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Efficacy and safety of combined thermocoagulation radiofrequency and pulse radiofrequency in the treatment of trigeminal neuralgia

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ABSTRACT

Aims: The aim of this study was to evaluate the efficacy and safety of radiofrequency thermocoagulation (RFT) combined with pulsed radiofrequency (PRF) of the Gasserian ganglion in patients with V2/V3 trigeminal neuralgia (TN).

Methods: We evaluated 27 patients with V2/3 TN who had undergone combined RFT and PRF of the Gasserian ganglion. Patients were treated with PRF (42°C, 45 V, 20 ms, 120 s), RFT (65°C, 60 s), RFT (70°C, 60 s), and PRF (42°C, 45 V, 20 ms, 120 s), consecutively. Visual analogue scale (VAS) and Barrow Neurological Institute Pain Intensity Scale (BNI) scores were evaluated before and after (1st month, 6th month, and 12th month) the procedure. A BNI score of 1-3 was considered as an effective treatment, while a BNI score of 4 or 5 indicated unsuccessful treatment.

Results: VAS scores were significantly lower than the baseline values in all post-treatment evaluation visits (1st month, 6th month, 12th month) during the 12-month follow-up period ($p<0.001$). After treatment, 26 patients (96.2%) at 1 month, 25 patients (92.5%) at 6 months, and 20 patients (74%) at 12 months had BNI scores of 1-3. No association was found between improvement in BNI and variables such as age, gender, duration of pain, TN side, affected branch, or pre-treatment VAS scores ($p>0.05$).

Conclusion: Combined RFT and PRF to the Gasserian ganglion is a safe and effective therapeutic approach in the treatment of TN. However, its efficacy partially decreases after one year.

Keywords: Trigeminal neuralgia, Gasserian ganglion, pulse radiofrequency, radiofrequency thermocoagulation

INTRODUCTION

Trigeminal neuralgia (TN) is characterized by short-term, extremely severe, paroxysmal electric shock-like pain in the facial region innervated by one or more trigeminal nerve branches.[1] Primarily affected branches are the 2nd, 3rd and less often 1st branch in TN.[2] The prevalence of TN is 12.6-28.9 per 10 million increasing with age, and the prevalence is almost twofold higher in women.[3]

The etiopathogenesis of TN has not yet been clearly explained. According to the most accepted firing hypothesis in pathophysiology, compression or demyelination in the afferent neurons of the trigeminal root or ganglion may lead to the sensitization of neurons and cause ectopic impulses.[4]

The first-line treatment of TN is carbamazepine, and approximately 70% of patients respond to carbamazepine.[5,6] In cases where medical treatment fails, or carbamazepine cannot be used due to side effects, many other interventional methods and surgical treatments (e.g., microvascular decompression, percutaneous balloon compression, radiofrequency applications, gamma knife, and percutaneous nerve blocks) can be applied.[6]

Radiofrequency thermocoagulation (RFT) of the Gasserian ganglion is a frequently applied effective method in the treatment of TN. However, some complications such as facial numbness, masseter muscle weakness, decreased corneal reflex, dysesthesia, and anesthesia dolorosa may be seen in patients treated with RFT.[7] Pulsed radiofrequency (PRF) has been tried as an alternative treatment for TN, but controversial results have been reported.[8-12] More recently, it has been reported that low-temperature RFT (<65°C) combined with PRF may be effective in the treatment of pain without increasing complications.[13,14] However, there is no consensus on parameters such as duration of radiofrequency, temperature, and voltage for combined PRF and RFT therapy in the treatment of TN. The purpose of this study was to evaluate the effect

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of combining 120 s of PRF before and after sequential RFT at 65°C and 70°C to the Gasserian ganglion in the treatment of V2/V3 TN.

METHODS

The study was carried out with the permission of Ankara City Hospital No:1 Clinical Researches Ethics Committee (Date: 19.10.2022, Decision No: E1-22-2967). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

The files of 27 patients who were treated with combined RFT and PRF to the Gasserian ganglion with a diagnosis of TN in our clinic between June 1, 2019, and August 31, 2021, were retrospectively analyzed. Since this study was conducted retrospectively, written informed consent was not required.

