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Randomized Controlled Trial

The Effect of Erector Spinae Plane Block With and Without Addition of Magnesium on Relief of Pain from Post-herpetic Neuralgia

Sameh Abdelkhalik Ahmed, MD, Amr Ahmed Magdy, MD, Mohammad Ali Abduallah, MD, and Amr Arafa Albadry, MD

From: Department of Anesthesia and Surgical Intensive Care, Faculty of Medicine, Tanta University, Egypt.

Address Correspondence: Sameh Abdelkhalik Ahmed, MD Saied st, Tanta Al gharbia governate, Egypt. E-mail: samehabdelkhalik1982@gmail.com

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Background: The best tool for management of postherpetic neuralgia (PHN) is a matter of debate. The use of ultrasound-guided erector spinae plane block (ESPB) in patients with PHN may decrease pain severity and the need for analgesics.

Objectives: The objective of this clinical study was to test the efficacy of ESPB with and without the addition of magnesium sulphate on pain control and analgesic consumption in patients with PHN.

Study Design: Randomized controlled double-blinded trial.

Setting: A single university center.

Methods: A total of 75 patients with PHN were included in the study. Patients were randomly divided into 3 equal groups. Group A received sham ESPB (2 mL normal saline), Group B received ESPB with 20 mL of bupivacaine (0.25%), and Group C received ESPB with 20 mL of bupivacaine (0.25%) and 100 mg magnesium sulphate. All patients received standard medical care. The pain score, the consumption of pregabalin and acetaminophen, the incidence of complications, and the patient's satisfaction were measured and recorded.

Results: In comparison to the control group, the use of real ESPB with or without the addition of magnesium significantly decreased the Numeric Rating Scale score for pain during the first week of follow-up ($P < 0.05$); decreased the mean daily consumption of pregabalin and acetaminophen from the third to the twelfth week of follow-up ($P < 0.05$); and increased the level of patients' satisfaction ($P = 0.03$). The addition of magnesium sulphate showed an insignificant difference in comparison to the use of bupivacaine alone in ESPB ($P > 0.05$).

Limitations: The study was limited by being a singlecenter study, using a single-level injection, and using a single volume of local anesthetic mixture.

Conclusion: ESPB with or without adding magnesium sulphate is an effective pain management tool for cases of PHN. It leads to a significant decrease in pain score and analgesic requirements.

Key words: Post-herpetic neuralgia, erector spinae plane, thoracic, lumbar, magnesium, pain score, pregabalin, paracetamol

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Herpes zoster is a common disease in the elder population that is usually complicated by acute neuralgic pain and postherpetic neuralgia (PHN). The incidence of PHN is widely variable (5-50%). This variation may be attributed to study design, age distribution, and the used definition (1,2). Management of PHN is highly challenging for pain physicians. It includes conventional methods and regional anesthesia techniques (3). Multiple regional anesthesia techniques have been used for the management of PHN, especially

epidural, paravertebral, intrathecal, and somatic nerve blocks. On the other hand, those regional anesthesia techniques carry the risk of complications, especially localized hematoma, local anesthetic toxicity, or pneumothorax (4,5).

The relatively recent ultrasound-guided (ULSD-g) erector spinae plane block (ESPB) was introduced for the management of acute and chronic pain conditions affecting the thoracic region. It is an interfacial plane block that targets both ventral and dorsal rami of the spinal nerves (6). This technique proved its analgesic efficacy in pain management for fractured ribs, thoracotomy, and pulmonary metastasis, either with a single injection or continuous catheter infusion (7-9). It has the advantage of being simple and safe, and it can be performed in patients with bleeding diathesis (9). Many case reports have confirmed its success in controlling the pain of PHN (10).

Magnesium, the voltage-dependent N-methyl-D-aspartate (NMDA) receptor blocker, has antinociceptive effects, prevents central sensitization, and decreases pain hypersensitivity. It has been found to relieve pain, hyperalgesia, and allodynia in cases of PHN if used intravenously in a dose of 30 mg/kg over 30 minutes (11,12).

