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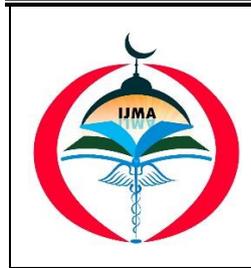
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Original Article

Pregabalin versus Pulsed Radiofrequency of Dorsal Root Ganglion for Treatment of Chronic Post Thoracotomy Pain Syndrome

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ABSTRACT

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Background: After thoracotomy surgery, 50% of patients suffer chronic pain, which interferes with their day life activities and decrease their quality of life. The primary purpose of this research was to investigate the effects of oral Pregabalin and dorsal root ganglion [DRG] pulsed radiofrequency [RF] in the treatment of chronic post-thoracotomy pain [CPTP]. In addition, evaluation of the degree of neuropathic pain, the requirement for rescue analgesia and the total amount of paracetamol and piroxicam administered are secondary aims.

Patients and Methods: Thirty participants were divided into two equal groups. Group **A** received oral Pregabalin with a dose ranging from 75 to 300 mg twice daily. Group **B** was subjected to pulsed RF of DRG. Visual analogue scale [VAS] score, Leeds Assessment of Neuropathic Symptoms and Signs scale [LANSS] score, the total amount of paracetamol and piroxicam used and side effects were assessed at 2 weeks, 1, 2 and 3 months, respectively. Patient satisfaction was assessed at the end of the study.

Results: The obtained results showed that VAS score was lower in the RF group than Pregabalin group with P values of 0.001, 0.006, 0.01 and 0.167 at 2 weeks, 1, 2 and 3 months, respectively. The RF group had a lower mean LANSS score at 2 weeks and 1 month, but the ratio was reversed at 2 and 3 months. The used total amount of paracetamol and piroxicam were lower in the RF groups. In addition, patients in the RF group developed hypoesthesia in the corresponding dermatome, while in the Pregabalin group suffered dizziness, somnolence and balance disorders. At the end of the study, patients were more satisfied with RF treatment compared to Pregabalin one.

Conclusion: Patients treated with pulsed RF had significant reduction in pain scores, less rescue analgesia consumed, tolerable side effects and were more satisfied with the treatment modality as compared to Pregabalin treated patients.

Keywords: Chronic Post-Thoracotomy Pain, Pregabalin, Pulsed Radiofrequency.



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INTRODUCTION

Chronic post-thoracotomy pain [CPTP] is regarded as one of the most severe types of chronic postsurgical pain. The prevalence of CPTP among patients who have had a thoracotomy is 50%, although severe pain is only seen in 3% to 18% of instances [1]. The presence of a pain at the site of the thoracotomy scar is the most common symptom [1, 2]; however, it may also be referred to the pectoral region, the arms, the shoulders and the scapula [3].

The character of the pain is variable; it may be cutting, drawing [4] or neuropathic pain with burning, sharp and dysesthetic character. According to the International Association for the Study of Pain, roughly 45 % of patients with CPTP have neuropathic symptoms [1]. The pain may also be continuous or intermittent, increased by movement [1], lifting a heavy object, or a sudden change in weather [2,3].

Postoperative pain is caused by surgical trauma to the intercostal nerve, either directly or indirectly via stretch and compression. This induces neuroinflammation at the site of surgical wound. Prolonged neuroinflammation and neural plasticity are two interrelated simultaneously occurring mechanisms that contribute to the development of chronic pain [5]. Management of chronic post-thoracotomy pain, like any pain condition, should begin with prevention. Preventive strategies include multimodal peri-operative analgesia; either pharmacological agents, thoracic epidural analgesia, paravertebral blocks or intercostal nerve blocks [6].