The inclusion criteria were V2/3 TN and treatment with combined RFT and PRF applied to the Gasserian ganglion, and had an assessment of pain and improvement with VAS at baseline, 1st, 6th and 12th months and BNI at 1st, 6th and 12th months. Patients with inadequate final needle position, patients with TN secondary to mass compression, and patients with a history of interventional procedures for TN other than radiofrequency treatment were excluded.

All procedures were performed under operating room condition according to routine clinical application of our clinic. In our RFT and PRF application for TN clinic blood pressure, pulse rate, and arterial oxygen saturation of the patients are monitored continuously after intravenous access was established. Nasal oxygen is administered to the patients during the procedure. Patients is placed in supine position with their heads slightly extended. The C-arm scope is angled to the ipsilateral oblique and caudal to view the medial foramen ovale of the mandibular ramus and a submental image is obtained. The needle entry point is determined as 2.5-3 cm lateral to the labial commissure. After disinfecting the insertion site, local anesthesia is applied with 2% prilocaine. A radiofrequency needle of 10 cm with a 22-gauge, 5-mm active tip is guided into the foramen ovale with tunnel visualization. After the needle is inserted into Meckel's cave, the C-arm scope is rotated laterally to determine the depth of penetration. The tip of the electrode is appropriately placed in the Gasserian ganglion (Figure 1). Electrical stimulation is applied at 50 Hz to determine the sensory threshold and at 2 Hz to determine the motor threshold. The final position of the needle is determined as the site of paresthesia in the pain area with 0.1 to 0.3 V and muscle contraction in the mandible with 0.1-1.5 V. After a negative aspiration test, the following procedures are performed sequentially on the Gasserian ganglion: PRF (42°C, 45 V, 20 ms, 120 s), RFT (65°C, 60 s), RFT (70°C, 60 s), PRF (42°C, 45 V, 20 ms, 120 s). 1 mg/kg propofol injection is used for sedation during RFT procedures.

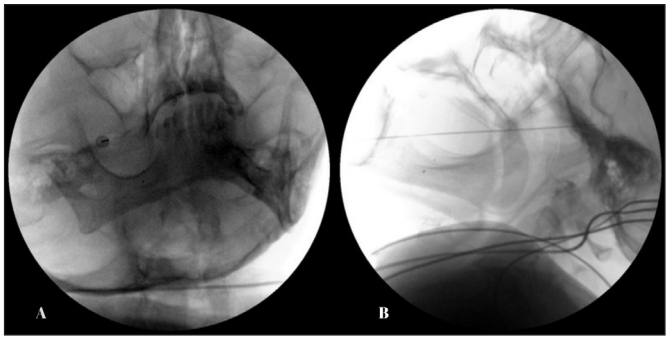

Figure 1. Placement of the radiofrequency needle in oblique submental (A) and lateral (B) cranial radiograph images.

Age, gender, painful side, duration of pain, affected branch, and visual analogue scale (VAS) and Barrow Neurological Institute Pain Intensity Scale (BNI) scores before and after (1st month, 6th month, and 12th month) the procedure were recorded.[13] Pain intensity was measured using the VAS (from 0: no pain, to 10: unbearably severe pain). The BNI score was used to evaluate the efficacy of treatment (Table 1). At 12th month after the procedure, a BNI score of 1 to 3 was considered to reflect effective treatment while a BNI score of 4 or 5 signified unsuccessful treatment. The primary outcome was defined as the effectiveness of treatment after 12 months. The secondary outcomes were VAS scores at the 1st, 6th, and 12th months after the procedure; BNI scores at the 1st and 6th months; and complications.