This clinical trial suggested that ULSD-g ESPB, with or without the addition of magnesium sulphate, may decrease pain severity in patients with PHN and decrease the need for analgesics. A dose of only 100 mg was used in this clinical study as magnesium sulphate was injected directly on the nerve. This randomized controlled double-blinded study was conducted to evaluate the effect of the use of ULSD-g ESPB (with or without the addition of magnesium) on the efficacy of pain relief and analgesic consumption in patients with PHN.

Methods

This randomized controlled double-blinded study was carried out over a period of 9 months, from September 2020 through June 2021. The study started immediately after gaining the approval of the institutional ethical committee. The study was registered on ClinicalTrials.gov before enrollment of the first patient. Informed written consent was signed by all patients after they had received a detailed explanation of the aim, advantage, technique, and potential hazards of the study.

Patients presented to the pain clinic with PHN in thoracic or lumbar dermatomes with a numeric rating scale score (NRS-11) (a metric score for assessment of pain: 0 for no pain and 10 for the worst pain) of 4 or more were included in this study. Patients excluded from the study were those who commenced opioids for causes other than PHN, had a secondary bacterial infection at the site of injection, were diagnosed with a psychiatric illness, were uncooperative, refused to participate in the study, were extremely obese with a body mass index (BMI) > 50 (kg/m^2), had suspected or diagnosed coagulopathy, or had a known history of allergy to local anesthetics.

An independent data manager randomly distributed the patients into 3 groups based on computer-generated randomization software, the results of which were placed in closed, opaque envelopes.

- Group A patients received routine medical treatment in addition to sham erector spinae plane block (2 mL of normal saline).
- Group B patients received routine medical treatment and real ULSD-g erector spinae plane block with an injection of 20 mL of bupivacaine (0.25%).
- Group C patients received routine medical treatment and ULSD-g erector spinae plane block with an injection of 20 mL consisting of bupivacaine (0.25%) and 100 mg magnesium sulphate.

Once the patient was admitted to the pain clinic and diagnosed with PHN, adequate assessment was done through taking the history of the patient, examination, and requesting appropriate investigations. The diagnosis of PHN was confirmed by the presence of a history of herpetic eruption of a duration longer than 6 months, unilateral dermatomal pain confined to the distribution of the eruptions, and the presence of tactile allodynia. All patients received an adequate explanation of how to use the NRS-11 by recording the baseline pain score. All patients were prescribed to receive routine medical treatment composed of pregabalin and acetaminophen. Pregabalin was administered orally in doses of 150 mg every 12 hours (300 mg daily) for 2 weeks. The dose of pregabalin was then modified with each follow-up visit based on the NRS-11 score. The dose was gradually titrated down to 50 mg daily, and then it was stopped when the NRS-11 score was controlled. Patients also received 1 g of acetaminophen orally every 6 hours for 2 weeks (4 g daily) modifying the dose with each follow-up visit based on the NRS-11 value. The dose was gradually titrated down when the NRS-11 reached 3 or less.

The patients were then admitted to the operating

theater for real or sham ULSD-g ESPB under complete aseptic precautions and full monitoring. An anesthesia resident who was not participating in the study, and had no subsequent role in it, helped in the preparation of local anesthetics, tools required to perform the ESPB, and resuscitation equipment.

ESPB Technique

The procedure was performed by personnel who are experts in ULSD-g regional anesthesia techniques. It was performed under complete aseptic precautions with the patients in a sitting position. Unilateral ESPB was performed at the affected side using an ULSD machine (Philips CX 50 Extreme edition) and an 8 cm echogenic needle. The laminae were counted from the sacrum up to the ideal level of injection. The probe was placed longitudinally in the midline over the vertebral spine (a low-frequency probe was used in most cases, but in thin cases [BMI < 25 kg/m^2], the high-frequency probe was sometimes used, especially at the thoracic level). The probe was then slid laterally until identification of the transverse process and paraspinal muscles. The needle was introduced from the cephalic aspect of the probe targeting the transverse process. Negative aspiration was done to exclude intravascular placement of the tip of the needle. Then, the pre-prepared local anesthetic mixture was slowly injected in the plane between the transverse process and the anterior fascia of the erector spinae muscle with adequate visualization of the spread of the injectate by ULSD (13).

The patients were monitored for 6 hours after injection. They were discharged on the same day and scheduled for follow-up visits every week for the first 4 weeks, and then every 2 weeks for the next 8 weeks. None of the patients received another injection during the follow-up period.