The first step in treating CPTP is to determine the kind and source of the pain, as well as to rule out tumor recurrence or other reversible illnesses [e.g., lung herniation or occult rib fracture]. Treatment for CPTP is pharmacologic, with first-line drugs such as tricyclic antidepressants, serotonin-norepinephrine re-uptake inhibitors and gabapentinoids being used. Second-line treatments include the administration of topical lidocaine, capsaicin and weak opioid analgesics [tramadol]. Furthermore, strong opioids [oxycodone, morphine] and subcutaneous botulinum toxin injections are used as third-line therapies. Other treatments for CPTP include transcutaneous electrical nerve stimulation, acupuncture, nerve blocks and pulsed radiofrequency neurolysis for the intercostal nerve or dorsal root ganglion, as well as cryoneurolysis for the intercostal nerve [7]. There is currently no gold standard treatment or intervention for CPTP syndrome that has been proven to be effective as a single therapeutic modality; therefore, more clinical trials are needed in order to paving the way to concise guidelines of such illness.

The study's primary purpose was to examine the effects of oral Pregabalin with DRG RF in the treatment of CPTP. The determination of degree of neuropathic pain, the necessity for rescue analgesia and the total amount of paracetamol and piroxicam utilized are all secondary aims.

PATIENTS AND METHODS

This randomized clinical trial was carried out at Mansoura University Hospitals. The study included thirty patients of both sexes, having age between 20 and 60 years old. The selection of patients was performed based on the American Society of Anesthesiologists physical status [ASA] I, II, and III, and underwent elective or emergent open thoracotomy surgeries. Patients who were eligible had a persistent pain score of ≥ 5 on the VAS for three months or more and had not responded to paracetamol 500 mg every 12 hours for two successive weeks. The clinical portion of the trial took place from January 1st to June 1st, 2019, after being approved by Mansoura University's Institutional Research Board [IRB] with the a code number of MS/17.12.159. It was registered to Clinical Trials.gov with registry number of NCT03942796. Before being assigned to the trial, each patient signed an informed written consent form. Patients with coagulopathy, uncooperative patients, ASA IV patients, patients receiving opiate medication, patients with impaired conscious level, and patients with recurrent malignancy were all excluded from the trial. Eligible patients were randomly selected using simple random sampling method and patients were assigned by a computer-generated randomization table using the Statistical Package of Social Sciences [SPSS] version 21 for Windows [SPSS, 2016, Inc., Chicago, IL, USA] to select number of patients within each group; thereafter, group assignments were concealed in sequential number sealed opaque envelopes into 2 equal groups as follows:

- Group A [n=15] received oral pregabalin 75 mg twice daily, and the dose was titrated weekly up to 600 mg per day following a flexible dose titration regimen [8].
- Group B [n=15] received fluoroscopic guided pulsed RF of the DRG at the level of the thoracotomy incision.

Patients in both groups were continuing their treatment on paracetamol 500 mg/12 hours. All patients in group A initiated oral treatment by 150 mg as a total daily dose, which was the titrated weekly to 300mg, 450mg, with a maximum of 600mg daily dose based on patient response and tolerance [8]. All patients in group B received pulsed RF in the operating theatre at Mansoura University Hospital under fluoroscopic monitoring. The patient's pulse, blood pressure and oxygen saturation were continuously monitored, during and for an hour after the procedure. A 22 Gauge intra-venous cannula was inserted and secured, and the patients were administered conscious sedation with midazolam 10-50 mcg/kg [dose range 0.5-4 mg] and fentanyl 25-50 mcg/dose slow IV injection over 1-2 min for conscious sedation. The patient was positioned prone with the C-arm set cephalocaudal until the thoracic intervertebral disc endplates were lined. Then the image intensifier was tuned obliquely from 5 to 15 degree towards the ipsilateral side to expose the intervertebral foramen [subpedicular foramen or safe triangle]. The RF needle tip was inserted in a slightly medial and cephalic direction under the transverse

