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Conventional Radiofrequency of the Peripheral Branches of the Trigeminal Nerve versus Conventional Radiofrequency of the Gasserian Ganglion for Treatment of Idiopathic Trigeminal Neuralgia

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: Trigeminal neuralgia (TGN) is the most prevalent kind of neuralgia. Conventional radiofrequency (CRF) of the Gasserian ganglion provides the highest rate of total pain alleviation. CRF of the peripheral trigeminal branches is considered a minimally invasive and safe operation. The aim of this work was to compare the safety and efficacy of CRF for the peripheral trigeminal branches with CRF of the Gasserian ganglion for treating idiopathic trigeminal neuralgia (ITGN).
Methods: This prospective randomized controlled trial was conducted on 60 cases aged 21-65 years, with confirmed diagnosis of ITGN, refractory to medications for TGN for an adequate period. Patients were subdivided in to two groups: group I (study group): 30 cases underwent CRF of the peripheral trigeminal branches and group II (control group): 30 cases underwent CRF of the Gasserian ganglion. All patients were subjected to history taking, physical examination and magnetic resonance imaging (MRI) of the brain.
Results: NRS and barrow neurological institute (BNI) pain intensity scale were insignificantly different between both groups at all times of measurements. Pain relief and patients' satisfaction were insignificantly different at all measurements between both groups. The incidence of numbness and ccomplications were insignificantly different between both groups.
Conclusions: Peripheral nerve branches CRF is a safe and effective procedure as gasserian ganglion CRF for treatment of ITGN.

Keywords: Conventional radiofrequency; peripheral branches; trigeminal nerve; Gasserian ganglion; idiopathic trigeminal neuralgia.

1. INTRODUCTION

"Trigeminal neuralgia (TGN) is the most prevalent kind of neuralgia, with an annual incidence of 5/100000" [1]. "The International Association for the Study of Pain (IASP) defines TN as sudden, severe, usually unilateral, stabbing, brief, and repeated bouts of pain in the distribution of one or more of the trigeminal nerve branches. Frequent causes of paroxysmal attacks are teeth brushing, mastication, talking, laughing and even smiling" [2].

"The pathophysiology of TN is yet unknown. According to the "ignition theory," TN is caused by afferent neurons abnormalities of the trigeminal ganglion or root. Any axons' injury can cause hyperexcitability, resulting in this painful neuropathic condition. Some of the risk factors in developing TN are older age, hypertension, multiple sclerosis (MS), stroke and tumors in the trigeminal nerve root region. In Idiopathic Trigeminal Neuralgia (ITGN), vascular nerve compression is the typical etiology, while secondary TN is related to the compression by MS or tumor" [3].

"In clinical practice, treating cases suffering with ITGN is difficult and conservative management typically starts with gradually increasing medications' dosage such as oxcarbazepine or carbamazepine" [4]. "However, around 25-30% of cases grow resistant to treatment or experience intolerable adverse effects from high-dose drugs, necessitating interventional pain management" [5].

"Among the numerous interventional pain treatments, conventional radiofrequency (CRF) of the Gasserian ganglion has the best rate of full pain alleviation, particularly for cases with a high surgical risk or who are unfit for other operations" [6].

"More than 90% of cases treated with CRF of the Gasserian ganglion have exhibited considerable pain alleviation, according to previous research. However, multiple complications have been documented on long-term follow-up of these cases such as weakness and paralysis of masseter muscle, decreased corneal reflex, keratitis, anesthesia dolorosa, transient paralysis of cranial nerves and dysesthesia" [7,8].

CRF of the peripheral trigeminal branches is considered a minimally invasive and safe operation. A previous research [9] assessing the effectiveness of peripheral division CRF versus CRF of Gasserian ganglion for treating first division ITGN, has shown 93% immediate pain alleviation in cases who underwent CRF of the supra-orbital nerve which was comparable to those who underwent CRT of Gasserian ganglion (95%).

Multiple sporadic case reports have also shown the effectiveness of CRF of the peripheral trigeminal branches for alleviation of refractory chronic neuropathic facial pain conditions other than TN [10-12].