Measurements

An assistant resident who was not participating in the study and was blinded to its groups helped in obtaining and recording the measurements during the routine visits. The postoperative NRS-11 pain score (primary outcome) was assessed every day by telephonic communication during the first week, and then every visit with modification of the dose of pregabalin and acetaminophen according to the severity of pain. Each reading of NRS-11 represents the highest pain score rated by the patient during the period of measurement. The consumed daily dose of pregabalin and acetaminophen during each period of follow-up was recorded. Also, the incidence of complications including pruritis, nausea and vomiting, shivering, or pneumothorax was recorded. The patients were asked at the end of 12 weeks of follow-up to rate their degree of satisfaction where (0 = poor, 1 = fair, 2 = good, and 3 = excellent).

Statistical Analysis

The required sample size was calculated using the IBM SPSS Sample Power version 3.0.1 (IBM Corp.). A sample of 24 patients in each group will have 80% power to detect a 1.0 point difference in the mean pain score, assuming that the standard deviation is 1.75, as reported by Aydın and his coworkers (14) using one group t-test with a 0.05 two-sided significance level. The recorded data were analyzed statistically by the SPSS computer program (SPSS Inc., Chicago, IL, USA, Version 25). Categorical data were analyzed by χ-square test and presented as numbers and frequencies (%). Parametric data were analyzed by one-way analysis of variance test and post-hoc Tukey's HSD test and expressed as mean ± standard deviation. The postoperative pain score and patients' satisfaction were expressed as median and interquartile range after analysis by the Kruskal-Wallis test with intergroup comparison carried out using the Mann–Whitney U test. The results were considered statistically significant when the *P* value was less than 0.05.

Results

Ninety patients with PHN were assessed for eligibility for this study; 15 of them were excluded (12 did not meet the inclusion criteria and 3 refused to participate), and the other 75 patients were randomly allocated into 3 groups. All patients received the allocated intervention with successful follow-up and analysis of their data (Fig. 1). The basic demographic data of the studied patients including age, body mass index (BMI), gender, site of affection, and side of affection were comparable among the 3 groups ($P = 0.818$, 0.129, 0.852, 0.675, and 0.688 respectively). The incidence of complications, including nausea and vomiting, pruritis, and shivering, were statistically insignificant among the studied groups ($P = 0.685$, 0.854, and 0.581 respectively). No patient developed pneumothorax in the 3 groups (Table 1).

The baseline NRS-11 was statistically comparable among the 3 groups ($P = 0.462$) (Table 2). The NRS-11 was statistically significantly decreased in groups B and C compared to group A ($P < 0.05$) with an insignificant difference between groups B and C ($P > 0.05$) during the

