ORIGINAL ARTICLE

Effectiveness of Fluoroscopic Guided Gasserian Ganglion Pulsed and continuous Radiofrequency Versus Ultrasound Guided Pulsed and Continuous Radiofrequency via Lateral pterygoid Plate For The Management of Trigeminal Neuralgia

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Abstract

Background: ***The trigeminal nerve (V) is the largest and fifth cranial nerve, and its function is to detect sensory inputs originating from the craniofacial region.***

Aim: ***To compare Fluoroscopic Image-Guided Pulsed Radiofrequency (PRF) and Ultrasound-Guided PRF, aiming to find an effective, safe, and minimally destructive treatment after ineffective conservative treatment.***

Patients and methods: ***This prospective trial was performed at Al-Azhar University Hospitals and started in October 2022, with a duration of 2 years.***

Results: ***An insignificant distinction was observed in the quality of life among the groups at the beginning of the investigation ($p>0.05$). Nevertheless, there significant variances have been observed in the quality of life among the groups following one month, three months, and six months. ($p<0.05$). Additionally, there were significant variances in case satisfaction among the groups following one month and highly significant distinctions following three months and six months ($p<0.05$).***

Conclusion: ***Fluoroscopic-guided Gasserian Ganglion Pulsed and continuous Radiofrequency are more effective and safer than Ultrasound-Guided pulsed radiofrequency combined with low-temperature continuous radiofrequency for the Management of Trigeminal Neuralgia.***

Keywords: Trigeminal Neuralgia; Ultrasound Guided Pulsed; Fluoroscopic Guided Gasserian

1. Introduction

The trigeminal nerve is the biggest and fifth cranial nerve, and its function is to detect sensory inputs originating from the craniofacial region. The nerve is physiologically separated into three branches: maxillary (V2), ophthalmic (V1), and mandibular (V3). The cell bodies of these branches are situated in the trigeminal ganglia and establish connections with 2nd-order neurons in the trigeminal brainstem sensory nuclear complex. [1]

The trigeminothalamic tract carries ascending projections that relay sensory information to the thalamus and other brain areas involved in the analysis of sensory information. Trigeminal neuralgia is a prevalent type of craniofacial pain.[2]

Trigeminal neuralgia is defined by abrupt, brief, and extremely agonizing facial pain attacks in one or more branches of the trigeminal nerve, resulting in a significant decline in the overall well-being of affected cases.[3]

Their mode of operation involves altering the function of voltage-gated sodium channels, resulting in a reduction in the activity of neurons.[4]

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Continuous radiofrequency (CRF) is a minimally invasive radiofrequency method that eliminates the requirement for endotracheal anesthesia and requires a relatively brief hospital stay.[5]

The aim of this study was to compare Fluoroscopic Image-Guided PRF and Ultrasound-Guided PRF for treating primary trigeminal neuralgia, aiming to find an effective, safe, and minimally destructive treatment after ineffective conservative treatment.

2. Patients and methods

This prospective study was performed at Al-Azhar University Hospitals, starting in October 2022, for a duration of 2 years. The study included 146 patients who had primary trigeminal neuralgia, which were randomized and divided into 2 groups:

Group I: 73 patients had Fluoroscopic Image Guidance PRF combined with low temperature CRF to the Gasserian ganglion, group II: 73 patients had Ultrasound-Guided pulsed radiofrequency combined with low temperature CRF To the lateral pterygoid plate.

Inclusion criteria: The cases that have been diagnosed with trigeminal neuralgia depend on the criteria outlined in the International Classification of Headache Disorders, 3rd edition (ICHD-3). They are between the ages of twenty-one and sixty-five and have severe trigeminal neuralgia that cannot be efficiently relieved through conservative medical treatments like oxcarbazepine and carbamazepine. Prior to the procedure, they have a numeric rating scale (NRS-11) score of seven or higher and have agreed to provide informed consent.

Exclusion criteria: 2ry trigeminal neuralgia, like trigeminal neuralgia caused by multiple sclerosis or space-occupying lesion, or trigeminal neuralgia affecting the ocular division, cannot be detected by ultrasound in the lateral pterygoid plate. Additionally, there is a risk of infection at the puncture site. An account of psychiatric illness, The illness is identified using standard blood tests, renal function tests, hepatic function tests, coagulation function tests, electrocardiograms, or chest x-rays. It is also associated with major systemic disorders like uncontrolled hypertension or diabetes, as well as heart dysfunction (classified as New York Heart Association grade II-III). A history of the misuse of opioids, Prior exposure to continuous radiofrequency therapy targeting the Gasserian ganglion or its glycerol rhizolysis, peripheral branches, Gamma knife, balloon compression, or any other neuroablative therapies. A record of undergoing microvascular decompression surgery in the past.

