26	0.366
		After 4w	68.86 ± 20.53	75.51 ± 17.12	0.145
		After 8w	78.94 ± 23.61	76.83 ± 19.64	0.685
		After 12w	75.83 ± 17.61	74.49 ± 19.33	0.762
Satisfaction score			8(4 - 10)	5(3 - 9)	0.091

Data are presented as mean ± SD or median (IQR).

tions between groups that may refer to the US ability to determine the precise location of the blood vessels (vertebral, carotid, and thyroid vessels), nerves (cervical and phrenic nerve roots and recurrent laryngeal nerves), and other soft tissue structures (trachea, LCM, esophagus, and thyroid) that allows for safe and effective treatment (5).

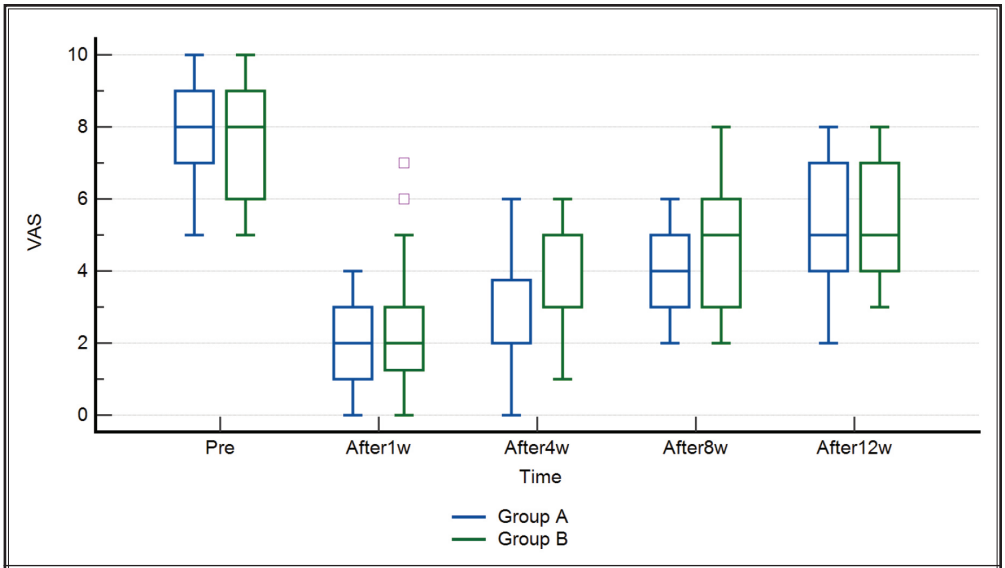

Fig. 6. *Visual analog scale (VAS) measurements of the studied patients.*

The relatively small sample size and short follow-up period with no control group receiving the usual treatment of PMPS are limitations to our study. To generalize our findings, a larger-scale, multicenter research is required. Further studies are needed to compare different concentrations and volumes of alcohol.

Conclusion

US-guided SG destructions with alcohol or thermal RF were safe and effective for managing PMPS by improving the quality of life and performance status with superiority towards alcohol for lower pain score, oxycodone, and pregabalin consumption.

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