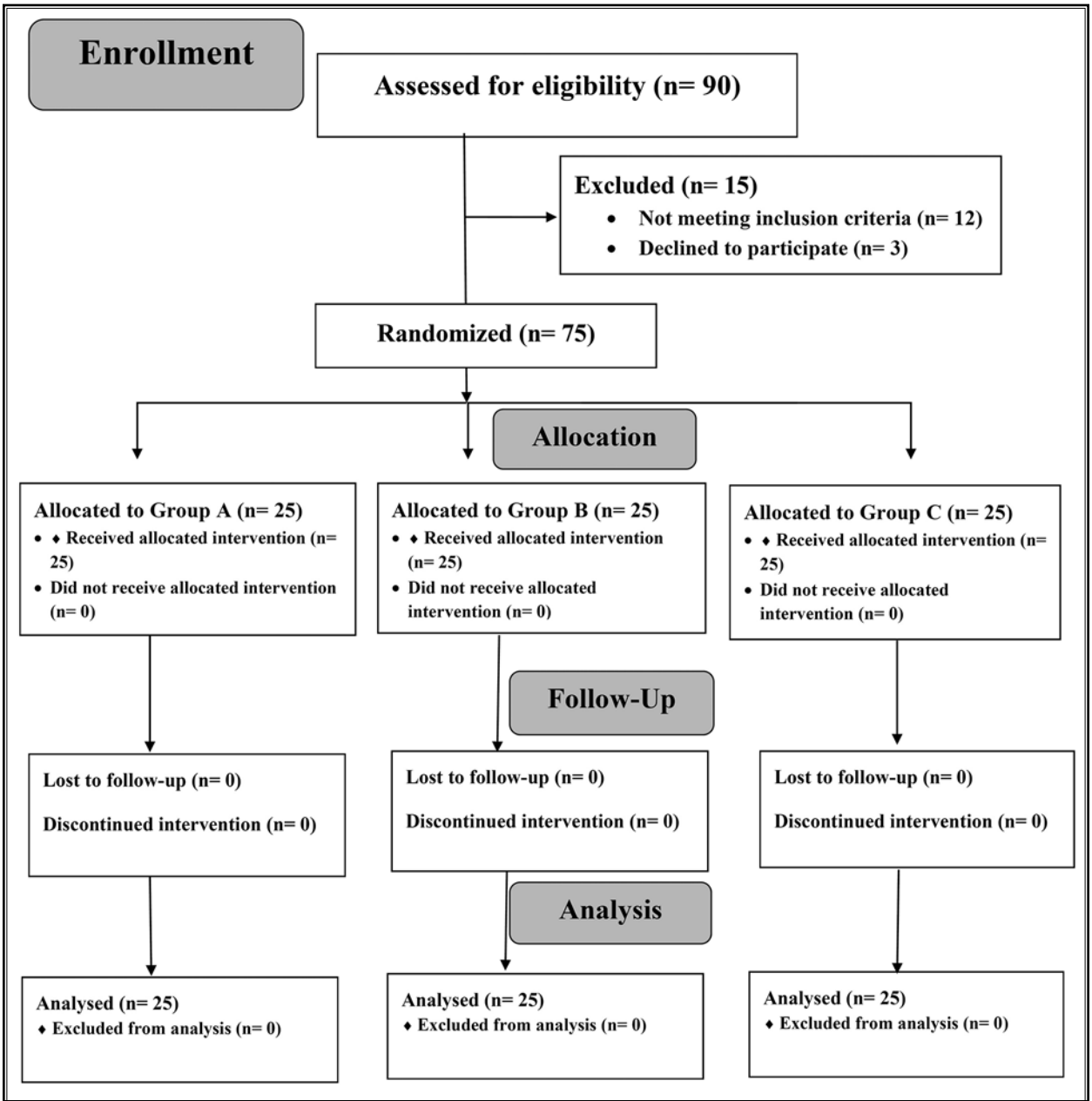

Fig 1. *Consolidated Standards of Reporting Trials (CONSORT) flow chart of the study.*

first 6 days after performing ESPB. However, the NRS-11 was comparable among the 3 studied groups one, 2, 3, 4, 6, 8, 10, and 12 weeks post-ESPB (P = 0.176, 0.504, 0.630, 0.743, 0.460, 0.333, 0.645, and 0.958 respectively).

Moreover, the pregabalin mean daily dose consumed during the whole period of follow-up was significantly decreased in groups B and C compared with group A (P < 0.05); there was an insignificant difference between groups B and C (P > 0.05). Furthermore, the acetaminophen mean daily dose consumed during the follow-up period was significantly increased in group A in comparison with groups B and C (P < 0.05); there was an insignificant difference between groups B and C (P > 0.05) (Table 3).

There was a statistically significant difference in the level of patient satisfaction at 3 months of follow-up in the 3 groups (P = 0.03). The patients in groups B

Table 1. *Demographic data and incidence of complications of the studied groups.*

		Group A	Group B	Group C	*P* value
Age (years)		54.36 ± 10.35	56.16 ± 10.37	55.76 ± 10.89	0.818
BMI (kg/m^2)		28.56 ± 1.36	28.24 ± 1.45	27.72 ± 1.56	0.129
Gender	Men	13 (52%)	14 (56%)	12 (48%)	0.852
	Women	12 (48%)	11 (44%)	13(52%)	
Site	Thoracic	15 (60%)	17(68%)	14 (56%)	0.675
	Lumbar	10 (40%)	8 (32%)	11 (44%)	
Side	Right	14 (56%)	13 (52%)	11 (44%)	0.688
	Left	11 (44%)	12 (48%)	14 (56%)	
Incidence of complications	N&V	3 (12%)	4 (16%)	2 (8%)	0.685
	Pruritis	2 (8%)	3 (12%)	2 (8%)	0.854
	Shivering	3 (12%)	2 (8%)	1 (4%)	0.581
	Pneumothorax	0	0	0	-

Group A (Sham ESPB) (25 patients)), Group B (Real ESPB with bupivacaine alone [25 patients]), Group C (real ESPB with bupivacaine and magnesium [25 patients]). Data were presented as mean ± standard deviation (SD) or number and %. P value represents the comparison between the three groups.
BMI, body mass index.