Table 1. Barrow neurological institute (BNI) pain intensity scale

1	No pain, no medical treatment
2	Occasional pain, no need for medical treatment
3a	No pain, continuing medical treatment
3b	Pain controlled with medical treatment
4	Partial pain, no adequate pain control with medical treatment
5	Severe pain, no pain control

Statistical Analysis

All analyses were performed using IBM SPSS Statistics 25.0 for Windows (IBM Corp., Armonk, NY, USA). Normality analysis was assessed using the Shapiro-Wilk test. Normally distributed quantitative data such as age were represented as mean±standard deviation and non-normally distributed quantitative data such as VAS scores were represented as median (minimum-maximum). Comparisons of numerical data between two dependent measurements were evaluated using the Wilcoxon signed-rank test. For variables that did not show normal distribution, the Friedman test was applied for more than two repeated measurements. Binary logistic regression analysis was used to determine factors

associated with the change in BNI pain intensity scale scores. P<0.05 was accepted statistically significant.

RESULTS

The demographic and clinical characteristics of the patients with TN are summarized in Table 2. Two-thirds of the patients were female. The mean age of the patients was 62.93±10.82 years and mean pain duration was 7.02±5.02 years. Right-sided TN was present in two-thirds of the patients. The most commonly affected branch was V3. V2 was affected in 25.9% (n=7) of the cases, V3 in 44.4% (n=12), and V2+V3 in 29.6% (n=8). There was no systemic disease in 22.2% of cases. Hypertension (59.3%) and multiple sclerosis (25.9%) were the most common associated systemic diseases. The combination of carbamazepine and pregabalin (48.1%) and carbamazepine alone (37%) were the most commonly prescribed medical treatments.

Table 2. Demographic and clinical characteristics of the patients

	Mean±SD or n (%)
Age, years, mean±SD	62.93±10.82
Gender, n (%)	
Female	18 (66.7)
Male	9 (33.3)
Duration of pain, years, mean±SD	7.02±5.02
Painful side, n (%)	
Right	18 (66.7)
Left	9 (33.3)
Affected branch, n (%)	
V2	7 (25.9)
V3	12 (44.4)
V2+V3	8 (29.6)
Systemic diseases, n (%)*	
None	6 (22.2)
Hypertension	16 (59.3)
Diabetes	3 (11.1)
Multiple sclerosis	7 (25.9)
Coronary artery disease	3 (11.1)
Congestive heart failure	1 (3.8)
Hyperlipidemia	1 (3.8)
Cerebrovascular disease	1 (3.8)
Buerger's disease	1 (3.8)
Rectal cancer	1 (3.8)
Drugs used, n (%)	
Carbamazepine	10 (37.0)
Carbamazepine and baclofen	2 (7.4)
Carbamazepine and gabapentin	2 (7.4)
Carbamazepine and pregabalin	13 (48.1)

*: Numbers indicate the total number of diseases; SD: standard deviation

VAS scores are presented in Table 3. The median VAS scores were 9.0 (8.0-10.0) before the intervention, 2.0 (0.0-9.0) at the 1st month, 2.0 (0.0-9.0) at the 6th month, and 3.0 (0.0-9.0) at the 12th month. VAS scores were significantly lower than those at baseline at all post-treatment assessment times (1st month, 6th month, 12th month) during the 12-month follow-up period (p<0.001). There was a significant change in VAS scores over time (p<0.001). Significant differences were found between the baseline VAS score and the VAS score at the 1st month and between the VAS scores at the 6th and 12th months (p<0.001), but not between the VAS scores at the 1st and 6th months (p=0.286).

The BNI pain intensity scores of the patients are shown in Table 4. BNI scores were 1-3 in 26 patients at the 1st month, 25 patients at the 6th month, and 20 patients in the 12th month after treatment. Treatment success was 96.2%, 92.5%, and 74% at the 1st, 6th, and 12th months, respectively. At the 12th month, 4 (14.8%) patients had a BNI score of 1, 6 patients (22.2%) had a BNI score of 2, and 10 patients (37%) had a BNI score of 3 [5 (18.5%) BNI 3a, 5 (18.5%) BNI 3b]. Pain control was not achieved (BNI of 4 or 5) in 7 (25.9%) of the patients. Binary logistic regression analysis revealed no association between improvement in BNI as reflected by a decrease in pain intensity from 4-5 to 1-2-3 and variables such as age, gender, duration of pain, side of TN, affected branch, or pre-procedural VAS score (p>0.05).

