

Combined Conventional and Pulsed Radiofrequency (CCPRF) Ablation versus Pulsed Radiofrequency (PRF) Ablation in Patients with Refractory Typical Trigeminal Neuralgia. A Multicentric, Retrospective and Comparative Study

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BACKGROUND: The prevalence of typical trigeminal neuralgia (TN) in Egypt is 29.5/100,000. The combined conventional and pulsed radiofrequency (CCPRF) ablation is a novel combined ablation technique that starts by pulsed radiofrequency (PRF) ablation followed by conventional radiofrequency (CRF) ablation at low temperature of 60°C. The CCPRF is thought to control the symptoms for longer durations better than PRF ablation and with little accepted side effects.

OBJECTIVE: This study aimed to assess the outcome of PRF ablation as a monotherapy in the management of TN in comparison to the CCPRF ablation.

PATIENTS AND METHODS: This is a multicentric, single surgeon, retrospective comparative study. Databases of the hospitals were searched for patients with classic TN who underwent PRF ablation (pulsed lesioning only at 42°C for 360 seconds) or CCPRF ablation (combined lesion starts by the PRF followed by a conventional lesion of 60°C for 180 seconds) between March 2017 and January 2020. Exclusion criteria were patients with atypical TN, multiple sclerosis (MS) or iatrogenic post dental interventions. Data included patients' demographic data, medical history, any comorbidities, and their clinical evaluation by the Barrow Neurological Institute (BNI) scale for pain preoperatively and the BNI scale for pain and numbness immediately postoperative and at 3, 6 and 12 months postoperatively, as well as the trigeminal segment affected.

RESULTS: Among 43 included patients with classic TN, 23 underwent PRF ablation and 20 underwent CCPRF ablation. Patients' preoperative facial pain showed no significant difference between PRF ablation and CCPRF ablation groups. The immediate results for pain BNI scale for the PRF and CCPRF groups improved significantly to 2.7 ± 0.59 and 2.55 ± 0.68 , respectively. There was a significant difference in the BNI scale for facial numbness between PRF and CCPRF groups in the immediate postoperative period, with means of 1.39 ± 0.49 and 1.85 ± 0.67 , respectively. At 12-months follow-up CCPRF ablation had better pain control over PRF ablation as the means of BNI pain was 2.2 ± 0.76 for the CCPRF group and 3 ± 1.2 for the PRF group with 3 patients with total relapse to the original pain intensity in the PRF group. The postoperative numbness gradually improved in the follow up period and the difference between both groups became nonsignificant.

CONCLUSION: The CCPRF ablation has proven to obtain long term pain relief over PRF ablation with less bothering side effects than CRF due to the utilization of less temperature for the lesion.

KEYWORDS: Conventional, Pain, Pulsed, Radiofrequency, Trigeminal Neuralgia.

INTRODUCTION

Typical (classic) trigeminal neuralgia, a morbid condition that commonly causes unilateral, episodic facial pain which is characterized as a burst of electric shocks in one or more branches of trigeminal nerve.¹ Typical TN usually occurs due to a stimulus such as facial touch, eating or drinking, which is called allodynia.² The prevalence of typical TN in Egypt is 29.5/100,000, with higher female predominance.^{3,4} TN is termed 'the suicidal disease' due to its implications in the daily activities of the persons suffering from it, consequently, it is a very morbid situation.⁵ Typical TN commonly results from neurovascular compression at

the root entry zone of trigeminal nerve, this is termed classic TN according to the international classification of headache disorders.^{6,7} Other causes are idiopathic TN or secondary TN.⁶

According to the guidelines of the American Academy of Neurology (AAN), approach to classic TN is based on conservative management, and carbamazepine is the drug of choice that have a symptom relief rate of 80%. However, it is not well tolerated, and its efficacy decreases by 50% over time.⁸ The AAN advised to offer the surgical option which is microvascular decompression (MVD) to patients who are refractory to medications,⁹ as MVD has been able to control pain in 90% of patients,⁸ however, not all patients accept undergoing a brain surgery to relieve pain. Consequently, there are many alternative minimal invasive interventions to manage TN for example, radiofrequency of the Gasserian ganglion, retro

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Gasserian glycerol injection and Gamma knife.¹⁰