The aim of this work was to compare the safety and efficacy of CRF of the peripheral trigeminal branches with CRF of the Gasserian ganglion for the treatment of ITGN.

2. PATIENTS AND METHODS

This prospective randomized controlled trial was conducted on 60 cases aged 21-65 years, both genders, with confirmed diagnosis of ITGN according to IASP definition, numerical rating scale (NRS) > 3, refractory to medications for TGN (simple analgesic drugs, antiepileptics and opioids) for an adequate period at Tanta University Hospitals from April 2020 to March 2022.

Exclusion criteria were parent refusal, pregnant and lactating women, coagulopathy, severe cardiac, hepatic, and renal decease, severe psychiatric illness and history of substance abuse.
The patients were randomly divided into 2 groups; group I (study group): 30 cases underwent CRF of the peripheral trigeminal branches and group II (control group): 30 cases underwent CRF of the Gasserian ganglion.

During the intervention, the patients' electrocardiogram, blood pressure, and peripheral oxygen saturation were measured. A line for intravenous (IV) delivery of fluids and medications was established. In order for the patient to respond to test stimulation when performed, only a light sedation was administered in the form of IV midazolam (1-2 mg).

All participants were subjected to history taking (site, duration, nature, and severity of pain, treatment history regarding the use of all drugs including duration, dosages, and side effects), physical examination to exclude any systemic diseases or localized infection at the injection site and magnetic resonance imaging (MRI) of the brain.

2.1 Group I (Study Group)

Underwent CRF of the peripheral trigeminal branches. It was conducted according to the different trigeminal nerve divisions' involvement. injection site was the supraorbital foramen in case the pain involved 1st division. Site of injection was infraorbital foramen, mandibular notch or mental foramen respectively in case the pain involved 2nd or 3rd division, the. The needle's position was confirmed via fluoroscopic imaging and by eliciting paresthesia corresponding to the pain location. After excluding any motor involvement, CRF was conducted 3 times at 70°C for 60 seconds.

2.2 Group II (Control Group)

Received CRF of the Gasserian ganglion under fluoroscopy. The cases were laid in supine position with the head in submentovertex position; after administrating 2% lidocaine local infiltration, a 22-gauge 10 cm RF needle with 5 mm active tip was injected on the affected side from a point 3 cm away from the angular oris and advanced towards the foramen ovale with caudal incline of 30-degree. The needle tip correct position was confirmed via fluoroscopy, sensory and motor stimulation tests. The sensory stimulation up to 1 volt at 50 Hz was performed till the paresthesia evoked by electrical stimulation corresponds to the facial pain location and motor stimulation up to 2.0 volt was utilized to exclude any muscular contractions. CRF was performed post last needle positioning 3 times at 70 degree for 60 seconds each.

In both groups, 1 to 2 mL 2% lidocaine with 4 mg dexamethasone was injected after the operation prior to needle withdrawal. The cases were evaluated for sensation loss with pin prick along the nerve distribution on the side where operation was performed. Before discharge, they were monitored in the recovery room for vitals and any adverse effect for 1-2 h.

The adequacy of pain alleviation was evaluated using Numeric Rating Scale (NRS) at 30 and 60 minutes. No medications were prescribed in cases that had total pain alleviation. However, in case of inadequate pain alleviation (NRS > 3), the cases were instructed to continue taking their analgesics.

During their visit, pain intensity was evaluated via the barrow neurological institute (BNI) pain intensity scale and the NRS scale [13]. Pain alleviation was deemed effective if there was more than 50% reduction in pain using the NRS from baseline at any point of time.

Improvement in pain was deemed excellent if cases had total pain alleviation (NRS < 3) without any analgesics (BNI I and II), good if there was significant pain reduction (>50%) with or without analgesics (BNI III), and poor if there was less than 50% pain reduction with analgesics (BNI IV and V).

