

Efficacy and safety of pulsed radiofrequency and steroid injection for intercostobrachial neuralgia in postmastectomy pain syndrome - A clinical trial

ABSTRACT

Background: Breast cancer is a common neoplastic tumor in women, and the postmastectomy pain syndrome has been reported frequently after surgical treatment. The injury of the intercostobrachial nerve is considered the major cause of this type of pain.

Purpose: Evaluation of efficacy and safety of pulsed radiofrequency (PRF) and steroid injection on the 2nd and 3rd thoracic (T2 and T3) dorsal root ganglions (DRGs) for intercostobrachial neuralgia (ICBN) postmastectomy.

Patients and Methods: This study was conducted on 100 patients with ICBN postmastectomy. The PRF waves were applied for 120 s twice on T2 and T3 DRGs then 1 ml of 4 mg dexamethasone and 1 ml of bupivacaine 0.25% were injected at each level then the technique was repeated three times 1 week apart for each patient.

Results: After 6 months from the latest intervention, the mean of visual analog scale dropped from 7.48 to 4.7 ($P = 0.005712$) and the mean of the quality of life scale improved to 6.88 after being 4.66 ($P < 0.00001$) before the intervention and 64.68% of the patients decided that they would certainly repeat the procedure if they could go back in time and 66.64% would certainly recommend the same procedure to a family member. The analgesics consumption decreased mainly in the 1st month but increased again after 6 months (not significant). No serious complications were recorded.

Conclusions: PRF and steroid injection on T2 and T3 DRGs assumed an effective and safe method for ICBN postmastectomy treatment.

Key words: Dorsal root ganglions; intercostobrachial neuralgia; neuropathic pain; postmastectomy pain syndrome; pulsed radiofrequency

Introduction

Our purpose is an evaluation of efficacy and safety of pulsed radiofrequency (PRF) and steroid injection on the 2nd and 3rd thoracic (T2 and T3) dorsal root ganglions (DRGs) for intercostobrachial neuralgia (ICBN) postmastectomy.

Breast cancer is the most common malignancy worldwide for females and the 2nd most common malignancy overall, according to the universal incidence of cancer.^[1,2] In Egypt, the breast cancer is the most common malignancy among

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Egyptian females and represents 29% of National Cancer Institute (NCI) cases.^[3]

Most patients with breast cancer are treated surgically, and many cases reported a persistent pain related to this treatment, such as postmastectomy pain syndrome. Although the development of the pain is multifactorial, injury of the intercostobrachial nerve is the major cause of this type of pain.^[4]

Patients who are suffering from ICBN usually presented with sharp, shocking pain along the nerve distribution (the axilla and the medial side of the arm) and rarely resolve spontaneously or even by conventional analgesics. It occurs in 18%–50% of patients post mastectomy, and can seriously influence the postoperative quality of life for patients with breast cancer.^[5,6]

PRF is an alternative therapeutic technique that has recently been developed and used by pain practitioners as a minimally invasive technique for relief of chronic pain without radiofrequency thermal injury.^[7]

Regarding the transforaminal epidural steroid injection for radicular pain, most investigators believe that the main benefits of epidural steroids are their anti-inflammatory effect, which is obtained from inhibition of phospholipase A2 enzyme beside their neurolytic effects on unmyelinated C-fibers.^[8,9]

Patients and Methods

This is a clinical trial registered under the number MD2010014033.3. This clinical trial was held at the NCI, Cairo University from April 2015 to February 2017 after institutional review board approval and consents were signed by patients before being recruited into the study. One hundred patients with ICBN postmastectomy were selected from the pain clinic according to the following criteria:

Inclusion criteria

Patients between 18 and 65 years, who are suffering from the postmastectomy ICBN and the pain was refractory in its character in spite of receiving the therapeutic doses of morphine sulfate (MST) and pregabalin.

Pain defined as refractory, regardless of etiology, when:^[10]

- Failure of treatment goals achievement in spite of using multiple evidence-based biomedical therapies and modalities in proper and acceptable fashion
- Psychosocial disorders that could seriously influence pain outcome measures have been assessed and appropriately addressed.