processes and it was gradually advanced into the thoracic intervertebral foramen using a lateral fluoroscopic imaging. Test stimulation was carried out at 50 Hz, and the point of maximum stimulation pointed the site of the DRG. Then, Omipaque contrast dye was injected to confirm the site of DRG. Once needle position was adjusted, 2 ml of lidocaine 2% were injected, and pulsed RF was performed using [Neuro Therm TM 1100] using the following settings: 2-Hz frequency, 20-ms pulses in a 1-second cycle, 2 minutes' duration and 42°C temperature, repeated 3 times i.e., 6 minutes. Impedance ranges between 150 and 250 Ohms at all levels. Patients with VAS score > 3 after reaching the maximum tolerable dose of pregabalin, or after 2 weeks of pulsed RF were given an oral dose of paracetamol [500 mg] every 6 hours with a maximum dose of 4 gm daily, and patients with persistent VAS score > 3 were administered an oral dose of piroxicam 10 mg every 12 hours with a maximum daily dose of 40 mg. The number of patients who needed rescue analgesia and the total amount of paracetamol and piroxicam were calculated. The study's primary endpoint is the change in the severity of pain as measured by VAS score from 0 to 10. The patient was asked to rate the severity of the pain on a scale of 0 to 10, with 0 representing no pain and 10 being the most severe pain. The secondary outcome measure is the change in the severity of neuropathic symptoms as measured by the LANSS score. The questionnaire consists of 7 items which are summarized to one summary score with a scaling range between 0 and 24. Scores ≥ 12 indicate probable neuropathic pain [9]. The number of patients who needed rescue analgesia, the total amount of paracetamol and piroxicam used, and the number of patients who developed side effects of treatment, like dizziness, somnolence, imbalance, nausea, constipation, edema, increased appetite, local hypoesthesia and pneumothorax were also recorded at 2 weeks, 1, 2 and 3 months following the treatment. Patients were asked to rate their treatment on a scale of 5-Excellent, 4-Very Good, 3-Good, 2-Fair, and 1-Poor at the end of the three-month follow-up period [10]. The physician collecting data was blinded and unaware of group allocation.

Sample size calculation:

The sample size was calculated using the success rate of medical treatment in relieving pain in patients with post-thoracotomy pain syndrome, as determined by the previous research [11]. The G power programme version 3.1.9.4 was used to calculate sample size based on predicted difference of 50% using 2-tailed test, error = 0.05, and power = 80.0 %, the total computed sample size was 15 in each group.

Statistical analysis:

Data were collected, revised, verified then analyzed using the SPSS version 21 software for Windows [SPSS, Inc., Chicago, IL, USA]. Mean and standard deviation [SD] were used for all quantitative normally distributed values, and/or number of cases while [%] was used for qualitative values. The distribution of tested variables was examined with Shapiro-wilk test for normality. The

significance of differences between continuous variables was determined with independent samples t- test for parameters with normal distribution and Mann Whitney U test for non-normally distributed data. Chi- square or Fisher exact test were used for comparison between qualitative variables, as appropriate. Univariate analysis was performed to define significant factors that affect response; thereafter, significant factors were subjected to a multivariate logistic regression model. All statistical analyses in this study were considered significant if the *P* value was < 0.05.

RESULTS

Thirty patients, ranging in age from 20 to 60 years old, were randomized to receive either oral pregabalin therapy with a flexible dose titration regimen or fluoroscopic guided pulsed RF of DRG at the level of the thoracotomy incision [Figure 1]. The following table summarizes the patient demographics and surgical incision types [Table 1].

Age, sex, duration of symptoms and type of incision were homogeneous between the two groups. The mean VAS scores of the RF treated group of patients were significantly lower than the PG group at 2 weeks, 1 month and two months of treatment with *P* values of 0.001, 0.006 and 0.01, respectively. At a three-month interval, the mean VAS score was likewise lower in the same group, although the difference was not statistically significant [*p*=0.167] [Figure 2].