Methods

All cases involved in the investigation have been exposed to Detailed history taking and careful clinical examination.

Procedures: Fluoroscopic Image-Guidance PRF + Continuous to Gasserian ganglion Group: The case is located in a supine position with the neck in a slightly stretched position. The head rotates twenty degrees away from the same side; device temperature was controlled and was adjusted at 80 degrees for the maximum and 40 degrees for the minimum, and the X-ray beam is directed at the foramen ovale at a fifty-five degrees downward angle from the orbitomeatal line. To prevent the foramen ovale from overlapping with the petrous bones or the mandibular ramus, it is recommended to slant the central beam at least forty degrees caudal to the orbitomeatal line. The needle is directed toward the anterolateral portion of the foramen ovale to prevent it from coming too close to the carotid artery. The picture intensifier can be rotated laterally to determine the depth of needle penetration. Following the administration of two percent lidocaine by local infiltration, the cannula is inserted with the assistance of fluoroscopic guidance. Test stimulation is administered to induce paresthesia in the painful division of the trigeminal nerve and assess the threshold for masseter muscle activity.

Pulsed radiofrequency technique: The therapy involved administering a pulse radiofrequency frequency of two hertz at a voltage of seventy Volts and a temperature of forty-two degrees Celsius. The pulse width will be twenty milliseconds, and the treatment time will be six hundred seconds. Additionally, a low-temperature continuous radiofrequency therapy will be done at a temperature of sixty degrees Celsius and a treatment time of 270 seconds.

Ultrasound guided PRF + Continuous Group: The study used ultrasound-guided trigeminal nerve scanning to visualize the lateral pterygoid plate, lateral pterygoid muscle, zygomatic bone, maxillary bone, mandibular condyle, lateral pterygoid plate. The technique involved positioning the probe longitudinally on the affected side of the face, identifying the lateral artery using color power Doppler, and inserting an insulated echogenic needle. The case's mouth has been kept open with an oral airway; the probe has been tilted slightly to avoid the acoustic shadow of the coronoid process.

Assessment: BNI score: The Barrow Neurological Institute pain intensity score was assessed on the first day, at one and two weeks, and at one, two, three, and six months following the procedure.NRS-11 score: The study assessed the numeric Rating Scale-eleven scores on the first day following one and two weeks and following two,

three, and six months after the procedure. The dosage of oxcarbazepine or carbamazepine was documented during the procedure.

The evaluation of case satisfaction scores has been conducted using a five-point Likert scale, ranging from one (poor) to 5 (excellent). The scores were assessed at one, three, and six months following the procedure.

Quality of life: The scores on the WHOQOL-BREF (World Health Organization were assessed at one, three, and six months after the surgery. Numbness: The barrow neurological institute facial numbness scores 7 were assessed on the first day as well as following the first and second weeks, and after two, three, and six months following.

Follow-Up: After the procedure, patients were discharged and regularly monitored through outpatient and telephone follow-ups at 1, 6, and 6 months. A single trained doctor conducted follow-ups, encouraging patients to report recurrence of pain and adverse reactions via phone or instant messaging.

Study Outcomes: Data on demographic and baseline characteristics will be gathered.

1ry Outcome: The revised barrow neurological institute 7 will be utilized to assess the effectiveness of the therapy. Cases that have barrow neurological institute scores of I to III six months following the surgery will be considered to have had effective therapy. The main measure of interest will be the efficacy and safety of the therapy at the six-month mark.

2ryOutcome: The patient's facial sensation, masticator weakness, corneal anesthesia, keratitis, and adverse reactions will be assessed within 6 months of the technique. The ophthalmologist will investigate eye dryness, pain, photophobia, lacrimation, and excess mucus. Adverse reactions, such as nausea, Vomiting, facial hematoma, headache, dizziness, and cerebrospinal fluid leakage, will also be recorded.

Statistical analysis

The data will be entered using an alphanumeric code, and the statistician will use IBM SPSS V25.0 for analysis. Normal and nonnormally distributed variables will be presented as means and medians. Mann Whitney/Wilcoxon signed-rank tests, Two-sample t-tests, Fisher exact tests, x2 tests, repeated measures analysis, Bonferroni correction, descriptive analysis, and safety assessment will be performed.

