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Standard Pulsed Radiofrequency Versus Super-Voltage Pulsed Radiofrequency Glossopharyngeal Nerve Therapy in Management of Oropharyngeal Cancer Pain: Randomized Clinical Trial

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Abstract:

Background: Pulsed radiofrequency (PRF) therapies are a safe substitute to neurolytic blocks. It involves applying a short PRF to neural tissues, resulting in a neuromodulatory impact without causing significant tissue damage. The objective of this study was to assess the effects of standard voltage PRF and super-voltage PRF on pain associated with glossopharyngeal nerve in patients with oropharyngeal cancer (OPC).

Methods: This randomized clinical study had been conducted on 60 participants aged from 18 to 70 years old, both genders, American Society of Anesthesiologists II, III physical status under pain management for OPC, visual analogue scale (VAS) ≥6 cm in spite medical treatment. Patients were divided into two equal groups: Group A: received super voltage PRF glossopharyngeal nerve block and group B: received standard voltage PRF glossopharyngeal nerve block.

Results: VAS was significantly lower at 3 weeks after procedure in group A contrasted to in group B (P <0.001). Morphine and gabapentin consumption were significantly lower in the post-procedure than pre-procedure. Morphine and gabapentin consumption were significantly lower at 3 weeks after procedure in group A contrasted to in group B (P<0.05). satisfaction of patient, percentage of functional improvement and quality of life (QOL) at baseline were insignificantly various among the two groups. QOL was significantly higher at 3 weeks after procedure in group A contrasted to in group B (P =0.047). Failure of the procedure, local anesthetic toxicity did not happen to any patients in either group. Bradycardia was insignificantly various among the two groups.

Conclusions: Super-voltage PRF is more effective than standard PRF to relief pain due secondary glossopharyngeal neuralgia due to OPC and safe procedure.

Keywords: Standard Pulsed, Radiofrequency | Glossopharyngeal Nerve Therapy, Super-Voltage Pulsed, Oropharyngeal Cancer, Pain.

1. Introduction

The glossopharyngeal nerve is the ninth cranial nerve. The trigeminal and facial nerves possess sensory, motor, and parasympathetic functions [1].

It is related to the posteromedial border of the styloid process. It gives tonsillar, tympanic, stylopharyngeal, carotid sinus, lingual and communicating branches to cranial nerve X (Vagus nerve). The glossopharyngeal nerve mostly consists of unique visceral efferent fibers, which provide motor impulses to the stylopharyngeus muscle. This muscle is crucial for raising the pharynx and larynx, especially throughout swallowing and speaking. The parotid glands receive parasympathetic innervation from general visceral efferent neurons. This section of the tongue also receives taste signals through specialized sensory fibers [2].

Neuropathic pain refers to pain that arises from damage or disease affecting the peripheral or central somatosensory system[3]. Glossopharyngeal neuralgia (GPN) is a rare condition, representing only 0.2%–1.3% of cases including facial pain [4, 5].

Pain is frequently intensified by coughing, speaking, and ingesting. The pain in the GPN exhibits a recurring and alternating pattern [6]. Vasoglossopharyngeal neuralgia can be linked to severe cardiovascular symptoms such as hypotension, syncope, and arrhythmias of the heart, which pose a threat to life. This is in contrast to trigeminal neuralgia [7].

According to pain of oropharyngeal cancer (OPC), it is rarely pure somatic, visceral or neuropathic types but rather is a complex syndrome due to mixed mechanisms either inflammatory, ischemic or neuropathic [8].

GPN can be treated either pharmacologically or surgically. Pharmacological intervention is the initial line of therapy. Surgical interventions ought to be contemplated when pharmacological inefficacy, intolerance, or allergies are present. The pharmaceutical therapy for GPN involves the use of anticonvulsant medicines, such as pregabalin [9, 10].

Conventional pain relievers are not effective, however certain antidepressants such as amitriptyline can be beneficial either on their own or when used together with anticonvulsant drugs [11].