Table 2. *The Numeric Rating Scale score in the studied groups.*

		Group A	Group B	Group C	*P* value	P1	P2	P3
NRS	Before injection	7 (6-8)	7 (6-8)	7 (6-8)	0.462	-	-	-
	1st day	4 (1-5)	2 (1-5)	2 (1-5)	< 0.0001*	< 0.0001*	< 0.0001*	0.805
	2nd day	3 (1-5)	2 (1-5)	2 (1-5)	0.0009*	0.0003*	0.006*	0.3560
	3rd day	4 (1-5)	2 (1-5)	2 (1-5)	0.0009*	0.005*	0.0005*	0.496
	4th day	4 (1-5)	2 (1-5)	2 (1-5)	0.0016*	0.004*	0.004*	> 0.999
	5th day	4 (1-5)	2 (1-5)	2 (1-5)	< 0.0001*	0.0001*	0.0001*	0.898
	6th day	4 (1-5)	2 (1-5)	2 (1-4)	< 0.0001*	< 0.0001*	< 0.0001*	0.362
	7th day	2 (1-5)	2 (1-3)	2 (1-3)	0.176	-	-	-
	2 weeks	2 (1-5)	2 (1-4)	2 (1-3)	0.504	-	-	-
	3 weeks	2 (1-5)	2 (1-4)	2 (1-3)	0.630	-	-	-
	4 weeks	2 (1-4)	2 (1-3)	2 (1-3)	0.743	-	-	-
	6 weeks	2 (1-3)	2 (1-3)	2 (1-3)	0.460	-	-	-
	8 weeks	2 (1-3)	2 (1-2)	2 (1-2)	0.333	-	-	-
	10 weeks	1 (1-3)	1 (1-3)	1 (1-3)	0.645	-	-	-
	12 weeks	1 (1-3)	1 (1-3)	1 (1-2)	0.958	-	-	-

Group A (Sham ESPB) (25 patients), Group B (Real ESPB with bupivacaine alone [25 patients]), Group C (real ESPB with bupivacaine and magnesium [25 patients]). Data are presented as median and interquartile range. *P* value represents comparison among the 3 groups. P1 represents comparison between groups A and B, P2 represents comparison between groups A and C, P3 represents comparison between groups B and C. * Denotes significant change.

and C were more satisfied than those in group A (P = 0.03 and 0.04) with an insignificant difference between groups B and C (P = 0.969) (Fig. 2).

Discussion

This randomized controlled double-blinded study shows that the use of ULSD-g ESPB (with or without the addition of magnesium sulphate) in patients with PHN significantly decreased the NRS-11 for pain during the first week after injection, prolonged the duration of analgesia, decreased the consumed doses of pregabalin and acetaminophen, and increased the patients'

