EGYPTIAN DENTAL JOURNAL
www.eda-egypt.org
Vol. 68, 1349:1355, April, 2022
Print ISSN 0070-9484 • Online ISSN 2090-2360
Oral Surgery
Submit Date : 23-12-2021 • Accept Date : 23-01-2022 • Available online: 30-03-2022 • DOI : 10.21608/edj.2022.112385.1922

EVALUATION OF THE EFFICACY AND THE SAFETY OF PULSED RADIOFREQUENCY AS A RECENT TECHNIQUE IN THE MANAGEMENT OF TRIGEMINAL NEURALGIA

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ABSTRACT

Objective: To evaluate the efficacy and the safety of pulsed radiofrequency as a recent technique in the management of trigeminal neuralgia.

Methodology: This study was included 10 patients form outpatient clinic of pain clinic from faculty of medicine, Cairo University and Faculty of Dentistry, Cairo University. All patients suffered from trigeminal neuralgia with sharp and sever pain along the course of the second or third division of the trigeminal nerve. Pain of TN described by the patient as a paroxysmal attack of sharp, lancating pain with history of drug consumption more than 6 months without any signs of improvement. The patients received PRF therapy by use of (NT1100 Radiofrequency Generator- Neuro Therm). The patients were clinically followed up for one year in the outpatient clinic. Pain strength was recorded at 3,6,9 and 12 months postoperatively using the visual analogue scale (VAS). Also, consumption of analgesics (pre-procedure and post-procedure) were recorded.

Results: The current study was conducted on ten patients (6 Male and 4 Female ranging from 40 to 65 years with mean age of 54 years). There was significant decrease in VAS score 3,6,9 and 12 months postoperatively in comparison to the preoperative record and there was significantly reduced in analgesics consumption after two weeks and completely stopped for all the patients after 12 months. No severe postoperative complication was noticed for any patients or during the procedure.

Conclusion: The present study recommended that patients suffering from TN pain after medical treatment for 6 months can do PRF as it is easy, secure and efficient procedure before any trial to perform intra-cranial procedure. PRF can be used successfully as first line of treatment of TN cases to avoid unexpected systemic side effects of drugs.

KEYWORDS: pulsed radiofrequency, trigeminal neuralgia, carbamazepine.

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INTRODUCTION

Craniofacial area pain is a distressing feeling and considered as one of the most common causes to visit the dentist's office. Common causes of craniofacial area pain include trigeminal neuralgia (TN) and temporomandibular joint dysfunction. [1] Trigeminal neuralgia is characterized by paroxysmal attacks of pain whish follow the course of the branches of the trigeminal nerve. Pain remains for seconds to minutes and no pain is felt between the paroxysmal attacks. [2-4] Pain of (TN) is characterized by sharp, lancating, shooting pain and can be like an electric shock. This pain could be evoked by touch or even breeze to the trigger zone on the face or mouth or it is evoked spontaneously. Patients with history of the disease that last for a long duration, may suffered from sensory loss. [4-6]

The first line of treatment of TN is carbamazepine but it had many side effects as drowsiness, fatigue, dizziness, nausea and a sense of exhaustion. [7] If the patient is unable to tolerate the side effects of carbamazepine or the drug was used for more than 6 months without any improvement, in this case the other treatment option is the surgical intervention; as microvascular decompression (MVD), trigeminal root section, radiofrequency thermocoagulation of the Gasserian ganglion, glycerol injection of the Gasserian ganglion, balloon compression and radiosurgery (Gamma knife). [8]

Pulsed radiofrequency (PRF) treatment is a new therapeutic technique for TN pain management which is a minimally invasive technique with multiple therapeutic applications. PRF treatment use radiofrequency short pulse delivered to the nerve tissues through a needle tip without any thermal lesions occurred to the nerve. [9]

Pulsed radiofrequency (PRF) has been developed by Sluijter et al. [10] It is a technique which uses RF at 2 Hz with 45 V as a voltage output, frequency at 500 kHz, for a period of 20 ms. and for 480 ms as a period of rest. These parameters enable the heat "obtained during the period of treatment 20 ms" to distributed during the resting period of 480 ms; thus, the needle temperature is set under 42 °C; so, no neural tissues damage will be occurred.

A study performed by Chua et al. showed an excellent pain relief (>80 % pain relief) for 36 patients suffering from TN and treated by PRF. Chua et al. showed a percentage with excellent satisfactory pain relief result (>80 % pain relief) 73.5 % at two months, 61.8 % at six months, and 55.9 % at twelve months. The previous study showed that no sever postoperative complication had been reported for any patients and there was no need for the patients to stay in the hospital after recovery. [11] A recent study of CT-guided PRF showed an excellent satisfactory pain relief result for twenty patients with idiopathic TN after one year of follow up. [12]

Recently, PRF applied for 6 minutes at 45 V, with a pulse width of 20 ms. and a pulse frequency of 2 Hz. The temperature of the cut-off needle tip was set at 42°C. Pulsed radiofrequency (PRF) had showed a high promising result in the management of TN pain as it is a simple and safe technique and it is less invasive in comparison to other surgical techniques. [13-15]

The aim of the study is to evaluate the efficacy and the safety of pulsed radiofrequency as a recent technique in the management of trigeminal neuralgia.