Neurolytic nerve blocks, ganglion blocks, and intrathecal pump procedures have been attempted as invasive therapies for treating severe oral cancer pain. These methods have shown different levels of effectiveness and have been associated with various side effects [12, 13]. Pulsed radiofrequency (PRF) therapies is a safe substitute to neurolytic blocks. It involves applying a short pulse of radiofrequency to neural tissue, resulting in a neuromodulatory impact without causing significant damage to the tissue [14].

The purpose of this study was to contrast between standard voltage PRF and super-voltage PRF of the glossopharyngeal nerve in the OPC pain.

Patients and Methods:

This randomized clinical work had been conducted on 60 participants aging from 18 to 70 years old, both genders, American Society of Anaesthesiologists (ASA) II, III physical status receiving pain management for OPC (due to either unsuccessful medical therapy or inability to tolerate the drug's adverse effects), visual analogue scale (VAS) ≥ 6 cm in spite medical treatment. The work had been performed from February 2022 to January 2024 following approval from the Ethics Committee National Cancer Institute, Cairo, Egypt. All subjects provided a written well-informed consent.

Criteria for exclusion included individuals with systemic or local sepsis, unstable cardiovascular conditions, uncorrectable coagulopathy, a history of cognitive and psychiatric disorders, allergies to the medications utilized, an inability to lie supine, local anatomical distortion (either congenital, post-radiotherapy or post-surgical) that would make the intervention challenging and hazardous, and an elongated styloid process measuring more than 25 mm.

Randomization

Patients were assigned at random into two groups equally: Group A: obtained supervoltage PRF glossopharyngeal nerve block. Group B: obtained standard voltage PRF glossopharyngeal nerve block.

Anesthetic technique:

ASA standard monitoring, including ECG, pulse oximetry, and non-invasive blood pressure, has been connected to the subjects. Intravenous catheter (18 G) and O2 (3L /min) through nasal prong was applied. Midazolam 0.02 mg/kg and fentanyl 1 ug/kg was received intravenously for conscious sedation, if the bradycardia occurred (pulse is less than 48 beat per minute) atropine was given at 0.02 mg/kg, if hypotension occurred ephedrine 0.5 mg incremental doses to keep the plug pressure of 20% – 25% of the patient blood pressure. The participant positioned in a supine posture with the head fixed by strip of adhesive tape. The patient sterilized and draped then visualization of the styloid process in lateral view was obtained by C-arm Fluoroscopy which may be facilitated by cephalic orientation of the C-arm or sometimes by rotating the patient head to opposite side. The point of entry is midway between mastoid process and angle of mandible. Local anesthetic (lidocaine 1%) was given by 25 G needle. Then RF needle (22 G, 10 mm active curved tip, 54 mm in slender patient or 100 mm needle in obese patients) is advanced from port of entry perpendicular to skin (tunnel technique was not a must) towards apex of styloid process until bony contact was made then the styloid process is bypassed in posterior direction for further 0.5 cm depth. This was the final needle position and after negative aspiration for C.S.F. or blood, 1-2 ml of contrast medium Iohexol (omnipaque) was introduced. Glossopharyngeal nerve appears as a slender longitudinal structure nearby the back of styloid process. Figure 1