Exclusion criteria

The bleeding tendency, local infection at the site of the intervention, psychological disorders, disturbed anatomy (congenital, traumatic, and postsurgical), which increase the intervention difficulty, allergy to used medication (local anesthetics and contrast) and inability to lie comfortably during the intervention as the cardiopulmonary distress.

Description of interventions

Patients were lying prone on radiolucent table (after American Society of Anesthesiologists ASA standard monitoring, IV access and sterilization) then through the true posterior-anterior view of C-arm, ribs are accurately counted from cranial to caudal to determine the level of T2 and T3 vertebrae.

By moving the C-arm slightly cephalic, the lower end plates of T2 and T3 were being aligned just as one line then the C-arm were turned obliquely from 5° to 15° toward the ipsilateral side to expose the intervertebral foramen.

After marking an entry point within the safe triangle^[11] 1% lidocaine is utilized for local anesthesia to steer the Baileys radio frequency (RF) 22G, 10 cm, curved, sharp needles with 10 mm active tip to face the T2 and T3 DRGs using a tunnel vision technique guided by C-arm fluoroscopy.

We confirmed the latest position of the needles by the C-arm fluoroscopy after injection of 0.2–0.4 ml of nonionic contrast then the sensory and motor stimulations were done by the RF generator to get sensory paresthesia along T2 and T3 dermatomes at 0.4–0.8 V and intercostal fasciculation were obtained at double the sensory amplitude [Figures 1-4].

The PRF course was carried out at 42°C for 120 s twice at the same session followed by injection of 1 ml bupivacaine 0.25% + 1 ml dexamethasone 4 mg in a total volume of 2 ml at each level. The PRF course and steroid injection repeated once weekly for 3 consecutive weeks.

Aftercare, we transferred all patients to a recovery room to make sure of hemodynamic stability.

Patients on discharge were instructed to call us urgently if they developed any complications as intense pain, neurological deficits, moderate to high fever >38°C and evolving dyspnea or chest pain (i.e., pneumothorax have developed).

Duration of treatment and follow-up

The follow-up program was held along 6 months through regular scheduled visits after 1 week, 4 weeks, and 3 months

from the latest interventions to document the visual analog scale (VAS), the quality of life scale (QOLS), medications and side effects, then after 6 months for VAS, QOLS, medications, side effects, and patient satisfaction documentation.

Primary outcome measures

- Pain intensity post procedures according to VAS
- MST and pregabalin consumption post procedures.

Secondary outcome measures

- Impact of the pain reduction on the patient’s quality of life according to QOLS
- Degree of patient’s satisfaction, which was assessed by two questions. The two questions were: “If you could go back in time, would you like to repeat the procedure?” and “Would you recommend the same procedure for a family member or a friend?” Answers were classified as: certainly, would repeat/recommend, probably would repeat/recommend, probably would not repeat/recommend and certainly would not repeat/recommend.^[12]

Statistical analysis

Categorical variables were assessed using the Chi-square. VAS, drug consumption and QOLS and were presented at the mean (standard deviation) and were analyzed using two-way analysis of variance with repeated measures. The pain scores were analyzed with VAS of pain through self-report, observational (behavioral), or physiological data. A $P < 0.05$ was considered statistically significant. SPSS version 24.0 for Windows software (SPSS, Inc, Chicago, IL, USA) was used to do the statistical analysis.

Results

One hundred patients enrolled in this study; only ninety-eight patients have completed the follow-up system since one of them refused to continue after the second intervention as she did not get satisfactory results and the other patient passed away before the last follow-up visit due to aggressive tumor complications.

Visual analog scale

The best results regarding VAS were after 1 month from the latest intervention [Tables 1-2]

Morphine sulphate and pregabalin consumption

The least doses of MST and pregabalin were recorded in the 1st and 3rd month's follow-up visits, which matched with the degree of pain reduction according the other used pain scoring scales [Tables 3-4] despite of insignificant results of pregabalin consumption (P not < 0.05) in all follow-up visits and MST in 3rd and 6th month's visits [Tables 5-6].