3. Results

Table 1 demonstrations that, there statistically insignificant variance has been observed among examined groups according to age and sex p-value more than 0.05.

Table 1. Distribution of general characteristics among the examined groups.

	GROUP A (NUMBER=SEVENTY THREE)	GROUP B (NUMBER=SEVENTY THREE)	TEST	P VALUE
AGE (YEARS)				
MEAN ± SD	41.02±11.12	43.6±9.09	t=1.534	0.127
GENDER				
MALE	35 (47.9%)	26 (35.6%)	X^2=2.281	0.13
FEMALE	38 (52.1%)	47 (64.4%)		

P value >0.05: Not significant, P value <0.05 is statistically significant, p<0.001 is highly significant., SD: standard deviation, t: T test, x2: qui square test.

Table 2 illustrations that there statistically significant variance has been observed among examined groups according to complications p-value less than 0.05.

Table 2. Distribution of Complications among the examined groups.

	GROUP A NUMBER=SEVENTY THREE)	GROUP B (NUMBER=SEVENTY THREE)	TEST	P VALUE
NO COMPLICATIONS	70 (95.9%)	60 (82.2%)	X^2=7.85	0.04
MASSETER WEAKNESS	1 (1.4%)	4 (5.4%)		
DYSESTHESIA/ DYSISTHESIA	2 (2.7%)	5 (6.8%)		
VOMITING	0 (0%)	4 (5.4%)		

Table 3 demonstrations that, there statistically insignificant variance has been observed among examined groups according to NRS-11 score at baseline p>0.05, after three months, there was statistically significant variance among studied groups according to NRS-11 score at first day, following one month, and after 6 months p-value less than 0.05.

Table 3. Distribution of NRS-11 score among the examined groups.

	GROUP A NUMBER=SEVENTY THREE)	GROUP B NUMBER=SEVENTY THREE)	TEST	P VALUE
BASELINE				
MEAN ± SD	8.86±1.09	9.24±1.15	t= 1.6177	0.1
AT DAY 1				
MEAN ± SD	1.42±0.59	1.64± 0.69	t= 2.0557	0.04
AFTER 1 MONTH				
MEAN ± SD	1.31±0.46	1.49±0.6	t=2.0342	0.04
AFTER 3 MONTHS				
MEAN ± SD	1.02±0.16	1.07±0.25	t=1.2565	0.2
AFTER 6 MONTHS				
MEAN ± SD	0±0	0.15±0.36	t=3.56	<0.001

Table 4 demonstrations that there statistically insignificant variance has been observed among examined groups according to BNI score at Baseline and after six months p-value more than 0.05 while there statistically significant variance

has been observed among studied groups according to BNI score at day one, following one month & after three months p-value less than 0.05.

Table 4. Distribution of BNI score among the examined groups.

	GROUP A NUMBER=SEVENTY THREE)	GROUP B NUMBER=SEVENTY THREE)	TEST	P VALUE
BASELINE				
IV	41 (56.2%)	38 (52.1%)	X^2= 0.24	0.618
V	32 (43.8%)	35 (47.9%)		
AT DAY 1				
I	55 (75.3%)	42 (57.6%)		
II	11 (15.1%)	13 (17.8%)		
III A	6 (8.2%)	7 (9.6%)	X^2= 10.43	0.03
III B	1 (1.4%)	8 (10.9%)		
IV	0 (0%)	3 (4.1%)		
AFTER 1 MONTH				
I	58 (79.5%)	41 (56.2%)		
II	10 (13.7%)	15 (20.5%)		
III A	4 (5.4%)	9 (12.3%)	X^2= 11.34	0.023
III B	1 (1.4%)	7 (9.6%)		
IV	0 (0%)	1 (1.4%)		
AFTER 3 MONTHS				
I	60 (82.2%)	47 (64.5%)		
II	11 (15.1%)	15 (20.5%)		
III A	2 (2.7%)	8 (10.9%)	X^2= 8.79	0.032
III B	0 (0%)	3 (4.1%)		
AFTER 6 MONTHS				
I	52 (71.3%)	41 (56.2%)		
II	16 (21.9%)	17 (23.4%)		
III A	4 (5.4%)	8 (10.9%)	X^2= 7.33	0.119
III B	1 (1.4%)	5 (6.8%)		
IV	0 (0%)	2 (2.7%)		

Table 5 illustrations that, there statistically insignificant variance has been observed among examined groups according to Dose of carbamazepine at baseline and following three months p-value more than 0.05. While there highly statistically significant variance has been observed among examined groups according to Dose of carbamazepine at day one and after one month p<0.05.