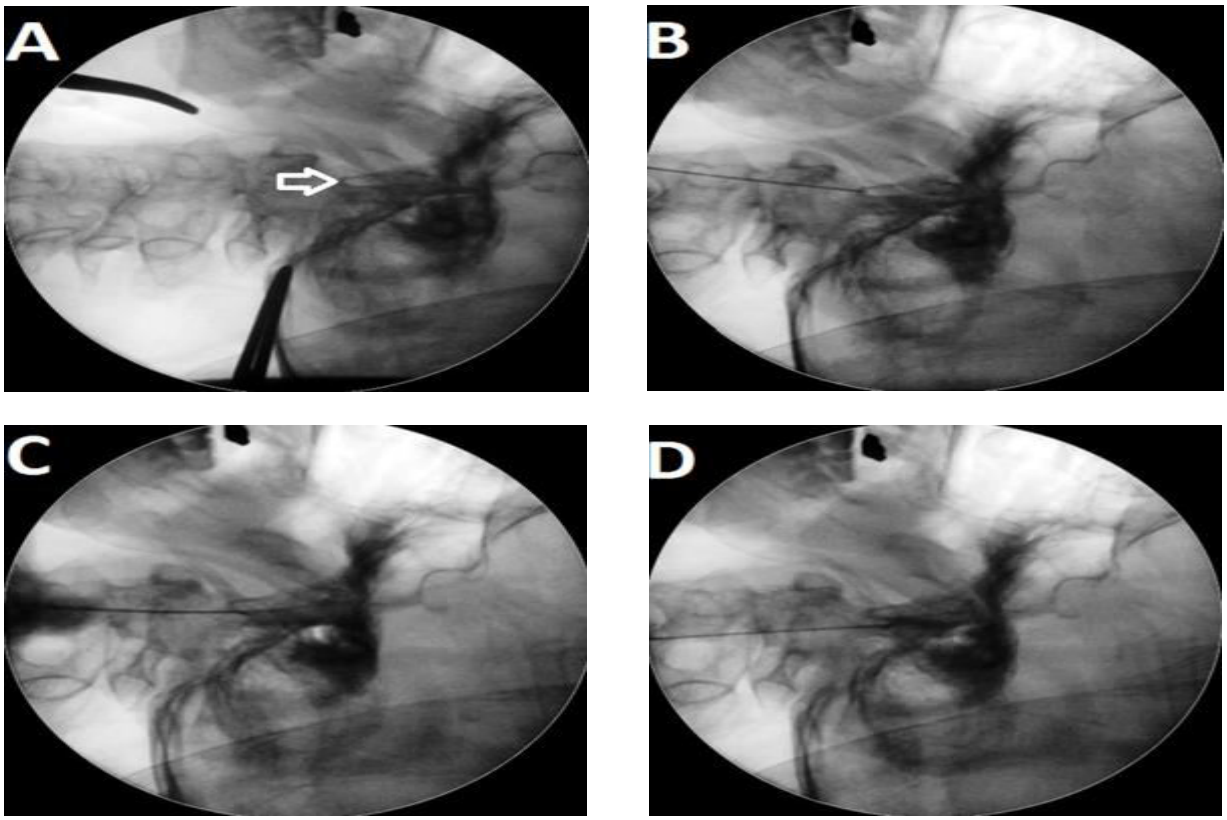

Figure 1: (A) lateral view showed upper pointer=Angle of the mandible; arrow=Styloid process; lower pointer= Mastoid process, (B) lateral view showed the RF needle resting on tip of styloid process, (C) lateral view showed the RF needle at the posterior border of styloid process, (D) Lateral view showed the RF needle at the posterior border of styloid process after contrast injection

Super-voltage (60-75V) pulsed radiofrequency glossopharyngeal block:

The stimulation was administered utilizing a Baylis generator, with sensory stimulation at a frequency of 50 Hz and a voltage range of 0.5-1.0 V. The patient reported feeling tingling sensations at the base of the tongue, ear, throat, and side of the upper neck. Motor stimulus was also performed at a frequency of 2 Hz and a voltage range of 1-2 V, resulting in the patient experiencing contractions of the stylopharyngeus muscle. Following the administration of 1 ml of 2% lidocaine and 1 ml (4 mg) of Betamethasone (Diprofos), the purpose was to enhance pain relief and reduce impedance, which typically ranged from 200-300 ohms due to its proximity to bone. A high-voltage PRF treatment was performed for 8 minutes, using a voltage range of 60-75 volts based on the patient's tolerance. The pulse width was set at 5 milliseconds, and the pulse frequency was 2 Hertz.