PATIENTS AND METHODS

Study Design

This study was included 10 patients form outpatient clinic of pain clinic from faculty of medicine, Cairo University and Faculty of Dentistry, Cairo University. All patients suffered from trigeminal neuralgia with sharp and sever pain along the course of the second or third division of the trigeminal nerve. Pain of TN described by the patient as a paroxysmal attack of sharp, lancating pain with history of drug consumption more than 6 months without

any signs of improvement. The Ethics Committee of the Faculty of Dentistry, Cairo University approved the protocol, and a detailed informed written consent including the details of surgery and the possible complications was obtained from all patients.

Eligibility Criteria

The patients were selected as:

Inclusion Criteria

- Complaining of trigeminal neuralgia at least 6 months.
- All patients hadn't any significant medical disorder.
- Age from 40- 65 years old.
- Both sexes were included.

Exclusion criteria

- Infection in the area of point of needle entry.
- Patients suffering from neurological disorder.
- Patient with any blood diseases that interfere with the surgical procedure.
- Patients with history with other surgical intervention used for the treatment of TN.

Preoperative Preparation

Full physical examination of the patients and details laboratory investigations were obtained from the patients to assure his/her accommodation to the surgery. For all the patients steroids therapy regimen were begun at the night before operation in the form of I.V Dexamethasone (Dexamethasone produced by Amrya for Pharmaceutical Industries, Alexandria – Egypt.) 4mg ampule to decrease postoperative edema.

Surgical techniques

In the operating theatre, standard monitors such as electrocardiogram (ECG), non-invasive blood pressure monitoring, and pulse oximetry were connected to the patient, and O_2 was administered via a nasal prong.

The patient was placed in the supine position with slight hyperextension of the neck.

First, the patient receives a conscious sedation in the form of fentanyl and midazolam. After that, propofol injection was done, 0.75 mg/kg. Then, the skin at the area of needle puncture was disinfected and draping was done. 1% lidocaine was injected in the point of needle penetration to anesthetized the skin.

By the aid of C-arm (Fluoroscopic X-ray system, Model ZEN-2090 Pro. GENORAY Co., Ltd, KOREA) a lateral view of the skull was obtained to determine the correct depth of the needle tip penetration until reach the lateral pterygoid plate.

The point of needle (PRF needle Neurotherm) penetration is just below the preglenoid plane of the zygomatic arch. The needle was penetrated the skin perpendicularly until it reaches the lateral pterygoid plate (Figure 1). For maxillary nerve the needle was outgoing a little bit and redirected cephalo-anteriorly about 1 cm to reach the pterygopalatine fossa (Figure 2). For mandibular nerve, the needle was outgoing a little bit and redirected posteriorly to a reach the area just behind the posterior border of the lateral pterygoid plate (Figure 3).

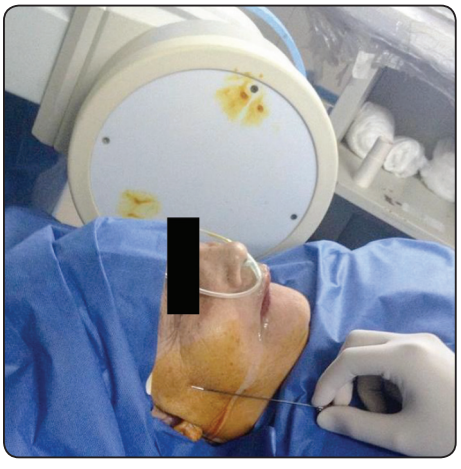

Fig. (1) Photograph showing the C-arm and the point of entry of the PRF needle.

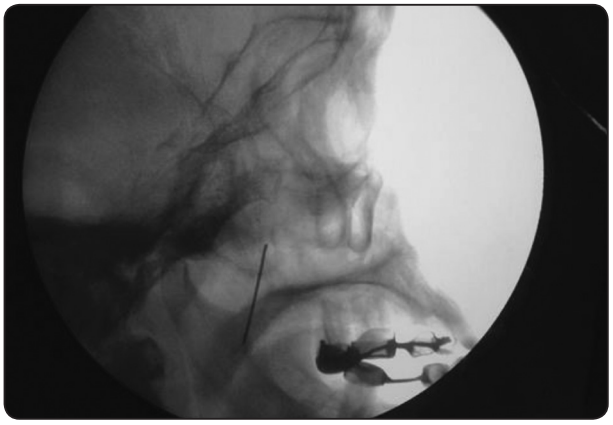

Fig. (2) Radiograph showing lateral view of PRF needle at the pterygomaxillary fissure (course of maxillary nerve).