Table 1: Pre- and post-intervention follow up of pain score as regard visual analogue scale

	Preintervention	Postintervention follow-up			
		1 week	1 month	3 month	6 month
Mean±SD	7.48±1.46	5.01±2.61	3.26±2.37	4.44±2.8	4.7±2.88
Median	8	5	3	4	4

Postintervention follow-up of pain intensity among patients along 6 months (1 week, 1 month, 3 months, 6 months) regarding the VAS in comparison to the preintervention period. VAS: Visual analog scale; SD: Standard deviation

Table 2: T- and P- value calculated for visual analog scale at different follow-up stages

VAS	Hypothesized mean	t	P	Results
After 1 week	5.5	-1.868	0.032344	Significant at $P < 0.05$
After 4 weeks	5.5	-9.409	<0.00001	Significant at $P < 0.05$
After 3 months	5.5	-3.772	0.000139	Significant at $P < 0.05$
After 6 months	5.5	-2.579	0.005712	Significant at $P < 0.05$

T - value: In statistics, the t-statistic is the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error, P - value: clinical experiment or epidemiological study, given that the null hypothesis is true. calculated for VAS at different follow-up stages (1 week, 1 month, 3 months, 6 months) to determine the significant results. VAS: Visual analog scale

In the 6th month visit the mean of both MST and pregabalin started to build up again. [Tables 3-4].

Quality of life scale

The mean much improved up to the 6th month visit when the P values were statistically significant in all follow-up visits ($P < 0.00001$) [Tables 7-8].

Patient satisfaction

Regarding the question “If you could go back in time, would you like to repeat the procedure?” 64.68% certainly would repeat it, 14.7% probably would, 1.96% probably would not and 16.66% certainly would not.

Regarding the question “Would you recommend the same procedure to a family member or friend?” 66.64% certainly would recommend it, 13.72% probably would, 4.9% probably would not and 12.74% certainly would not.

Complications

Pain at the site of needling was the most common complication recorded by 60% of patients, which was controlled by nonsteroidal anti-inflammatory drugs for a few days postintervention and the patients assumed that it was a mild pain in comparison to the original pain and totally different in its character and site. Eleven diabetic patients (out of 24 patients) showed mild to moderate elevation of blood glucose level and were controlled

Table 3: Pre- and post-intervention follow-up of morphine sulfate consumption

	Preintervention	Postintervention follow-up			
		1 week	1 month	3 month	6 month
Mean±SD	142.3±49.32	141.92±49.42	121.7±45.29	126.24±50.12	140.14±51.98
Median	150	150	120	120	150

T - value: In statistics, the t-statistic is the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error, *P* - value: clinical experiment or epidemiological study, given that the null hypothesis is true. SD: Standard deviation; MST: Morphine sulfate

Table 4: Pre- and post-intervention follow up of pregabalin (mg) consumption

	Preintervention	Postintervention follow up			
		1 week	1 month	3 month	6 month
Mean±SD	234.5±66.93	232.83±66.69	218.84±69.07	224.19±70.56	237.5±69.8
Median	200	200	200	200	300

T - value: In statistics, the t-statistic is the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error, *P* - value: clinical experiment or epidemiological study, given that the null hypothesis is true. SD: Standard deviation

Table 5: *T*- and *P*- value calculated for morphine sulfate at different follow-up stages

MST	Hypothesized mean (mg)	<i>t</i>	<i>P</i>	Results
After 1 week	132.3	1.936715	0.02783	Significant at <i>P</i> <0.05
After 4 weeks	132.3	-2.26891	0.012793	Significant at <i>P</i> <0.05
After 3 months	132.3	-1.11564	0.13388	Not significant at <i>P</i> <0.05
After 6 months	132.3	1.27115	0.103942	Not significant at <i>P</i> <0.05

T - value: In statistics, the t-statistic is the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error, *P* - value: clinical experiment or epidemiological study, given that the null hypothesis is true. MST: Morphine sulfate

Table 6: *T*- and *P*- value calculated for pregabalin at different follow-up stages

Pregabalin	Hypothesized mean (mg)	<i>t</i>	<i>P</i>	Results
After 1 week	228	0.7204	0.236496	Not significant at <i>P</i> <0.05
After 4 weeks	228	-1.3197	0.095008	Not significant at <i>P</i> <0.05
After 3 months	228	-0.5202	0.302078	Not significant at <i>P</i> <0.05
After 6 months	228	1.2474	0.107877	Not significant at <i>P</i> <0.05