Table 3. *The mean daily consumption of pregabalin and acetaminophen.*

		Group A	Group B	Group C	*P* value	P1	P2	P3
Pregablin consumption (mg)	2nd - 3rd week	284.00 ± 37.42	244.00 ± 50.66	248.00 ± 50.99	0.006*	0.003*	0.006*	0.782
	3rd - 4th week	250.00 ± 59.51	192.00 ± 47.17	202.00 ± 54.92	0.0006*	0.0004*	0.005*	0.493
	4th - 6th week	228.00 ± 63.05	174.00 ± 41.13	168.00 ± 53.77	0.0002*	0.0008*	0.0007*	0.660
	6th - 8th week	200.00 ± 72.17	150.00 ± 42.70	148.00 ± 50.48	0.002*	0.0045*	0.0049*	0.880
	8th - 10th week	169.00 ± 67.03	123.00 ± 47.82	120.00 ± 46.21	0.0029*	0.0075*	0.004*	0.822
	10th - 12th week	124.00 ± 51.27	84.00 ± 40.75	83.00 ± 41.28	0.0019*	0.0037*	0.0031*	0.932
Acetaminophen consumption (g)	2nd - 3rd week	3.80 ± 0.41	3.48 ± 0.51	3.40 ± 0.50	0.009*	0.018*	0.003*	0.578
	3rd - 4th week	3.44 ± 0.71	2.76 ± 0.66	2.88 ± 0.73	0.002*	0.001*	0.008*	0.545
	4th - 6th week	3.08 ± 0.81	2.48 ± 0.64	2.44 ± 0.69	0.003	0.0055*	0.0044*	0.833
	6th - 8th week	2.74 ± 0.97	2.14 ± 0.67	2.08 ± 0.72	0.007*	0.014*	0.0087*	0.761
	8th - 10th week	2.34 ± 0.89	1.72 ± 0.74	1.66 ± 0.70	0.0048*	0.01*	0.0045*	0.769
	10th - 12th week	1.70 ± 0.76	1.18 ± 0.54	1.16 ± 0.55	0.004*	0.0077*	0.006*	0.897

Group A (Sham ESPB) (25 patients), Group B (Real ESPB with bupivacaine alone [25 patients]), Group C (real ESPB with bupivacaine and magnesium [25 patients]). Data were presented as mean ± standard deviation (SD). *P* value represents comparison among the 3 groups. P1 represents comparison between group A and B, P2 represents comparison between group A and C, P3 represents comparison between group B and C. * Denotes significant change.

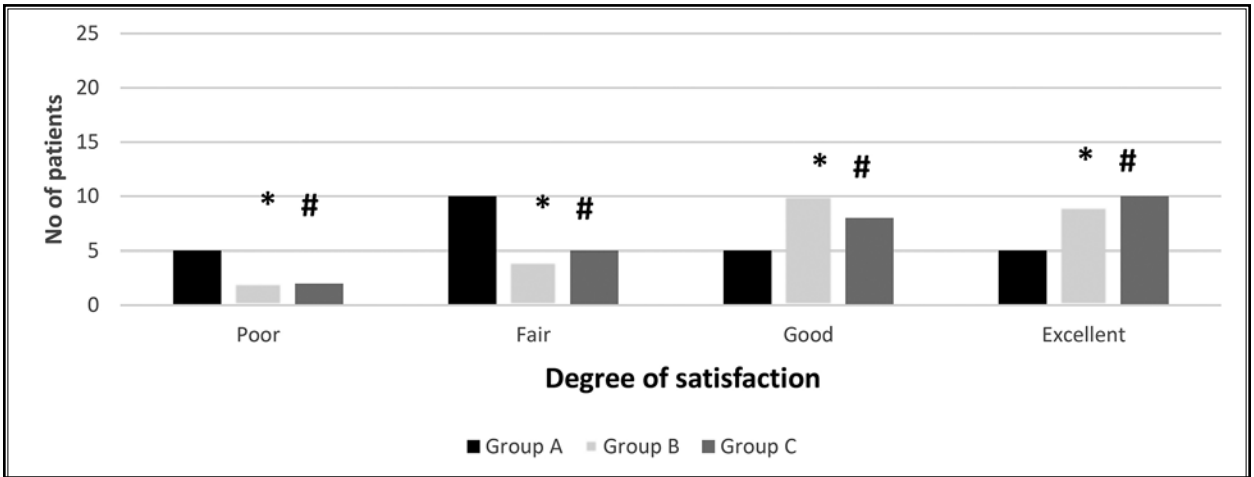

Fig 2. *Patient satisfaction in the 3 studied groups at 3 months follow-up.*
Group A (Sham ESPB) (25 patients), Group B (Real ESPB with bupivacaine alone [25 patients]), Group C (real ESPB with bupivacaine and magnesium [25 patients]). Data are presented as number of patients. *P* value represents comparison among the 3 groups (0.03). * denotes significant change between groups A and B ($P = 0.03$), # denotes significant change between groups A and C ($P = 0.04$).

satisfaction. The addition of magnesium sulphate to bupivacaine in ESPB had insignificant results compared with the use of bupivacaine alone.