Radiofrequency ablation is a simple, safe and minimal invasive intervention for refractory classic TN.¹¹ There are two methods of implying RF which are CRF and PRF. CRF utilizes a high degree and continuous high temperature that may reach up to 90°C, resulting in direct tissue degeneration. CRF ablation has good results in pain control, however, it has unbearable side effects such as bothering numbness and dysesthesia.^{12,13} In contrast, PRF acts in a pulse mode where between the 2 pulses there is a period of drop in temperature and its highest temperature does not rise more than 42°C. PRF acts by reprogramming the pain fibers rather than tissue degeneration.¹⁴ The modulation in the pain fibers ‘nociceptive fibers’ results in pain relief with little tissue damage thus less side effects.¹⁵ PRF ablation was reported to be ineffective as a monotherapy for TN with less ability to control pain and limited long term results.^{16,17} The combination of PRF and CRF termed CCPRF technique has been recently implied to improve the outcome of RF and limit the unbearable side effects of CRF ablation alone.¹⁸ This study was implemented to assess the outcome of PRF ablation as a monotherapy in the management of TN in comparison to the CCPRF ablation.

PATIENTS AND METHODS

This is a multicentric, single surgeon, retrospective comparative study. Databases of the hospitals were searched for patients with classic TN who underwent PRF ablation or CCPRF ablation between March 2017 and January 2020. Selection criteria were typical (classic) trigeminal neuralgia, any age, complete records with follow-up period of 12 months. Exclusion criteria were patients with atypical TN, MS or iatrogenic post dental interventions. Data obtained for analysis were the demographic data of the patients, history of their illnesses, any comorbidities in addition to their clinical evaluation by the Barrow Neurological Institute (BNI) scale for pain preoperatively and the BNI scale for pain and numbness immediate postoperative, and 3, 6 and 12 months postoperatively¹⁹, as well as the trigeminal segment affected. Total number of cases was 43 cases, 20 cases underwent PRF ablation, and 23 cases underwent CCPRF ablation. In addition, complications related to the procedure were analyzed. In this study we followed the World Medical Association (WMA) Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. All patients were consented for the surgical intervention along with a research consent for the publishing of the medical data. This study was approved by the Institutional Review Board (IRB) for publishing.

Intervention procedure

Patients were positioned supine with a pillow beneath their shoulders to obtain a hyperextended head

position. A mark was put on the skin 2.5 cm lateral to the ipsilateral oral commissure to obtain an entry for the needle standard submental approach (**Fig. 1**).

Local anesthesia was achieved with Lidocaine 1% and general sedation was achieved by Propofol 1 mg/kg. Afterwards, fluoroscopically guided by C-arm, a RF needle (22-G curved needle with 2-mm active tip) was introduced after obtaining the foramen Ovale in anteroposterior position (**Figs. 2, 3a**) and proceeding towards the foramen Ovale in a lateral view to confirm the needle in the petroclival junction (**Fig. 3b**).



Fig 1: An image of the patient lying supine with a skin mark exactly 2.5 cm lateral to the angle of the mouth.



Fig 2: A submental approach where the C-arm is positioned to localize the foramen ovale in the ipsilateral side.

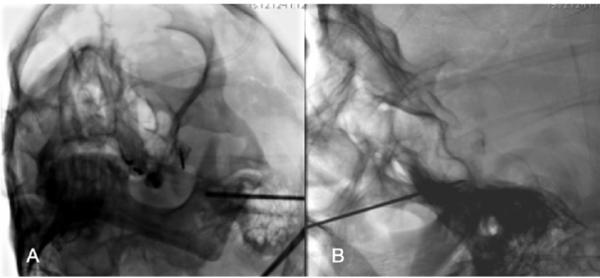


Fig 3: A: Submental approach in anteroposterior fluoroscopic view where the needle is located inside the foramen Ovale. B: Lateral fluoroscopic view where the needle tip is lying before the clival line (targeting V3).