Table 4. BNI scores of patients over time

	1st month	6th month	12th month
BNI score (%)			
1	6 (22.2)	5 (18.5)	4 (14.8)
2	7 (25.9)	7 (25.9)	6 (22.2)
3A	9 (33.3)	10 (37.0)	5 (18.5)
3B	4 (14.8)	3 (11.1)	5 (18.5)
4	1 (3.7)	2 (7.4)	6 (22.2)
5	-	-	1 (3.7)

BNI: Barrow Neurological Institute Pain Intensity Scale

After the treatment, the dose of medication was reduced in 74.1% (20/27) patients. Complications (transient abducens paralysis in one patient and transient perioral numbness in one patient) were observed in 7.4% (2/27) of the patients, and no other significant complications or side effects were found.

Table 3. VAS scores of the patients over time

	Median (min-max)							
	Baseline	pa	1st month	pa	6th month	pa	12th month	pb
VAS	9.0 (8.0-10.0)	<0.001	2.0 (0.0-9.0)	0.286	2.0 (0.0-9.0)	<0.01	3.0 (0.0-9.0)	<0.001

VAS: Visual analogue scale, pa: Wilcoxon signed-rank test, pb: Friedman test

DISCUSSION

Pain management is challenging in patients with TN. For patients who do not respond to medications or tolerate, RFT to the Gasserian ganglion is one of the most widely accepted and frequently performed interventional procedures. Low morbidity rates and no mortality are the major advantages of RFT compared to surgical methods.[15,16] With RFT of 65°-80° applied to the Gasserian ganglion, small heat-sensitive nerve fibers (A-δ and C-type fibers) that transmit pain sensations are thermocoagulated and denatured, preventing action potential generation and providing analgesia.[10,17] Although there is no difference in pain-free periods with RFT applied at low (<75°C) and high (>80°C) temperatures, more side effects have been reported with RFT applied at high temperatures.[18,19] When the literature was examined, it was observed that RFT treatment was effective in approximately 70% to 90% of cases in the treatment of TN at 1 year after the procedure.[15,16,20] Although RFT is effective in the treatment of TN, it causes many serious complications, including facial numbness, difficulty in chewing, and decreased corneal sensation has led to consideration of PRF as an alternative to RFT. PRF provides analgesia through neuromodulation without thermal lesions of the nerve.[21,22] Studies have shown that the effects of PRF can occur at microscopic and subcellular levels, with C fibers being affected more than A-β or A-δ fibers.[23,24] Conflicting results have been reported with PRF in the treatment of TN. Some studies have reported positive effects of PRF without neurological side effects or complications.[11,25] However, Erdine et al.[26] showed that PRF was not as effective as RFT, with the short-term success achieved for only 10% of patients with TN in a randomized controlled trial.

Recently, studies have been published reporting that PRF combined with low-temperature RFT (<65°C) in the treatment of TN improves the efficacy of the treatment without significantly increasing the complications. In a randomized controlled trial, Elawamy et al.[14] applied PRF to 11 patients at 42°C, RFT to 12 patients at 75°C, and PRF at 42°C followed by RFT at 60°C to 20 patients. They observed the best results (pain-free status at 12 months) in the PRF+RFT group (70%), followed by the RFT group (50%), while pain-free status was achieved by 0% of the patients in the PRF group. The highest number of complications was observed in the RFT group among 45.4% patients, followed by the PRF group with 25% and the PRF+RFT group with 20%. The most commonly noted complications were numbness and weakness at 18.2% in the RFT group, followed by paresthesia at 10% in the PRF+RFT group. Ali Eissa et al.[27] reported the efficacy of RFT at 60-65°C together with PRF applied for 21 patients to be 66.7% at 1 year after the procedure. Ding et al.[28] compared RFT at 68°C with RFT+PRF in 40 patients and found that treatment was more effective in the RFT+PRF group than the RFT group over the course of 2 years (97.5% vs. 85%). They also reported fewer side effects and faster recovery times in the RFT+PRF group. Arıcı et al.[12] applied RFT (65°C) + PRF (42°C) for 12 patients. While there was a significant reduction in pain for 10 patients (83.3%) at the 1st month after the procedure, similar efficacy was observed for 8 patients (66.6%) at the 6th month, 5 patients (41.6%) at the 12th month, and 2 patients (16.6%) at the 24th month. Abdel-Rahman et al.[29] compared the effect of adding PRF to RFT (60°C) with the effect of RFT alone (70°C) in the treatment of recurrent TN after microvascular decompression. Treatment efficacy was similar between the groups for 2 years, but the complication rate in the RFT+PRF group was statistically lower than that in the RFT-alone group (5.61% vs. 36.8%).