T - value: In statistics, the t-statistic is the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error, *P* - value: clinical experiment or epidemiological study, given that the null hypothesis is true

Table 7: Pre- and post-intervention follow up of quality of life quality of life scale

	Preintervention	Postintervention follow up			
		1 week	1 month	3 month	6 month
Mean±SD	4.66±1.95	6.44±2.22	7.52±2.13	6.88±2.35	6.88±2.4
Median	5	7	8	8	7

T - value: In statistics, the t-statistic is the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error, *P* - value: clinical experiment or epidemiological study, given that the null hypothesis is true. SD: Standard deviation; QOLS: Quality of life scale

Table 8: *T*- and *P*- value calculated for quality of life scale at different follow-up stages

QOLS	Hypothesized mean	<i>t</i>	<i>P</i>	Results
After 1 week	5.5	4.235292	2.6E-05	Significant at <i>P</i> <0.05
After 4 weeks	5.5	9.412207	<0.00001	Significant at <i>P</i> <0.05
After 3 months	5.5	5.830557	<0.00001	Significant at <i>P</i> <0.05
After 6 months	5.5	5.683071	<0.00001	Significant at <i>P</i> <0.05

T - value: In statistics, the t-statistic is the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error, *P* - value: clinical experiment or epidemiological study, given that the null hypothesis is true. QOLS: Quality of life scale

medically by their internal medicine physician with no hazards. Two patients reported insomnia on the day of intervention, but it did not last and it may be occurring due to patient's obsession about the results. Only one patient reported fever on the night of intervention of unknown etiology and was controlled by

paracetamol tablets and cold packs, and it did not last more than this night and only one patient complicated by a vasovagal attack during intervention, which was controlled by 0.5 mg atropine intravenous. No neurological deficits or pneumothorax reported.

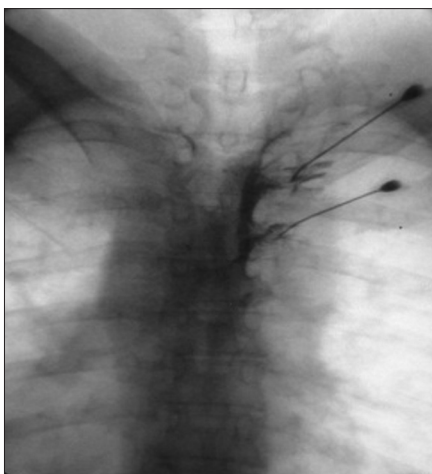


Figure 1: Antero-posterior view of the latest position of the radio frequency needles after injection of nonionic contrast. The needles appear below the pedicles and the contrast diffused to the epidural space through transforminal approach

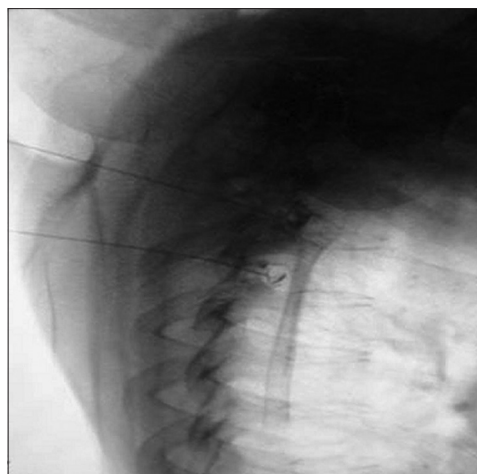


Figure 2: Lateral view of the latest position of the radio frequency needles after injection of nonionic contrast. The needles appear within the 2nd and 3rd Thoracic foramens



Figure 3: Antero-posterior view of the final position of radio frequency needles (below 2nd and 3rd thoracic pedicles) before nonionic contrast injection