Table 5. Distribution of Dose of carbamazepine among the examined groups.

	GROUP A NUMBER=SEVENTY THREE)	GROUP B NUMBER=SEVENTY THREE)	TEST	P VALUE
BASELINE				
MEAN ± SD	822.6±58.96	833.7±58.2	t=1.1448	0.25
AT DAY 1				
MEAN ± SD	528.4±44.4	800.6±53.2	t=33.562	≤0.001
AFTER 1 MONTH				
MEAN ± SD	265.2±25.47	301.5±28.57	t=8.1032	≤0.001
AFTER 3 MONTH				
MEAN ± SD	9.7±47.8	25±77.54	t=1.4351	0.15
AFTER 6 MONTH				
MEAN ± SD	0	0	-	-

Table 6 illustrations that, there statistically insignificant variance has been observed among examined groups according to quality of life at baseline p>0.05, there statistically significant variance has been observed among examined groups according to quality of life following one month, after three months and after six months p-value less than 0.05.

Table 6. Distribution of quality of life among the examined groups.

	GROUP A NUMBER=SEVENTY THREE)	GROUP B NUMBER=SEVENTY THREE)	TEST	P VALUE
BASELINE				
MEAN ± SD	26.33±7.42	25.85±5.7	t=0.4383	0.66
AFTER 1 MONTH				
MEAN ± SD	84.6±8.61	81.5±8	t=2.2536	0.02
AFTER 3 MONTHS				
MEAN ± SD	84.5±8.54	81.5±7.2	t= 2.2947	0.02
AFTER 6 MONTHS				
MEAN ± SD	81.68±10.14	79.29±10.31	t=2.1743	0.03

Table 7 demonstrations that, there statistically insignificant variance has been observed among studied groups according to BNI facial numbness scores at baseline and after six months p-value more than 0.05. While there was statistically significant variance among examined groups according to BNI facial numbness scores at day one, after one month and after three months p-vale less than 0.05.

Table 7. Distribution of BNI facial numbness scores among the examined groups.

	GROUP A NUMBER=SEVENTY THREE)	GROUP B NUMBER=SEVENTY THREE)	TEST	P VALUE
BASELINE				
III	71 (97.3%)	68 (93.2%)	X^2= 1.35	0.24
IV	2 (2.7%)	5 (6.8%)		
AT DAY 1				
I	67 (91.8%)	55 (75.3%)	X^2= 7.18	0.007
II	6 (8.2%)	18 (24.7%)		
AFTER 1 MONTH				
I	71 (97.3%)	65 (89%)	X^2= 3.865	0.04
II	2 (2.7%)	8 (11%)		
AFTER 3 MONTH				
I	73 (100%)	69 (94.5%)	X^2= 4.113	0.04
II	0 (0%)	4 (5.5%)		
AFTER 6 MONTH				
I	71 (97.3%)	70 (95.9%)	X^2= 0.207	0.64
II	2 (2.7%)	3 (4.1%)		

Table 8 demonstrations that there statistically significant variance has been observed among examined groups according to patient satisfaction after 1 month, there was highly statistically significant variance among examined groups according to patient satisfaction after 3 months and after six months p-value less than 0.05.

Table 8. Distribution of Patient satisfaction among the examined groups.

	GROUP A NUMBER=SEVENTY THREE)	GROUP B NUMBER=SEVENTY THREE)	TEST	P VALUE
AFTER 1 MONTH				
MEAN ± SD	3.8±0.81	3.5±0.68	t=2.4236	0.01
AFTER 3 MONTHS				
MEAN ± SD	4.54± 0.5	4.2±0.76	t=3.1932	≤0.001
AFTER 6 MONTHS				
MEAN ± SD	4.31±0.52	3.97±0.72	t=3.2708	≤0.001

4. Discussion

This research demonstrates that there was statistically insignificant variance among the groups in the investigation in terms of age and sex, with a p-value more than 0.05.[6,7]

The investigation conducted by Erdine et al.[8] aimed to assess the impact of pulsed radiofrequency compared to conventional radiofrequency in treating idiopathic trigeminal neuralgia. It was a prospective, randomized, double-blinded investigation. They discovered that there were insignificant variations among the groups in terms of age and gender.