The mean LANSS scores of the RF-treated group of patients were lower than the PG treated group at 2 weeks and 1 month of treatment with *P* values of < 0.01 and 0.11, respectively. In addition, the mean LANSS scores were lower in pregabalin treated patients at two and three-month of treatment with *P* values of 0.2 and 0.04, respectively [Figure 3]. The number of patients who needed rescue analgesia in the RF treated was significantly lower than PG group at one, two and three months of treatment with *P* values of 0.02, 0.001 and 0.001, respectively [Table 2].

The total amount of paracetamol and piroxicam consumption was significantly higher in the pregabalin group at two and three months compared with the RF one [Table 3].

The dose titration protocol for all pregabalin-treated patients was guided by the response and adverse events [Table 4]. Nine individuals were unable to tolerate the maximum dose of pregabalin due to dizziness and somnolence, four patients had musculoskeletal balance problems, and five patients had gastrointestinal manifestation. Three of the RF-treated patients developed hypoesthesia in the corresponding dermatome [Table 5].

Patient satisfaction assessments at the end of the three-month follow-up period showed that RF patients had better results, but these differences were not statistically significant [Table 6]. The current study evaluated 6

probable predictors of response at the end of the follow-up period rather than the treatment strategy itself. Those predictors were: Age, sex, and the duration of symptoms, type of surgical incision, basal VAS, and LANSS scores. Only the basal VAS score was shown to be significance in predicting the response. Based on the previously

discussed univariate logistic regression analysis, Bi-variate logistic regression model was constructed using the basal VAS score and modality of treatment either pregabalin or RF as independent predictors of response [Table 7].