Standard pulsed radiofrequency (45V) glossopharyngeal block:

The stimulation was conducted utilizing a Baylis generator. Sensory stimulus was applied at a frequency of 50 Hz and a voltage range of 0.5-1.0 V. The patient reported feeling tingling sensations at the base of the tongue, ear, throat, and side of the upper neck. Motor stimulus was

applied at a frequency of 2 Hz and a voltage range of 1-2 V, resulting in the patient experiencing contractions of the stylopharyngeus muscle. Following the injection of 1 ml of lidocaine 2% and 1 ml (4 mg) of Betamethasone (Diprofos), the aim was to enhance pain relief and reduce impedance, which typically ranged from 200-300 ohms due to the close proximity to bone. The PRF procedure was conducted for a duration of 8 minutes, with a pulse width of 5 milliseconds and a pulse frequency of 2 Hertz. Vital signs of all patients are checked for 2 hours.

VAS (0= no pain while 10= the worst pain imaginable) was assessed at the following time: [prior to procedure, one day after the procedure, after one, two, three and four week of the procedure, after two and three months of the procedure].

Morphine sulphate tablets and gabapentin capsules drugs consumption at the following times [before the block, one,two, three, four weeks after the block , and after two and three months].

The patient satisfaction score was evaluated using a scale ranging from 1 to 5, with 5 indicating very high satisfaction and 1 indicating very low satisfaction. The assessment was conducted at specific time intervals: 24 hours, one week, two weeks, and one month following the procedure. This is a self-reported analysis conducted to assess the main outcome following pain treatments. The division is based on four categories: 0-25% represents no or minor functional improvement, more than 25-50% indicates mild improvement, greater than 50-75% signifies moderate improvement, while greater than 75-100% indicates marked improvement. The Flanagan QOL scale, a 16-item questionnaire, is used to measure improvements in QOL scores. Each item on the questionnaire is rated on a scale of 1 to 7 points.

Possible Risk were failure of the procedure, localanaesthetic toxicity (such as: numbness in tongue and/or circumoral, metallic taste, dizziness, muscle twitching, convulsions, or arrhythmias), bradycardia, phrenic nerve block, hematoma formation, epidural injection, hypoglossal nerve injury and accessory nerve injury and weakness in trapezius muscle.

Sample Size Calculation:

Utilising g power, depending on a prior work by Cheng-fu wan, et al.[15] indicating the mean vas score after three months of treatment for standard voltage PRF as 3.05 ± 0.89 minutes, for super voltage PRF was 2.12±0.54to detect a true difference in means between groups with a power 80% and a level of significance of 5% (two sided) a total sample size of 52 patients was needed. I.e. 26 individuals in each group. 10% was added to account for possible dropouts, total sample size was 60 individuals (30 individuals in each group).

Statistical analysis

Statistical analysis had been conducted utilizing SPSS v26 (IBM Inc., Chicago, IL, USA). Shapiro-Wilks test and histograms had been utilized to evaluate the normality of the data distribution. Quantitative parametric variables had been displayed as mean and standard deviation (SD) and contrasted among both groups employing unpaired Student's t- test. Quantitative non-parametric data had been presented as median and interquartile range (IQR) and had been analyzed by Mann Whitney-test. Qualitative parameters had been presented as frequencies and percentages (%) and had been analysed employing the Chi-square test or Fisher's exact test when appropriate. A two tailed P value < 0.05 was considered statistically significant.

Results:

A total of Seventy-nine individuals were evaluated for eligibility, with 11 patients failing to fulfill the requirements and 8 patients declining to take part in the study. The remaining individuals were assigned at random to two groups equally, with 30 individuals in each group. All assigned patients underwent follow-up and statistical analysis. Figure 2