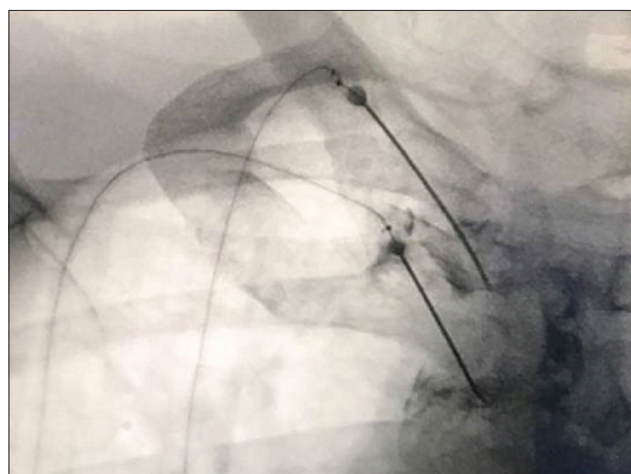


Figure 4: Antero-posterior view of the final position of radio frequency needles (below 2nd and 3rd thoracic pedicles) after nonionic contrast injection

Discussion

Due to the difficulty of the neuropathic pain (NP) management by the medical treatment, other algorithms or protocols development for minimally invasive pain relief interventions was a must. These interventions are involving ablation/modulation of targeted nerves or delivery of drugs into targeted areas.^[13,14]

The NP Special Interest Group published an article in 2013 in the Pain Journal about this recommended interventions. This article has many studies that tested the therapeutic effect of the PRF on the DRGs for the NP control and the results were remarkable about the pain intensity, drug consumption and thus improving patient's quality of life.^[13]

In 1974, the RF current application on sensory fibers began through a study which used conventional RF to create a thermal nerve lesion on trigeminal nerve for the trigeminal neuralgia treatment.^[15] PRF was innovated by modulation of the continuous RF (CRF) that delivers a current in short (20 ms) high voltage bursts that followed by silent phases (480 m sec) which allow for heat dissipation, keeping the target tissue controlled below 42°C to avoid nerve tissue destruction, neuritis, deafferentation pain and neurological deficits. Therefore, we can repeat it for long-term relief of pain.^[7,16]

Regarding the epidural steroid injection we preferred the transforminal approach through "Safe triangle" than interlaminar approach due to many beneficial purposes (a) to target the DRGs specifically, (b) direct anterior epidural access, (c) less risk of inadvertent dural puncture and

finally (d) demonstrated more therapeutic value in treating chronic radiculopathy.^[17]

The meta-analysis of 11 controlled studies which were published by Stafford *et al.* established a significant improvement for the sciatic pain (peripheral NP) in patients with lumbar disc herniation after epidural steroid injection in short-term (1–60 days) and for long-term (12 weeks to 1 year).^[18]

From the fact that the intercostobrachial nerve is originated from the second intercostal nerve laterally or from the third one in sometimes or both of them,^[19] we conducted our study on segmental DRGs T2 and T3.

From the previous mentioned results of our study, which we will discuss in details, we assumed that PRF and transforaminal epidural steroid injection on T2 and T3 is an effective technique for long-term pain relief of ICBN as more than 50% of patients reported significant improvement of pain for 6 months ($P = 0.0000096$).

These results are matching with the recently published data, such as a recent double-blind randomized controlled trial which compared the effect of PRF on the segmental DRGs, which responsible for the pain, once per week for 3 weeks to a sham group in 96 patients with postherpetic neuralgia PHN affecting the thoracic dermatomes. Postprocedure pain intensity scores and opioids (tramadol) consumption were decreased and the patient's quality of life score was also much improved through 6 months after treatment in the PRF group compared to the sham group.^[20]

Simopoulos *et al.* study also claimed that the average duration of successful analgesic response of PRF on DRGs in patients with chronic lumbar radicular pain was 3.18 months (± 2.81).^[21]

We repeated the PRF and steroid injection for each patient three times with one week apart as Ke, *et al.* study who repeated the PRF three times on the segmental DRGs in PHN treatment since the beneficial effects may be attributed to poststimulation action of PRF.^[20]

Most patients in our study (>90%) reported dramatic response to the injection for a few hours (ranged from 3 to 8 h) up to one day in some patients (<10%) but the pain relapsed again in more than 60% of patients who got pain relief, then gradually decreased again along the 1st week from the last intervention. This pain reduction occurs mostly due to cutoff the pain vicious cycle by the local anesthetics and the placebo effect of the

maneuver in our patients who were suffering from chronic persistent pain for a long period.