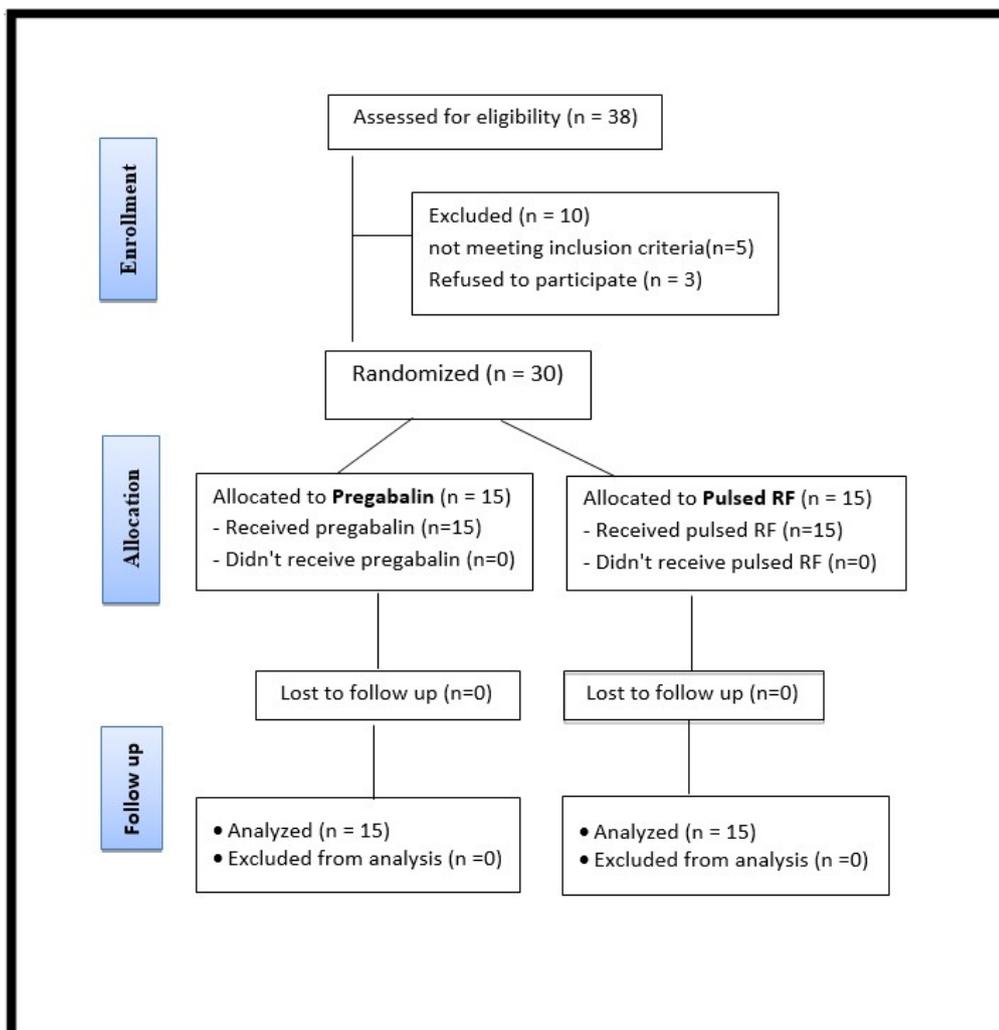


Figure [1]: CONSORT flow diagram

Table [1]: Demographic and clinical data in the studied groups

		Group A [n= 15]	Group B [n= 15]	P value
Age [Years]		45.27 ± 12.37	44.73 ± 14.24	0.92
Sex	Male	6 [40]	7 [46.7]	0.71
	Female	9 [60]	8 [53.3]	
Symptom duration [Month]		8.53 ± 2.44	7.33 ± 3.03	0.24
Incision	Antero-lateral	1 [6.7]	2 [13.3]	0.54
	Posterolateral	14[93.3]	13 [86.7]	

Group A = Pregabalin group, group B = pulsed radiofrequency group. Data are expressed as mean and standard deviation or median and range [minimum-maximum].

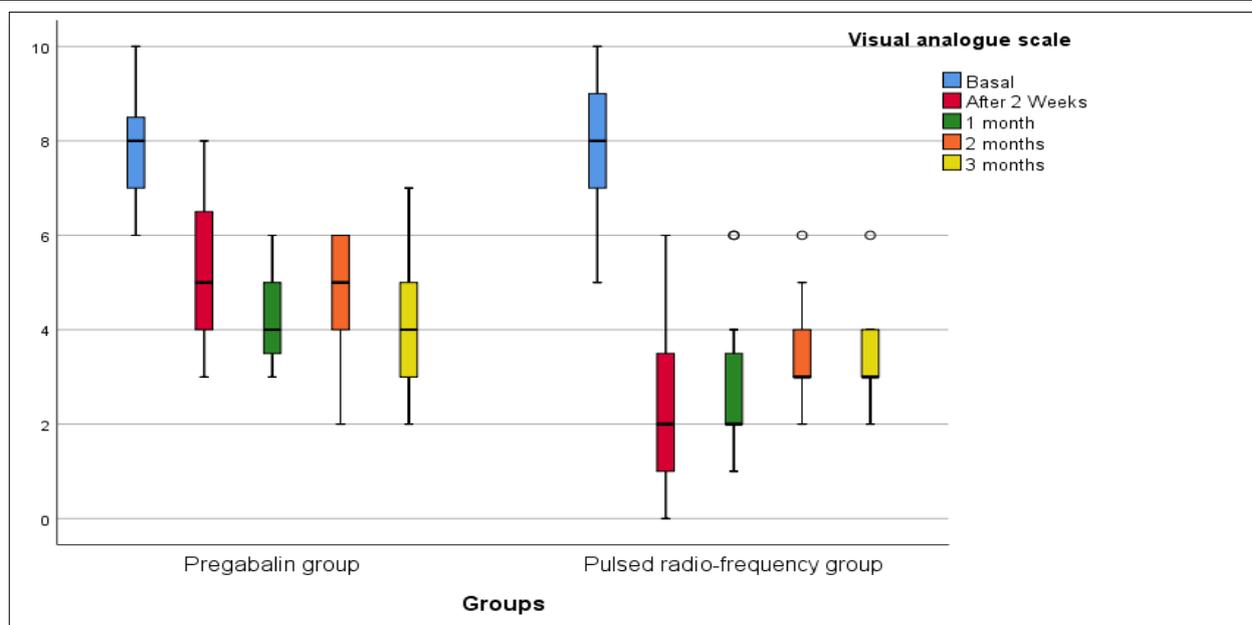


Figure [2]: Box & Whisker plot showing median Visual analogue scale [VAS] score [0-10] in the studied groups. Mann Whitney U test was used to compare between studied groups. Data are expressed as median and range [minimum-maximum] with higher median VAS score is detected among Pregabalin group.