Mandibular (V3) segment was targeted by stopping the needle before the clival line and maxillary (V2) segment

was targeted by proceeding until the clival line. After confirming the correct position, the patients were awaked and RF using Inomed Neuro N50 (Inomed Medizintechnik GmbH Emmendingen, Germany) sensory stimulation was performed to confirm the correct segment by 50 Hertz with 0.3-0.5 Volts (**Fig. 4**). Atropine 1mg was given intravenously to abolish the trigemino- cardiac reflex and patients were sedated once more for the beginning of the lesion. Afterwards patients were left in the recovery room for recovery from anesthesia for up to 2 hours and reassessed. In PRF ablation the temperature was set on 42°C for 360 seconds, while in CCPRF ablation PRF ablation was started as previously mentioned followed by a CRF lesion with a low temperature of 60°C for 180 seconds.

Table 1: Summary of demographic data

Parameters	PRF	CCPRF
N	23	20
Age	49.8±8.4	50.2±11.3
Sex	Females	15
	Males	8
Segment	V2	1
	V2-V3	7
	V3	15
Comorbidity	Hypertension	9
	Diabetes mellitus	10
	Ischemic heart disease	3
	Smokers	5
		8

Statistical analysis

The data collected from medical records were coded and entered using Microsoft Excel Software. Collected data was processed using the Statistical Packages for the Social Sciences (SPSS) version 19 (SPSS Inc., Chicago, IL, USA). The quantitative data was expressed as means ± standard deviation (SD) while the qualitative data was expressed as numbers and percentages (%). Chi Square was used to test significance of difference for the quantitative variables. Results were presented in tables and graphs. A probability value < 0.05 was considered statistically significant.



Fig 4: Electrode is connected to the needle and radiofrequency session is started.

RESULTS

Among total of 43 patients who underwent the RF ablation for classic TN, 23 underwent PRF ablation and 20 underwent CCPRF ablation from March 2017 to January 2020. **Table 1** summarizes the demographic data and the co-morbidities.

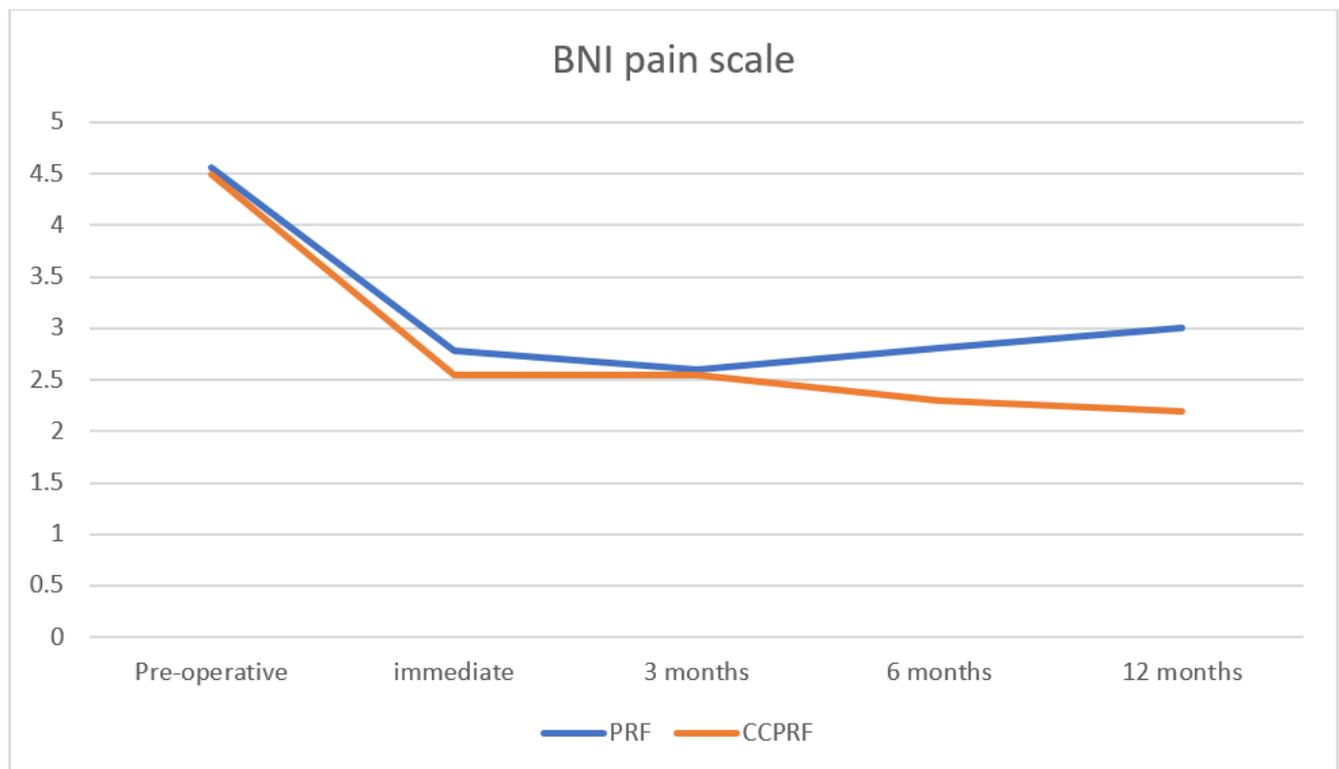
Clinical evaluation of patient's facial pain preoperatively using BNI scale showed nonsignificant differences between PRF and CCPRF groups with mean of 4.56 ± 0.50 and 4.5 ± 0.512 , respectively. The immediate results for BNI pain scale for the PRF and CCPRF groups improved significantly to 2.78 ± 0.59 and 2.55 ± 0.68 , respectively.