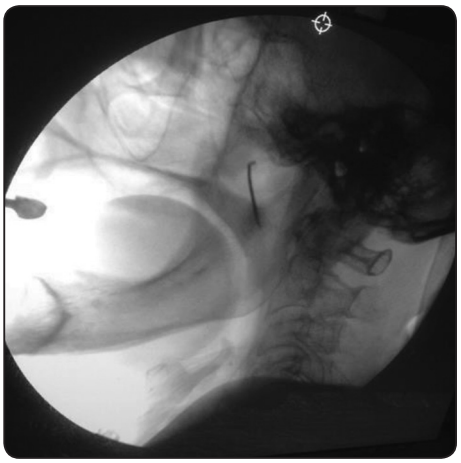

Fig. (3) Radiograph showing lateral view of PRF needle posterior to the posterior border of the lateral pterygoid plate (course of mandibular nerve).

The propofol sedation was stopped and the patient was allowed to be awakening. A grounded electrode was passed through the insulated needle to the tip, and sensory stimulation is carried out at 50 Hz. After sensory stimulation, PRF therapy was begun by use of (NT1100 Radiofrequency Generator- Neuro Therm) (Figure 4). PRF was applied for 6 minutes at 45 V, with a pulse width of 20 ms. and a pulse frequency of 2 Hz. The temperature of the cut-off needle tip was set at 42°C.

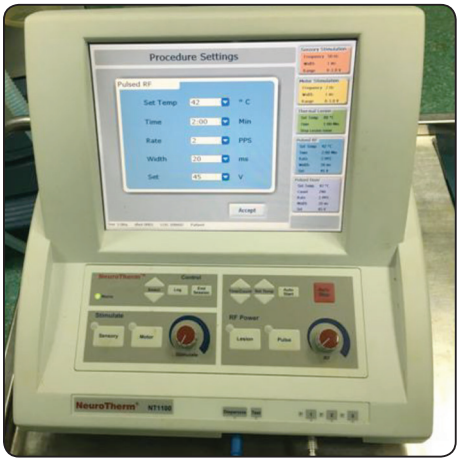

Fig. (4) Photograph showing NT1100 Radiofrequency Generator- Neuro Therm.

Post-Operative Management

All the patients were transported to the recovery room to monitor the vital signs, immediately after operation and for the first 24 hours. A postoperative steroid regimen was prescribed to the patients in the form of dexamethasone ampule 4mg I.V twice a day in the same day of surgery, 2mg twice in the day after the day of surgery and 1mg on the 3rd post-operative days. Also, a post-operative therapy was prescribed to the patients as follow: antibiotic (amoxicillin + clavulanic acid 1 gm 2 times per day) (Hibiotic, Amoun pharmaceutical Co. S.A.E.) and Anti-inflammatory and analgesic (diclofenac potassium 2 times per day) (Cataflam, Novartis Pharma AG, Basel, Switzerland).

Visual analogue scale (VAS) and analgesics consumption (preoperative and postoperative) were recorded. Less than 50 % decrease in VAS score was considered as unsatisfying result, 50–80 % decrease in VAS score was considered as satisfying result, more than 80 % decrease in VAS score was considered as excellent satisfying result of pain relief.

All patients were clinically followed up for one year in the outpatient clinic. Pain strength was recorded at 3,6,9 and 12 months postoperatively using the visual analogue scale (VAS) with a score from 0 to100, and classified as 0-10= absence of pain, >10-

40= mild pain, >40–70= moderate pain, >70–100= severe pain[16]. All the data was collected, analyzed using software program SPSS at level of significant 5%.

RESULTS

The current study was conducted on ten patients (6 Male and 4 Female ranging from 40 to 65 years with mean age of 54 years). All the patients were treated by application of percutaneous pulsed radiofrequency guided by C-arm through the course of maxillary nerve (at pterygomaxillary fissure) and mandibular nerve (at temporal fossa).

1. Visual analogue score (VAS)

There was significant decrease in VAS score 3,6,9 and 12 months postoperatively in comparison to the preoperative record.

At 3 months postoperatively, the percentage of patients who showed excellent satisfying result of pain relief (≥ 80% pain relief) were 60% (6/10) and the percentage of patient who showed satisfying result of pain relief (50–80% pain relief) were 30% (3/10) and the percentage of patient who showed unsatisfying result of pain relief (< 50% pain relief) were 10% (1/10).

At 6 months postoperatively, the percentage of patients who showed excellent satisfying result of pain relief (≥ 80% pain relief) were 60% (6/10) and the percentage of patient who showed satisfying result of pain relief (50–80% pain relief) were 40% (4/10) and the percentage of patient who showed unsatisfying result of pain relief (< 50% pain relief) were 0% (0/10).