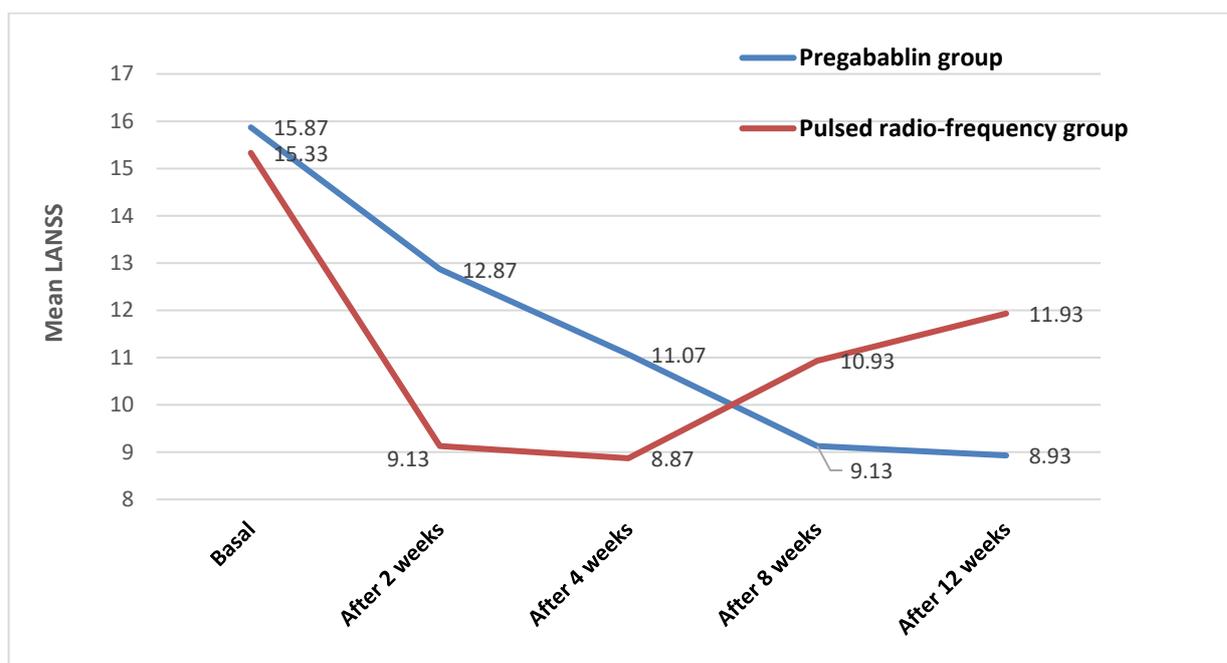


Figure [3]: line graph showing mean LANSS in the studied groups. Student t test was used to compare between studied groups. Data are expressed as mean and standard deviation.

Table [2]: The number of patients needed rescue analgesia in the studied groups

Time	Group A [n= 15]	Group B [n= 15]	P value
Two weeks	0[0%]	5 [33.3%] *	0.02
One month	11 [73.3%]	5 [33.3%] *	0.02
Two months	13[86.7%]	6 [40%] *	0.001
Three months	13 [86.7%]	6 [40%] *	0.001

* P values <0.05 is statistically significant compared to group A. Group A = Pregabalin group, group B = pulsed radiofrequency group. Data are expressed as number and percentage.