The mechanism of the pathophysiological development of PHN is unclear. It may be due to irritation of the nociceptive receptors that maintain spinal dorsal column sensitization. On the other hand, it may result from loss of the nociceptive afferents that induce a synaptic reorganization in the dorsal horn. Moreover, the massive degeneration of both myelinated and demyelinated primary afferents may have a role (15).

The ESPB was first described by Forero (6). It subsequently gained high popularity for controlling acute pain in different body regions. The technique is safer than other procedures owing to the easy sonographic anatomy (6,10). The analgesic effect of ESPB is mediated through the diffusion of the local anesthetic mixture to the adjacent paravertebral space which results in blocking of the spinal nerves (16). The effect of ESPB

on PHN pain relief and reduction of analgesic consumption may be a result of prevention of peripheral and central sensitization. Pain-free periods may interrupt the neural circuit between the nociceptive receptors and the central nervous system that leads to pain relief (17). Magnesium is commonly used as a local anesthetic additive in different regional anesthesia techniques as it possesses an NMDA receptor antagonist action that decreases neuropathic pain in humans (18,19). However, the exact dose of magnesium that can be added to the local anesthetic mixture is a matter of debate. It ranges from 100 mg to 300 mg (19).

To the best of our knowledge, no available randomized controlled studies have evaluated the use of ESPB in the management of pain in herpes zoster. However, the case report of Tekin (10) showed the success of ULSD-g thoracic ESPB in decreasing the pain score from 10 to zero in a 72-year-old patient suffering from cervical and thoracic herpes zoster with a successful pain control score during 3 months of follow-up. Furthermore, the case report of Ahiskalioglu (20) revealed that ESPB (20 mL of plain bupivacaine 0.25%) relieved the pain of lumbar acute herpes zoster in a 72-year-old patient after failure of medical treatment (amitriptyline, nonsteroidal anti-inflammatory drugs, and lidocaine patch) to control the pain. The case report of Balaban et al (21) also reported successful pain control in a 67-year-old woman with acute thoracic herpes zoster infection after bi-level ESPB (30 mL bupivacaine 0.25%). They used bi-level injections due to the wide spread of the vesicle and the wide dermatomal level of pain (T1-T8) (21).

The case series of Park et al (22) reported the ability of ESPB to control the pain of acute herpes zoster infection in 3 different cases and concluded that it is a safe technique for management of the pain of herpes zoster and prevention of PHN. Furthermore, the observational study of Aydin (14) suggested that the use of ESPB for patients with acute or chronic pain with herpes zoster decreased the pain score. They recommended the use of continuous catheter insertion, especially in patients with chronic pain (14).

The use of single-level injection in ESPB is sufficient in targeting the proposed dermatomes as explained by certain anatomical and cadaveric studies that have suggested that single-level injection of a 20 mL volume can block 3-8 levels of dermatomes (23,24).

Our results revealed a significant decrease in the consumption of pregabalin and acetaminophen with the use of ESPB, despite the use of local anesthetics that may act theoretically for 24 to 48 hours. This may be explained by controlling the acute pain condition that decreases the risk of developing subsequent chronic pain (25,26). This is in line with the case report of Dilip et al (27) who described 2 cases of acute herpes zoster admitted to the emergency department with severe pain that was managed by ESPB as an alternative to systemic opioids. The 2 cases showed adequate pain control and decreased the consumption of analgesics (27).

This clinical study was limited by being a single-center study, having a small sample size, and using a single-level injection. The use of a single volume and concentration of local anesthetics, the use of a single dose of magnesium, and the use of a single-bolus injection also added to the study limitations.

Conclusion

It can be concluded that ULSD ESPB (with or without adding magnesium) can relieve the pain of postherpetic neuralgia, decrease the consumption of analgesics, and increase the level of patient satisfaction without increasing the incidence of complications.

Authors' Contributions

Sameh Abdelkhalik Ahmed contributed to the conception and the design of the study and analysis and interpretation of the data. Also, he drafted the manuscript and approved its final version.

Amr Ahmed Magdy helped in collection and interpretation of the data, revised the final manuscript, and approved it.

Mohammad Ali Abduallah helped in data collection and analysis. Also, he drafted the manuscript and approved its final form.

Amr Arafa Albadry contributed to the study conception and design. Also, he helped in collection and analysis of the data. Moreover, he revised the manuscript and approved its final version.

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