At 12-month follow-up CCPRF ablation had the upper hand in pain control over PRF ablation as the means of BNI pain was 2.2 ± 0.76 for the CCPRF group and 3 ± 1.2 for the PRF group with 3 patients with total relapse to the original pain intensity in the PRF group. (**Table 2**). However, both showed statistically significant differences between preoperative BNI pain scale and 12-months later (**Graph 1**).

Regarding the numbness of the face as a side effect postoperatively, there was a significant increase in the numbness in the CCPRF group compared to the PRF group immediately postoperatively. However, the results showed resolution of the numbness at the 3, 6 and 12 months postoperatively and results were not significantly different from the PRF group.

There was no significant difference in the BNI scale for numbness between the PRF group and the CCPRF group from preoperatively (**Table 3**) with means from 1.304 ± 0.047 and 1.2 ± 0.41 to 1.39 ± 0.49 and 1.55 ± 0.604 after 12-months, respectively. In addition, there were no significant difference between the BNI scale for numbness at the durations of 3, 6 and 12 months postoperatively (**Table 4**).

There were no encountered complications related to the procedure like infections, facial hematoma, motor weakness, altered trigeminal reflexes, subarachnoid hemorrhage or severe bothersome numbness postoperatively.



Graph 1: Line graph presenting the correlation between the means of PRF and CCPRF in BNI pain scale.

Table 2: BNI scale for pain

Duration	PRF	CCPRF	t-score	p-value
Preoperative	4.56 ± 0.506 (4-5)	4.5 ± 0.51 (4-5)	-0.38	0.7
Postoperative				
Immediate	2.78 ± 0.599 (2-4)	2.55 ± 0.6 (1-4)	-1.2	0.2
3-months	2.6 ± 0.4 (2-3)	2.55 ± 0.6 (1-4)	-0.32	0.7
6-months	2.81 ± 0.8 (2-4)	2.3 ± 0.57 (1-3)	-2.3	0.022*
12-months	3 ± 1.2 (2-5)	2.2 ± 0.7677 (1-4)	-2.6	0.0124*

*Significant value < 0.05 with CI 95%.

Table 3: BNI scale for numbness

Duration	PRF	CCPRF	t-score	p-value
Preoperative	1.304±0.047 (1-2)	1.2±0.41 (1-2)	-1.21	0.2334
Postoperative				
Immediate	1.39±0.499 (1-2)	1.95±0.067 (1-3)	4.9	<0.0001*
3-months	1.39±0.499 (1-2)	1.72±0.58 (1-3)	2.006	0.0515
6-months	1.391±0.489 (1-2)	1.55±0.604 (1-3)	0.96	0.34
12-months	1.39±0.499 (1-2)	1.55±0.604 (1-3)	0.951	0.34

*Significant value <0.05 with CI 95%.

Table 4: BNI scale for numbness between pre-operative and 12-months follow-up

Lesion type	Preoperative	12-month follow up	t-score	p-value
PRF	1.304±0.047	1.39±0.499	0.823	0.41
CCPRF	1.2±0.41	1.55±0.604	2.144	0.0385

*Significant value <0.05 with CI 95%.