Table [3]: The total amount of paracetamol [gm/day] and piroxicam [mg/day] used in the studied groups

Time	Group A [n=15]	Group B [n=15]	P value
Paracetamol: Two weeks	1 [1-1]	1 [1-2] *	0.016
One month	2 [1-3]	2 [1-4]	0.421
Two months	4[1-4]	1 [1-4] *	0.023
Three months	4 [1-4]	1 [1-4] *	0.01
Piroxicam: Two weeks	0 [0-0]	0 [0-0]	1.0
One month	0 [0-10]	0 [0-0]	0.317
Two months	10 [0-30]	0 [0-20] *	0.028
Three months	30 [0-40]	0 [0-40] *	0.047

* P values <0.05 is statistically significant compared to group A. Group A = Pregabalin group, group B = pulsed radiofrequency group. Data are expressed as median and range [minimum-maximum].

Table [4]: The number of patients received titrated doses of pregabalin in Group [A] during the study period.

Time/dose	150 mg/d	300 mg/d	450 mg/d	600 mg/d
One week	15 [100%]	0 [0%]	0 [0%]	0 [0%]
Two weeks	0 [0%]	1 [6.7%]	14 [93.3%]	0 [0%]
Three weeks	0 [0%]	5 [33.3%]	3 [20%]	7 [46%]
One month	0 [0%]	5 [33.3%]	7 [46%]	3 [20%]
Two months	0 [0%]	5 [33.3%]	7 [46%]	3 [20%]
Three months	0 [0%]	5 [33.3%]	7 [46%]	3 [20%]

Group A = Pregabalin group. Data are expressed as number and percentage.

Table [5]: The incidence of side effects in the studied groups

Adverse effects	Group A [n=15]	Group B [n=15]
Hypoesthesia	0 [0%]	3 [20%]
Somnolence	5 [33.3%]	0 [0%]
Dizziness	4 [26.7%]	0 [0%]
Balance disturbance	3 [20%]	0 [0%]
Falling	1 [6.7%]	0 [0%]
Nausea	3 [20%]	0 [0%]
Constipation	2 [13.3%]	0 [0%]
Increased appetite	1[6.7%]	0 [0%]

Group A = Pregabalin group, group B = pulsed radiofrequency group. Data are expressed as number and percentage.

Table [6]: Patient satisfaction in the studied groups recorded at the end of the study

Response	Group A [n= 15]	Group B [n= 15]	P value
Poor	6 [40%]	4 [26.7%]	0.84
Fair	3 [20%]	2 [13.3%]	
Good	3 [20%]	1 [6.7%]	
Very Good	2 [13.3%]	4 [26.7%]	
Excellent	1[6.7%]	4 [26.7%]	

Group A = Pregabalin group, and group B = pulsed radiofrequency group. Data are expressed as number and percentage.

Table [7]: Logistic regression in prediction of response in the whole study population

Variable	Coefficient [β]	P value	OR [95% CI]
Univariate logistic regression analysis			
Basal VAS	- 0.623	<0.04	0.43 [0.28- 1.02]
Bivariate logistic regression analysis			
Modality of treatment 0=Pregabalin; 1=Radiofrequency	1.92	0.04	6.83 [1.03- 45.29]
Basal VAS	- 0.84	0.04	0.43 [0.18- 0.98]
Constant	5.42	0.01	

DISCUSSION

Pregabalin and pulsed RF of the DRG are compared in this randomized controlled trial for the treatment of chronic post-thoracotomy pain. The rationale for selection of RF targeting dorsal root ganglion is that DRGs are the cornerstones of neuroinflammation and central sensitization pathway, responsible for the transition from acute to chronic pain. Also, pulsed RF uses lower temperature impulses and therefore avoids pain, neuritis-like reactions, motor deficits and thermal destruction of undesired tissues associated with high temperature thermal RF ablation. Another explanation is that RF is relatively simple, safe and feasible in thoracic regions and many of other neuropathic pain syndromes in the thoracic region responded well to this therapy ^[12].