At 9 months postoperatively, the percentage of patients who showed excellent satisfying result of pain relief (≥ 80% pain relief) were 60% (6/10) and the percentage of patient who showed satisfying result of pain relief (50–80% pain relief) were 40% (4/10) and the percentage of patient who showed unsatisfying result of pain relief (< 50% pain relief) were 0% (0/10).

At 12 months postoperatively, the percentage of patients who showed excellent satisfying result of pain relief (≥ 80% pain relief) were 60% (6/10) and the percentage of patient who showed satisfying result of pain relief (50–80% pain relief) were 40% (4/10) and the percentage of patient who showed unsatisfying result of pain relief (< 50% pain relief) were 0% (0/10). (Table 1 and 2).

TABLE (1)Visual analogue scale for (VAS)

	Visual analogue scale (VAS)				
	Pre-operative	**Post-operative**			
		3 Months	6 Months	9 Months	12 Months
Case 1	90	20	20	20	20
Case 2	80	5	0	0	0
Case 3	85	15	10	10	10
Case 4	100	60	25	25	25
Case 5	95	30	30	30	30
Case 6	85	0	5	5	15
Case 7	100	10	10	10	15
Case 8	85	25	30	30	30
Case 9	80	0	0	0	0
Case 10	95	10	10	10	15

TABLE (2) SPSS of the Visual analogue scale (VAS)

	Mean	**Standard deviation**	**T test**
Pre-operative	89.5	7.619	15.351***
1 Month	18	17.512	
Pre-operative	89.5	7.619	15.429***
3 Months	17.5	17.989	
Pre-operative	89.5	7.619	13.839***
6 Months	14	11.499	
Pre-operative	89.5	7.619	12.752***
9 Months	14	11.499	
Pre-operative	89.5	7.619	13.390***
12 Months	16	10.750	

******VHS very highly significant.***

2. Analgesic (Carbamazepine) consumption

There was significantly reduced after two weeks and completely stopped for all the patients after 12 months (table 3).

TABLE (3) Medication Intake

	Medication Intake (Carbamazepine)					
	Pre-operative	Post-operative				
		1 Month	3Months	6Months	9Months	12Months
Case 1	800 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/day	0 mg/d
Case 2	800 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/day	0 mg/d
Case 3	600 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/day	0 mg/d
Case 4	1200 mg/d	400 mg/d	400 mg/d	0 mg/d	0 mg/d	0 mg/d
Case 5	1200 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d
Case 6	400 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d
Case 7	400 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d
Case 8	800 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d
Case 9	600 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d
Case 10	800 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d	0 mg/d

DISCUSSION

Management of patients with orofacial pain is one of the biggest challenges faced by professionals. Individuals with chronic pain have a multifactorial problem with physical and psychosocial symptoms. [17, 18] Sydney et al. [19] reported that patients with TN seem to had depression and even trying to end their life by suicide.

Carbamazepine as an anticonvulsant drug is the main drug and the first choice for the treatment of TN pain. The second line drugs are antiepileptic medicines and tricyclic antidepressants drugs. However, there are many side effects of these drugs as sedation, drowsiness, dizziness, nausea, vomiting, diplopia and memory problems. [20] These side effects were the main reason for the professionals to seek for anther line of treatment for TN.

As regard to the results obtained from our study, All the patient who receiving treatment with PRF had no severe complication and there is no need for patient hospitalization after the procedure, this finding was in accordance with Kang et al. [21] study whish concluded that the treatment with the pulsed radiofrequency is a safe, sample and consider as a less invasive procedure whish can be utilized for the treatment of chronic pain conditions. He also suggested that PRF is the treatment of choice for medically compromised patients and for patients who rejected intracranial surgical treatment.

As regarding the visual analogue scale and analgesics consumption, our study showed that there was a significant decrease in VAS score postoperatively after one year of follow up in comparison to the preoperative VAS score and also there was a significantly reduced in analgesics consumption after

two weeks postoperatively and completely stopped for all the patients after 12 months. These measures suggested that the excellent satisfying pain relief (≥ 80% pain relief) obtained by PRF treatment on the long run (after 12 months follow up) portend the long-term efficacy of the PRF as a recent technique in the management of TN. This result was in accordance with Chua et al. [22] who reported that among patients with TN treated with PRF, 67.6% continued to report satisfying pain relief after 2.3 ± 0.8 years of PRF treatment.

The present study recommended that patients suffering from TN pain after medical treatment for 6 months can do PRF as it is easy, secure and efficient procedure before any trial to perform intra-cranial procedure. PRF can be used successfully as first line of treatment of TN cases to avoid unexpected systemic side effects of drugs.

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