In the literature, there are reports on different applications regarding the type, duration, and RFT temperature in combined PRF+RFT treatment and their superiority over each other is not yet clear. In our study, unlike previous studies, we applied 2 consecutive rounds of 60 s each of RFT at 65°C and 70°C and 120 s each of PRF at 42°C before and afterwards. We did not exceed 70°C in the RFT applications due to the increased complication rates of RFT applied at high temperatures. In our study, we were able to achieve pain reduction for 96.2% of all patients in the 1st month (BNI 1-2: 48.1%; BNI 3: 48.1%), 92.5% in the 6th month (BNI 1-2: 44.4%; BNI 3: 48.1%), and 74% in the 12th month (BNI 1-2: 37%; BNI 3: 37%). Four patients (14.8%) were completely pain-free at the 12th month. The post-procedural pain scores of our patients were significantly lower at the 1st month, 6th month, and 12th month compared to preprocedural scores, which indicates that the effect of the procedure starts early and continues for 1 year. Our success rate at the 12th month is similar to that of Ali Eissa et al.[27] The reason for our higher success rate compared to that of Arıcı et al.[12] (41.6%) may be that they performed RFT at 65°C, which is relatively low compared to our procedure, and they performed PRF for a shorter time (120 s). Ding et al.[28] reported a high success rate of 97.5% in comparison to the literature. This may be because they performed PRF for 10 min. Although Elawamy et al.[14] and Abdel-Rahman et al.[29] performed PRF for 10 min, they performed RFT at a lower temperature (60°C) than Ding et al. (68°C), which may explain their lower success rate.

More recently, the reasons for the low efficacy of PRF in the treatment of cases of chronic pain, including TN, have been investigated. In a study of rats, Tanaka et al.[30]

showed more anti-allodynic effects in the group treated with PRF for 6 min than in the groups treated with PRF for 2 or 4 min. Similarly, Chua et al.[25] claimed that PRF treatment with a pulse width of 20 ms and frequency of 2 Hz for 2 min was insufficient for TN. These data may indicate that short-term PRF treatment is insufficient for good neuromodulatory effects on the Gasserian ganglion. Currently, there is no consensus on the treatment duration, temperature, or voltage parameters for PRF combined with RFT. Different applications and success criteria may explain the significant differences in efficacy reported in various studies. The most important reason for using BNI scores as the primary outcome in our study is that, unlike VAS scores, the BNI assesses both pain and medication use at the same time. For patients who do not respond to medical treatment before radiofrequency treatment, pain may decrease with medical treatment after radiofrequency treatment and these patients should be considered to have benefited from radiofrequency treatment.

Zhao et al.[31] claimed that combining RFT with PRF reduced complications such as facial numbness, masseter muscle weakness, and decreased corneal reflex. Arıcı et al.[12] reported numbness of the tongue lasting for 1 year in only one of 12 patients who underwent PRF+RFT. In our study, postoperative complications were seen in only two patients. Anesthesia dolorosa, infection, and permanent cranial nerve palsy were not observed in any of our patients. Only one patient experienced transient abducens paralysis and one patient had transient perioral numbness.

This study had certain limitations. First, it is a retrospective study. Second, the number of patients is relatively small and no control group was included. Finally, absence of a neuropathic pain scale records and functional outcome score are other limitations.

CONCLUSION

Combined PRF+RFT treatment (2 consecutive rounds of 65°C and 70°C RFT for 60 s each and 42°C PRF for 120 s each before and after) provides significant pain relief and reduction in using analgesic drugs in patients with TN for at least 12 months without any serious complications..

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Ankara City Hospital No:1 Clinical Researches Ethics Committee (Date: 19.10.2022, Decision No: E1-22-2967).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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