2.3 Magnetic Resonance Imaging of the Brain

Magnetic Resonance Imaging of the brain was conducted to exclude other TGN secondary causes such as neuromas, MS, gliomas, chordomas, other vascular conditions like arteriovenous malformation and aneurysms and lymphomas. Brain MRI with and without contrast enables differentiation between secondary TN causes and the idiopathic type. In younger than 60-year-old patients presenting with TGN, it is the imaging modality of choice and is advised to rule out malignancy. For example, MRI can show pontine gliomas and MS plaques.

2.4 Measurements

Duration of TGN was measured, severity of pain was assessed by NRS. NRS ranging from 0 to 10 (0: no pain and 10: worst pain possible) and barrow neurological institute (BNI) pain intensity scale was also utilized, numbness presence and degree were evaluated and categorized as mild (rare disruption of everyday routines), moderate (occasional disruption of everyday routines), and severe (frequent disruption of everyday routines), patients' satisfaction with the operation was evaluated at the end of 3 months a 5-point scale (1: ''absolutely dissatisfied'', 2: ''dissatisfied'', 3: ''neither dissatisfied nor satisfied'', 4: ''satisfied'' and 5: ''absolutely satisfied''). Any complication like masseter weakness, dysesthesia, keratitis, cheek hematoma, cranial nerve paralysis, and any neurological deficit were documented. The cases were followed up at the pain clinic at 1 week, 2 weeks, 1 month, 2 months, and 3 months post-radiofrequency.

2.5 Sample Size Calculation

The sample size is calculated at n ≥ 28 for every studied group based on 95% confidence limit, 80% study power, group ratio 1:1, the expected primary outcome (efficacy) ranged between 70-95% among control and study group [9]. 2 cases were added to overcome drop-out.

2.6 Statistical Analysis

SPSS v27 (IBM, Chicago, IL, USA) was used for statistical analysis. Using the Shapiro-Wilks test and histograms, the normality of the data distribution was determined. Unpaired student t-test was performed to compare measures within the same group. Non-parametric quantitative data were given as the median and interquartile range (IQR). The Mann Whitney test was utilized to compare the two groups, whilst the Wilcoxon test was utilized to compare measures within the same group. When applicable, the Chi-square test or Fisher's exact test was used to evaluate qualitative variables provided as frequency and percentage. A two-tailed P value ≤ 0.05 was deemed statistically significant.

3. RESULTS

No significant difference was found between the two groups regarding patient's demographic data and pain criteria Table 1.

NRS was significantly lower after 1week, 2 weeks, 1 month, 2 months and 3 months compared to baseline in study group and in control group (P <0.001)

NRS at all times of measurements was insignificantly different between both groups Table 2.

BNI was insignificantly different after 2-weeks, 1-month compared to 1week measurement and was significantly different after 2-months, 3-months compared to 1week measurement in study group and in control group Fig. 2.

BNI was insignificantly different at all measurements between both groups Table 3.

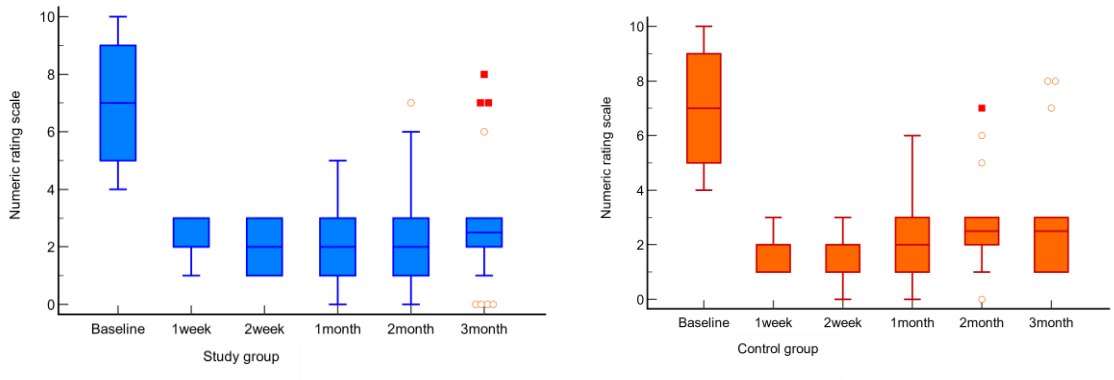
Pain relief and patients' satisfaction were insignificantly different at all measurements between both groups Table 4.