During the three-month follow-up period, the pulsed RF treated group had lower mean VAS scores than the pregabalin group. Similarly, Cohen *et al* ^[13] went almost to similar findings, they have found that patients who underwent pulsed RF of the DRG had improved treatment outcomes 3 months post-procedure compared to patients who underwent treatment with medications alone or pulsed RF of the intercostal nerves in cases with CPTP. The mean LANSS score was below 12 in both groups. It was lower in the pulsed RF treated group at 2 weeks, 1 month and higher in the same group than in the pregabalin treated group at 2 and 3 months. These findings are consistent with previous study demonstrating that the beneficial effect of pulsed RF decreases with time ^[14].

The average duration of pain relief in patients with CPTP after pulsed RF of the DRG ranges from 2.5 to 12 months as observed by Cohen *et al.* ^[13]. Also, titrating the pregabalin dose according to the patient's tolerance and side effects can take up to a month ^[8].

The number of patients who needed rescue analgesia, the total amount of paracetamol and piroxicam used were higher in the pregabalin group than RF group. Nine patients could not tolerate the maximum dose of pregabalin due to dizziness and somnolence, 4 patients experienced musculoskeletal balance disturbance and 5 patients developed gastrointestinal manifestation. These findings are similar to those of a placebo-controlled study that included patients with post-herpetic neuralgia and diabetic peripheral neuralgia who were administered pregabalin or placebo. The rate of adverse events among patients who were randomized to flexible-dose pregabalin was 68.8%, 17% of them were excluded from the treatment due to intolerable side effects compared to 7.7 % in the placebo group ^[8].

Three patients from the RF treated group experienced hypoesthesia in the corresponding dermatome. Whereas RF-related side effects were self-limited and tolerable, the potential exists for more serious complications to occur. Potential complications include pneumothorax, spinal cord ischemic injury, bleeding, infection, nerve injury and burns ^[15].

In the current study, at the end of the 3 months follow up period, 53.4% of patients who underwent pulsed RF of the DRG rated the procedure as very good to excellent compared to 20% in the other group.

In agreement with these result, Pevzner *et al.* ^[16] followed 28 patients with radiculopathy for 12 months after pulsed RF of the DRG. At their 3-month follow-up period, 50% of patients rated their pain relief as either good or excellent. At their 6 and 12-month follow up visits, these percentages declined to 32% and 29%, respectively. In cases with CPTP, 69% of patients treated by pulsed RF for the DRG were satisfied by the treatment results compared to 33% in the patients given medical treatment for 3 months ^[13].

The immediate, single session pain relief in the RF group, the relatively tolerable side effects, the lower VAS and LANSS scores, and the less rescue analgesia needed can all be used to highlight the difference in patient satisfaction between the two groups. Another attempt has been offered using a logistic regression analysis to adjust for any confounding clinical factors that may affect patient response to treatment. Many risk factors for the severity and persistence of post-thoracotomy pain have been explored in the past literature ^[17, 18].

From the 6 chosen clinical and demographic predictors, lower basal pain score is the strongest predictive factor for good response to treatment. Bivariate logistic regression model was constructed combining the basal VAS score and modality of treatment either radiofrequency or pregabalin as predictors for response. Both had a statistically significant predictive impact for treatment response with higher odds of favorable clinical outcome and pain relief with RF.

Limitations of the study:

Our current study design has some limitations that will hopefully be addressed in future studies. First of all, this study was a single center study, and the number of patients was relatively small. Secondly, the nerve level of pulsed RF treatment was plotted and conducted according to the site of incision, without comparing it to multiple nerve level pulsed RF. Finally, the patients were randomly collected regardless of the surgical technique, intra-operative anesthetic management and postoperative analgesic regimen in the acute stage.

Conclusion:

In a three-month follow-up period, patients treated with pulsed RF of the DRG had significantly lower pain levels, less rescue analgesia consumption, had self-limited, tolerable side effects and were more satisfied with the treatment modality than pregabalin-treated patients.

Conflict of interests: None

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