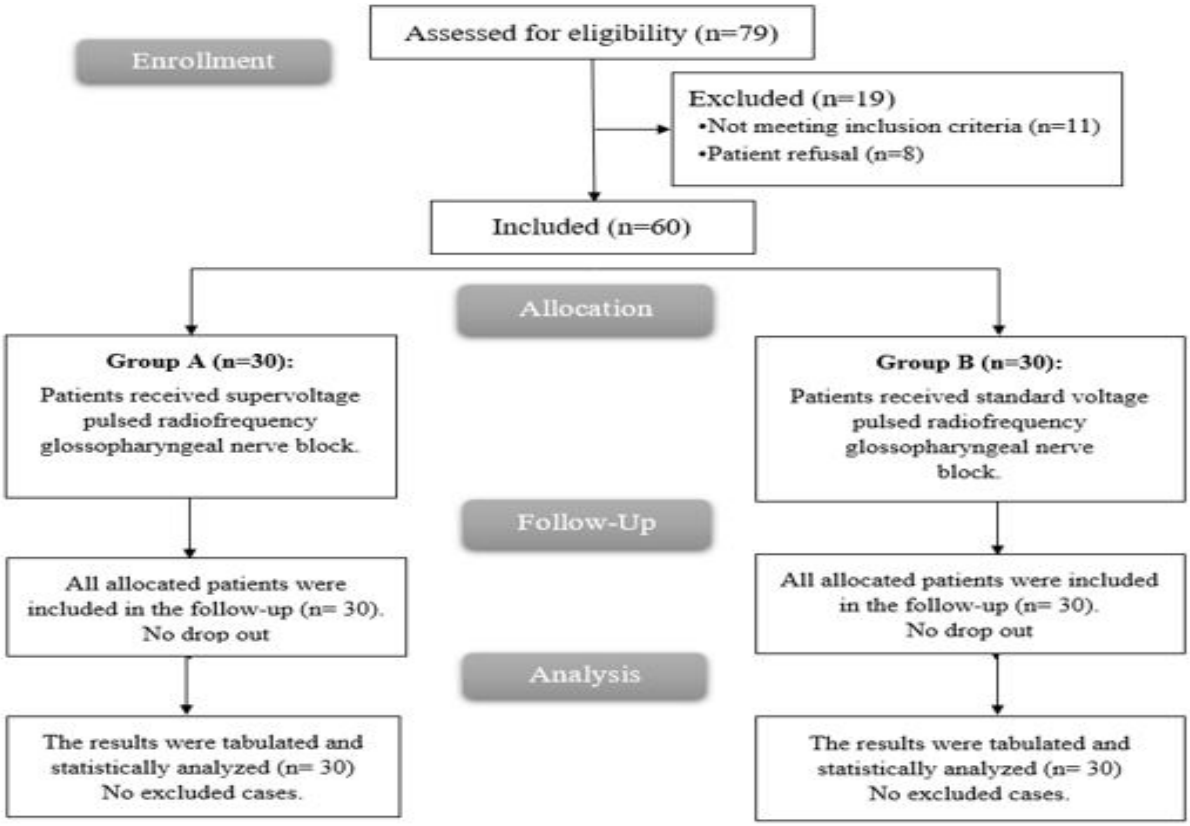

Figure 2: CONSORT flowchart of the enrolled patients

Age, weight, sex, height, ASA physical status, BMI, and duration of procedure were insignificantly various among the two groups. Table 1

Table 1: Demographic data and duration of procedure of the studied groups

		Group A (n=30)	Group B (n=30)	P
Age (years)		46.2±10.57	47.8±10.23	0.554
Sex	**Male**	13(43.33%)	16(53.33%)	0.438
	Female	17(56.67%)	14(46.67%)	

Weight (kg)		76.3±8.28	79.57±10.8	0.194
Height (cm)		167.33±6.84	167.87±5.76	0.745
BMI (kg/m^2)		27.3±2.99	28.25±3.63	0.276
ASA physical status	**II**	17 (56.67%)	19 (63.33%)	0.598
	III	13 (43.33%)	11 (36.67%)	
Duration of procedure (min)		25.67±4.1	27.83±5.52	0.090

Data are presented as mean ± SD or frequency (%). BMI: Body mass index, ASA: American society of anesthesiologists.