The incidence of numbness and complications were insignificantly different between both groups Table 5.

Table 1. Patient's demographic data and pain criteria of the studied groups

		Study group (n = 30)	Control group (n = 30)	P value
Age (years)		47.4 ± 11.58	48.4 ± 10.84	0.714
Sex	**Male**	14 (46.67%)	17 (56.67%)	0.598
	Female	16 (53.33%)	13 (43.33%)	
Weight (kg)		76.57±14.59	77.87±13.68	0.723
Height (m)		1.7 ± 0.08	1.7 ± 0.1	0.631
BMI (kg/m^2)		28.09 ± 6.02	27.45 ± 5.87	0.680
Pain duration (years)		5.1 ± 2.53	5.6 ± 2.24	0.485
Pain side	**Right**	19 (63.33%)	14 (46.67%)	0.598
	Left	11 (36.67%)	16 (53.33%)	
Pain nature	**Lancinating**	23 (76.67%)	20 (66.67%)	0.598
	Burning	7 (23.33%)	10 (33.33%)	

Data are presented as mean ± SD or frequency (%). BMI: Body mass index



(A) **(B)**

Fig. 1. (A) Numerical rating scale (NRS) of the study group, (B) Numerical rating scale (NRS) of control group

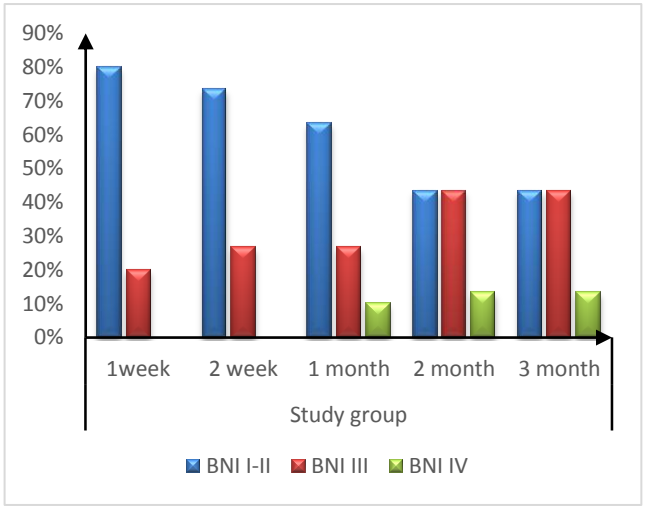
Table 2. Numerical rating scale of the studied groups

	Study group (n = 30) Median (IQR)	Control group (n = 30) Median (IQR)	P value
Baseline	7 (5 – 9)	7 (5 – 9)	0.742
1week	2 (2 – 3)	2 (1 – 2)	0.293
2 weeks	2 (1 – 2.75)	2 (1 – 2)	0.415
1 month	2 (1 – 3)	2 (1 – 2.75)	0.281
2 months	2 (1 – 3)	2.5 (2 – 3)	0.494
3 months	2.5 (2 – 3)	2.5 (1.25 – 3)	0.951

Data are presented as Median (IQR). IQR: Interquartile range

4. DISCUSSION

"TGN is a common neuropathic pain disorder with signs of electric-shock-like pain that is transient and affects one or more of the trigeminal nerve branches" [14,15]. ITGN is caused by vascular trigeminal nerve root compression, which is responsible for about 80%---90% of cases with TGN [16].