This research demonstrates a statistically significant distinction among the groups in the investigation based on Complications with a p-value of less than 0.05.

Our results supported with Goda Mohamed& El-Aaser[9] who reported that there was significance between the studied groups regarding Complications (Masseter weakness, Dysesthesia/Dysisthesia, and Vomiting).

This study illustrations that, there statistically insignificant variance has been obsrved among examined groups according to NRS-11 score at baseline p>0.05, after three months, there was statistically significant variance among studied groups according to NRS-11 score at day one, after one month, & after six months p-value less than 0.05.

Our results supported the findings of Li et al.[10] who stated that there was a significant difference in the average Numeric Rating Scale score prior to the surgery among the groups (p > 0.05). Following radiofrequency therapy, all cases had significant relief of pain. Following a period of twelve months, the percentage of participants having great pain reduction surpassed seventy percent in each of the three groups. There were statistically insignificant variations in the rate of excellent pain alleviation (p-value less than 0.05) and the average Numeric Rating Scale score among the groups (p > 0.05). Following a duration of three months, it was seen that two cases in the SCRF group, three cases in the LCRF group, and two cases in the PCRF group had minor pain, as indicated by a Numeric Rating Scale score ranging from one to three.

This investigation demonstrates that there was statistically insignificant variation among the groups under examination in terms of BNI score at the beginning and following six months, with a p-value more than 0.05. Nevertheless, a statistically significant distinction was observed among the groups in terms of BNI score on day one, following one month, and following three months, with a p-value less than 0.05.

This investigation demonstrates that there was statistically insignificant variance among the groups in the investigation in terms of the dosage of carbamazepine at the beginning and following a period of three months, with a p-value greater than 0.05. Significant variation was observed among the tested groups in terms of the dose of carbamazepine on day one and after one month of management, with a p-value of less than 0.05.

Our findings confirmed the findings of Elawamy et al.[11] who stated that there was statistically insignificant distinction among the groups in study in terms of the initial dosage of carbamazepine. Furthermore, the researchers discovered that there was statistically insignificant distinction among the groups being evaluated according to the dosage of carbamazepine at one month, six months, twelve months, & twenty-four months.

This investigation demonstrates that there was statistically insignificant distinction among the groups being evaluated in terms of quality of life at the beginning of the investigation. There was a statistically significant distinction in the quality of life among the tested groups following one month, three months, and six months of treatment, with a p-value of less than 0.05.

Li et al.[10] observed that the initial quality of life in all cases was 0.05. After one year following the operation, the quality of life of all cases showed significant improvements compared to the baseline value (p-value less than 0.01).

This research demonstrates that there was statistically insignificant variance among the groups in investigation with regard to of BNI facial numbness ratings at both the beginning and following a period of six months with a p-value higher than 0.05. There was a statistically significant distinction in BNI facial numbness scores among the study groups on day one, after a month, and after three months of management, with a p-value of less than 0.05.

Huang et al.[12] performed an investigation to evaluate the efficacy & safety of TRF therapy on the ophthalmic (V1) division of trigeminal branches in cases with idiopathic TN. Their research was carried out in China. In a retrospective research with a single-arm design, the rate of being pain-free at 3 months was 98.75 percent. 93.8 percent of cases have skin numbness in the forehead region.

This investigation demonstrates a statistically significant variance in case satisfaction among the examined groups after a single month. Furthermore, there is a very statistically significant variation in case satisfaction among the studied groups following three and six months, with a p-value of less than 0.05.

Nevertheless, Orlandini[13] criticized specific aspects of this article. He stated that the pain

reduction was achieved with the percutaneous PRF therapy of the Gasserian ganglion.

4. Conclusion

Regarding our results, complication was found lower, patients' satisfaction was higher observed in the Fluoroscopic Image Guidance pulsed radiofrequency combined with low temperature CRF than Ultrasound-Guided PRF combined with low temperature continuous radiofrequency.

So, we can conclude that the Fluoroscopic Guided Gasserian Ganglion Pulsed and continuous Radiofrequency is more effective, safer than Ultrasound-Guided pulsed radiofrequency combined with low temperature continuous radiofrequency for the Management of Trigeminal Neuralgia.

Disclosure

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