The mean of the VAS dropped from the 1st week, but mainly in the 1st month postintervention and this improvement was maintained for 6 months from the intervention. All results were significant as the P value (<0.05).

The most accepted explanation for these results after 1 week is the transforaminal epidural steroid effect as most of the studies suggest that the effect of PRF for pain relief may take up to several weeks to prove a full effect, and the onset is usually subtle, becoming progressively better. Sluijter^[22] divided the postoperative observational period after PRF procedure into four phases and found that the second phase associated with the highest postprocedure discomfort, which lasted up to 3 weeks.

Summation of steroids and PRF beneficial effects were the cause of the 1st month results. The results of the rest of the follow-up program mostly carried out by the PRF after the gradual limitation of steroid role, which also matches the analgesic duration of PRF as mentioned before in the earlier studies.

In the 1st visit of patients after 1 week after the latest intervention, we prescribed the same preintervention doses of the MST and pregabalin or slightly decreased them in some patients, who had a dramatic response to assess the patients carefully and give a chance to cut the doses gradually, while gradual improvement, considering the conceptual patient's fear of the recurrence of pain. Then, we started to decrease the doses in patients who reported a satisfactory pain reduction and the least doses recorded in the 1st and 3rd months follow-up visits, which matched with the degree of pain reduction according to the other used pain scoring scales despite of insignificant results of pregabalin consumption (P not <0.05) in all follow-up visits and MST in 3rd and 6th months.

In the 6th month visit, the mean of both MST and pregabalin (P not <0.05) started to build up again, which was explained by some patients increasing their home medication doses when the pain intensity started to build up again and some of them were afraid of the pain relapse after a reasonable period of pain relief.

In our study, 64.68% of the patients certainly would like to repeat the procedure if the time goes back, 66.64% certainly would recommend it for a friend or family member.

Silva Junior *et al.* reported their results about the patient's satisfaction after PRF on segmental DRGs for chronic pain as

82% of them said that they would repeat the procedure again as initially proposed and 87% of them would recommend the procedure to a friend or a relative.^[11]

The QOLS results were much improved, after 1 month from the latest intervention which was maintained up to 6 months, when the *P* values were significant in all follow-up visits ($P < 0.00001$).

Many studies have tried to test the efficacy of PRF results on patient's quality of life as Ke *et al.* who documented that there was a significant improvement of patient's quality of life in patients with intercostal PHN treated with PRF on segmental DRGs.^[20] Manolitsis and Elahi also assumed that PRF for occipital neuralgia treatment much improved the quality of life.^[23]

O'Connor AB published an article in *Pharmacoeconomics* journal about the impact of the NP on patient's quality of life under the name "NP: Quality-of-life impact, costs and cost-effectiveness of therapy." Reviewing of this article indirectly explain why patients who got a significant pain reduction reported that they got a new life.^[24]

As mentioned before in our results, only simple controllable complications were detected from our technique with no evidence of serious.

In 2011, Karaman *et al.* conducted a study to check the transforaminal steroid complication on 562 patients who underwent 1305 times transforaminal lumbar epidural steroid, which revealed that the overall incidence of vascular penetration encountered was 7.4% but no major complications occurred. The total incidence of all minor complications was 11.5%. The most common minor complication was a vasovagal reaction (8.7%), but all of other complications were transient and not serious.^[25]

Conclusion

PRF and steroid injection on T2 and T3 DRGs assumed an effective and safe method for ICBN post mastectomy treatment with significant pain reduction and improvement of patient's quality of life which achieves patient's satisfaction.

The limitation and recommendation of our study are, despite the widely use of the PRF in the clinical practice for NP control, the ideal parameter of it have not well-determined unlike the thermal radiofrequency. Limited number of patients and absent control group is another limitation, so further research with larger patient populations from multiple health centers is a must. Finally, the 6 months follow-up program might not have been

enough time to detect the long-term effects of the PRF for NP management.

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Conflicts of interest

There are no conflicts of interest.

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