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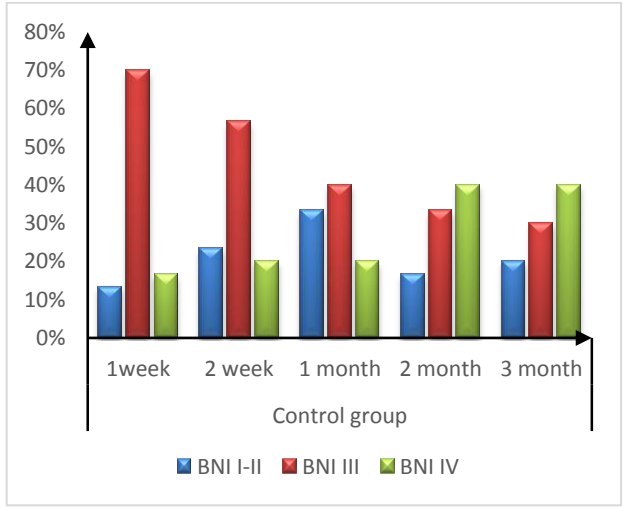

(B)

Fig. 2. (A) Barrow Neurological Institute (BNI) pain intensity scale in the study group, (B) Barrow Neurological Institute (BNI) pain intensity in control group

Table 3. Barrow Neurological Institute pain intensity scale between two groups

		1week	2 weeks	1 month	2 months	3 months
Study group	**BNI I-II**	24 (80%)	22 (73.33%)	19 (63.33%)	16 (53.33%)	15 (50%)
	BNI III	6 (20%)	8 (26.67%)	8 (26.67%)	10 (33.33%)	11 (36.67%)
	BNI IV	0 (0%)	0 (0%)	3 (10%)	4 (13.33%)	4 (13.33%)
Control group	**BNI I-II**	4 (13.33%)	7 (23.33%)	10 (33.33%)	4 (13.33%)	6 (20%)
	BNI III	21 (70%)	17 (56.67%)	12 (40%)	11 (36.67%)	9 (30%)
	BNI IV	5 (16.67%)	6 (20%)	6 (20%)	12 (40%)	12 (40%)
P value		0.371	0.822	0.868	0.224	0.184

Data are presented as frequency (%). BNI: Barrow Neurological Institute

Table 4. Pain relief, patients' satisfaction between the studied groups

	Study group			Control group			P value
	Excellent	**Good**	**Poor**	**Excellent**	**Good**	**Poor**	
1 month	19 (63.3%)	8 (26.7%)	3 (10%)	22 (73.3%)	6 (20%)	2 (6.7%)	0.703
2 months	13 (43.3%)	13 (43.3%)	4 (13.3%)	15 (50%)	12 (40%)	3 (10%)	0.85
3 months	13 (43.3%)	13 (43.3%)	4 (13.3%)	15 (50%)	12 (40%)	3 (10%)	0.85
Absolutely dissatisfied	1 (3.33%)			1(3.33%)			0.45
Dissatisfied	3 (10.00%)			2 (6.67%)			
Neither dissatisfied nor satisfied	4 (13.33%)			7 (23.33%)			
Satisfied	12 (40.00%)			6 (20.00%)			
Absolutely satisfied	10 (33.33%)			14 (46.67%)			

Data are presented as frequency (%)

Table 5. The incidence of numbness and complications of the studied groups

		Study group (n = 30)	Control group (n = 30)	P value
Numbness	**Mild**	16 (53.3%)	13 (43.3%)	0.474
	Moderate	3 (10%)	2 (6.7%)	
	Severe	1 (3.3%)	0 (0%)	
Masseter weakness		3 (10%)	2 (6.7%)	0.474
Eyelid edema		4 (13.33%)	2 (6.7%)	0.670

Data are presented as frequency (%).

In the current study, NRS in study group was significantly lower at 1week, 2-week, 1 month, 2 month and 3 months compared to baseline (P <0.001).

Similarly, Bharti et al. [17] study post-operative pain scores (NRS) reduction post -operative in both groups. The total pain reduction was comparable at every point of time among groups.

Also, Huibin et al. [9] studied population comprised of 50 patients. They reported that the immediate efficacy rates were 93% and 95% in the peripheral and the central group respectively without significant difference on follow-up, indicating that peripheral division RFT is an effective treatment for TGN. Also, pain recurrence rates without analgesia on follow-up in 3 and 5 years were not significantly different between groups.