VAS was significant lower in both groups of study than pre-procedure score. VAS was insignificantly distinct among the two groups at 1 day after procedure, 1 week after procedure, 2 weeks after procedure, 4 weeks following procedure, 2 months following procedure and 3 months following procedure. VAS was significantly lower at 3 weeks following procedure in group A than in group B (P <0.001). Table 2

Table 2: VAS of the studied groups

	Group A (n=30)	**Group B (n=30)**	**P**
Pre-procedure	9(8 - 10)	8(7.25 - 9)	0.059
1 day after procedure	8(7 - 8)	7(7 - 9)	0.766
1 week after procedure	4(3 - 5)	4(3 - 5)	0.664
2 weeks after procedure	5(4 - 6)	5.5(4 - 6)	0.502
3 weeks after procedure	1(1 - 2)	3(3 - 4)	<0.001*
4 weeks after procedure	2(1 - 3)	1(1 - 2)	0.139
2 months after procedure	2(2 - 2)	2(2 - 2)	0.085
3 months after procedure	2(2 - 2)	2(2 - 2)	0.085

Data are presented as median (IQR). * Significant as P value<0.05. VAS: Visual analog scale.

Morphine and gabapentin consumption were insignificantly distinct among both groups in the pre-procedure period. Morphine and gabapentin consumption were significant decreased in the post-procedure contrasted to pre-procedure. Morphine and gabapentin consumption were lower in group (A) contrasted to group (B) in 1week, 2weeks,1month,2month and 3 months after the procedure without significant different. Morphine and gabapentin consumption were significantly lower at 3 weeks after procedure in group A contrasted to in group B (P<0.05). Table 3

Table 3: Morphine and gabapentin consumption of the studied groups

	Group A (n=30)	Group B (n=30)	P
Morphine consumption			
Pre-procedure	130.67±19.99	136.53±30.56	0.382
1 week after procedure	120.67±19.99	130.33±30.9	0.156
2 weeks after procedure	125.67±20.46	133.67±30.9	0.242
3 weeks after procedure	118±18.83	131.33±30.03	0.044*
4 weeks after procedure	117.33±23.03	129.33±27.78	0.074
2 months after procedure	116.33±19.21	124.33±29.21	0.215
3 months after procedure	111.67±19.84	121.33±29.33	0.140
Gabapentin consumption			
Pre-procedure	843.33±155.26	915.67±169.5	0.090
1 week after procedure	833.33±155.26	908.67±167.88	0.076
2 weeks after procedure	825.67±150.74	897.33±182.21	0.102
3 weeks after procedure	811.33±148.36	895.67±169.84	0.045*
4 weeks after procedure	798±160.5	883.67±176.43	0.054
2 months after procedure	796.67±151.96	867.33±181.58	0.108
3 months after procedure	786.33±156.92	857.33±191.63	0.122

Data are presented as mean ± SD. *significant p value <0.05.

Patient satisfaction, percentage of functional improvement and QOL at baseline were insignificantly distinct among the two groups. QOL was greater in group (A) contrasted to group (B) after the procedure 2 weeks, 4 weeks, 2 months and 3 months without significant different. QOL was significantly higher at 3 weeks after procedure in group A contrasted to in group B (P =0.047). Table 4

Table 4: Patient satisfaction, percentage of functional improvement and QOL of the studied groups

	Group A (n=30)	Group B (n=30)	P
24 hours after the block	2.5(2 - 3)	2(2 - 3)	0.381
1 weak after the block	3(2 - 3.75)	3(2 - 4)	0.115
2 weak after the block	3.5(2.25 - 4)	3(2.25 - 4)	0.232
Percentage of functional improvement			
Minimal improvement	1 (3.33%)	6 (20%)	0.391
Mild improvement	5 (16.67%)	8 (26.67%)	
Moderate improvement	7 (23.33%)	(0%)	
Marked improvement	17 (56.67%)	(54.9%)	
QOL			
Baseline	47.53±13.34	46.3±14.61	0.734
2 weeks after procedure	52.4±13.28	47.5±15.22	0.189

3 weeks after procedure	55.23±13.12	48.43±12.77	0.047*
4 weeks after procedure	56.1±14.44	53.67±14.96	0.524
2 months after procedure	60.43±13.1	55.83±17.05	0.246
3 months after procedure	62.17±17.59	57.63±18.05	0.329

Data are presented as mean ± SD or frequency (%) or median (IQR). * Significant p value <0.05. QOL: Quality of life.