DISCUSSION

The results of this study revealed that both lesion types have similar results immediately and at 3-months post-operatively in pain relief (BNI scale). However, at 12-months postoperatively PRF ablation showed to be inferior in effectiveness in comparison to CCPRF ablation in pain control according to the BNI scale, with 3 patients relapsing to their original pain scale.

There was significant increase in the post-lesion numbness (BNI scale) in the CCPRF group in the immediate postoperative period, however, numbness gradually improved during the follow up period and the difference between both groups became nonsignificant.

Kim et al. in their study of 54 patients who underwent CRF ablation and PRF ablation in 2013 reported that PRF ablation showed less satisfactory rate among patients for long term pain control compared to CRF ablation.²⁰ Elawamy et al. in 2017 in their prospective study of 43 patients comparing the PRF, CRF and the CCPRF lesion procedures reported that after 12 and 24 months the CCPRF ablation had a statistically significant reduction in the visual analogue scale (VAS) score for TN than PRF ablation and CRF ablation. In addition, the CRF and the CCPRF groups has stopped medications (carbamazepine) for TN after 6-months postoperatively but the PRF group had to continue on medications.¹⁸ Erdine et al. in 2007 had very interesting results in comparing CRF ablation with PRF ablation, they reported that in the PRF group 2 patients from the 20 had pain relief that only lasted for 3 months and following this period they had relapse of the symptoms. They even concluded that PRF ablation is not an effective method to manage TN.¹⁶ Luo et al. in their study of the PRF ablation for classic TN reported that 39% achieved >50% control of the pain up to 6-months postoperatively and 6 patients had relapse

after 11-months, with total of 61% unsatisfied patients. They assumed that this might be related to the nature of the PRF which depends on the alteration of the synaptic transmission.¹⁵

PRF ablation appeared to cause less bothersome numbness immediately than CCPRF ablation. At 3, 6 and 12-months follow-up the numbness caused by the CCPRF ablation has decreased to a comparable result with PRF ablation. Kim et al. in their prospective study in 2013 reported that PRF ablation had less postoperative hypoesthesia compared to CRF ablation.²⁰ Elawamy et al. in 2017 reported that CCPRF group had postoperative dysesthesia along the course of the trigeminal nerve segment lesioned, however the PRF and the CRF groups reported no sensory changes.¹⁸ Raj et al. in their study reported that CRF ablation had an early success rate nearly up to 100%, however, they had 80% of the patients with facial numbness and 7% with anesthesia dolorosa.²¹

In this series we report no facial hematomas, motor weaknesses, seizures, anesthesia dolorosa or affected trigeminal reflexes in both groups. There has been recurrence of TN symptoms in 13% of the PRF group. and no recurrence in the CCPRF group. Elawamy et al. reported in their series in 2017 that motor weakness was found in 5% of the CCPRF group and 18.2% of the CRF group, while the PRF group had no motor weaknesses reported. Recurrence were reported in 9.1% of the CRF group only.¹⁸ Erdine et al. reported that 8 of the 40 patients in their series had headaches 24 hours post-procedure with mild hypoesthesia in the CRF group that resolved spontaneously and only 1 patient had developed anesthesia dolorosa.¹⁶ Some studies reported that for each increase in the temperature of the lesion above 43 C there is a 2-fold decrease in the time required to achieve the same destructive biologic effect.^{22,23}

CONCLUSION

The CCPRF ablation has proven to obtain long term pain relief over PRF ablation with less bothering side effects than CRF ablation due to the utilization of less temperature for the lesion.

List of abbreviation

AAN: American Academy of Neurology.
 BNI: Barrow Neurological Institute.
 CCPRF: Combined conventional and pulsed radiofrequency ablation.
 CRF: Conventional radiofrequency ablation.
 IRB: Institutional Review Board.
 MS: Multiple sclerosis.
 MVD: Microvascular decompression.
 PRF: Pulsed radiofrequency.
 RF: Radiofrequency.
 SD: Standard deviation.
 SPSS: Statistical packages for the social sciences.
 TN: Trigeminal neuralgia.
 VAS: Visual analogue scale.
 WMA: World Medical association.

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Disclosure

The authors report no conflict of interest in the materials or methods used in this study or the findings specified in this paper.

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