We found in our study that BNI was insignificantly different after 2-weeks, 1-month compared to 1week measurement and was significantly different after 2-months, 3-months compared to 1week measurement in study group.

In agreement with our study, Bharti et al. [17] the BNI scores were comparable from week 1 to 3 months among groups, except at 2 months as the control group was significantly better compared to the study group.

Our result showed that pain relief was insignificantly different at 1, 2, 3-month measurements between both groups.

In Wang et al. [18], they reported that the mean initial pain alleviation provided by RFT was 95.31%, whereas the range was 77.8-100%. Although the lowest reported initial pain alleviation rate was 77.8%. 92.4% of the trials had an initial pain alleviation rate of >90%.

Elahi et al. [12] reported that mental nerve RFT has provided significant pain alleviation in 2 cases who presented with refractory mental neuropathy post dental extraction.

Also, Bharti et al. [17] stated that cases in both groups were extremely satisfied with their therapy. There was no significant difference in satisfaction scores between the groups [8 (7-9) and 8.5 (8-9) in study and control group respectively.

Moreover, Liu et al. [19] enrolled 31 cases with recurrent TGN who were treated with PRT previously were recruited and subjected to repeated PRT (group A), and compared with 41 TGN cases who were subjected to the first initial PRT (group B) and reported that in group A, 27 cases (87.0%) didn't have any pain immediately, and 30 cases (96.8%) experienced pain alleviation at 48 h, whereas that was 37 cases (90.0%) and 40 cases (97.6%) in group B ($p \geqq 0.05$).

Furthermore, Huibin et al. [9], indicated follow-up data were taken 1-day post-operation prior cases discharge. Immediate post-operative pain alleviation (with or without a maximum dosage of 400 mg of carbamazepine on daily basis) was experienced in 19 out of 20 (95%) and 28 out of 30 (93%) cases in groups 1 and 2, respectively. Immediate postoperative pain alleviation without requiring any analgesics was experienced in 18 out of 20 (90%) and 26 out of 30 (87%) cases in groups 1 and 2, respectively. no significant difference was found between CRF and PRT treatments.

In Erdine et al. [7] who enrolled 40 patients and were randomly assigned to one of the two treatment groups. Each case in group 1 was treated with CRF, whereas each case in group 2 was treated by PRF. And they found that patient satisfaction improved significantly 1 day in group 1 group ($p<0.05$) post-operation.

In out study numbness was mild in 16 (53.3%) patients in study group and 13 (43.3%) patients,

moderate in 3 (10%) cases in study group and 2 (6.7%) cases in control group, and severe in 1 (3.3%) patient in study group and 0 (0.0%) in control group. Masseter weakness occurred in 3 (10%) and in 2 (6.7%), eyelid edema occurred in 4 (13.33%) and in 2 (6.7%).

In our current study regarding numbness, masseter weakness, eyelid edema was insignificantly difference between both groups.

Similarly, Liu et al. [19] there was an insignificant variation between both groups in incidence of complications between group A and group B as numbness and muscle weakness.

In Elawamy et al. [20] found that incidence of severe numbness (41.67%), and masseter muscle weakness (33.33%)recorded in the CRF group. In Tang et al. [21] found that incidence of masseter muscle weakness (8%) in the CRF group.

5. CONCLUSIONS

Peripheral nerve branches CRF is a safe and effective method as Gasserian ganglion CRF for treatment of ITGN. There was an insignificant difference in NRS, BNI pain intensity scale, efficacy, quality of pain relief, patient satisfaction and incidence of adverse effect between the study and control groups.

6. LIMITATIONS

This was not a blind study for both the cases and the anesthesiologist who conducted the operation, though the person who assessed the case during follow-up was blinded to the group assignment.

CONSENT AND ETHICAL APPROVAL

We obtained informed written consent from the cases. The trial was performed after approval from the institutional ethical committee.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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