Failure of the procedure, local anesthetic toxicity did not occur in any patient in the two groups.

Bradycardia was insignificantly distinct among the two groups. Table 5

Table 5: Complication of the studied groups

	Group A (n=30)	**Group B (n=30)**	**P**
Failure of the procedure	0 (0%)	0 (0%)	----
Local anesthetic toxicity	0 (0%)	0 (0%)	----
Bradycardia	2 (6.67%)	1 (3.33%)	0.655

Data are presented as frequency (%). PACU: Post anesthesia care unit.

Discussion

The occurrence of OPC has consistently increased among males in the United States since the 1970s. Significantly, the occurrence of OPC and the yearly count of instances (burden) in males have exceeded those in cervical instances. The findings of our work revealed a reduction in pain in group A than group B which was revealed by decrease in VAS score. The immediate analgesia following the procedure which was revealed by decrease in VAS score from the first day could be explained by high temperature spikes which occurred within 0.2 mm of the pointed needle tip. On the other hand, the delayed effect of PRF owed to the different mechanisms mentioned above due to high electrical field. A significant reduction in VAS score was existed in group A than group B at 3rd week after the procedure as the effect of standard PRF effect not started yet but the effect of super-voltage PRF started earlier than standard PRF. A decrease in VAS score was existed in group A than group B at 1st, 2nd and 3rd month after the procedure, but this was statistically insignificant. According to these results in VAS score, the effect of super voltage PRF is more potent than standard PRF. There was a decrease in morphine and gabapentin consumption after the procedure compared by values before the procedures.

A significant decrease in morphine and gabapentin consumption was existed at 3rd week after the procedure in group A.

Three cases of bradycardia were reported in current study and were managed successfully with atropine 0.02 mg/kg, and this is explained by irritation of vagus nerve during the procedure due to its close proximity to the glossopharyngeal nerve. No cases of dysthesia and anesthesia dolorosa were recorded.

In 2006, Teixeira and Sluijter[16] initially applied a high voltage PRF of 60 volts to the lumbar disc in order to alleviate lumbar disc-related discomfort. They successfully obtained satisfactory outcomes from this treatment.

Fang Luo, Tao Wang et al. [17]shown that the high-voltage PRF group had a postoperative one-year rate of response of 90%, that was significantly greater contrasted to the rate observed in the standard voltage PRF group (60%). Furthermore, out of the individuals in the high voltage group who had a positive response to the high voltage PRF treatment, 74% achieved total pain relief. As a result, they were able to stop taking the anti-epileptic drug carbamazepine and didn't experience any recurring pain throughout the one-year follow-up period.

Also, our study is consistent with the study done by Chen-Li Sun, Xiu-Liang Li et al. [18] showed that Administering high-voltage, long-duration PRF to the dorsal root ganglion (DRG) is both efficient and secure for treating neuralgia caused by HZ) at various phases. This treatment method can significantly alleviate pain in patients experiencing HZ neuralgia during the subacute stage. Abejon et al. [19] consider PRF of short clinical efficacy and could be repeated easily as it respects the mixed nature of 9th nerve (it preserves sensory and motor fibers. Bentley et al. [20] think that PRF is ineffective in secondary refractory GPN due to cancer invasion of peripheral segment of the 9th nerve as neuromodulation in this case failed to produce considerable pain relief, hence the real demand for conventional RF with its neuroablative properties of thermal lesioning.

Limitations

Limitations of the work involved a relatively small sample size. The work was in a single center. Need to compare super-voltage PRF versus conventional radiofrequency to assess potency.

Conclusions:

Super-voltage PRF is more effective than standard PRF to relief pain due secondary GPN due to OPC and safe procedure.

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Conflict of Interest: Nil

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