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Percutaneous Thermocoagulation Versus Pulsed Radiofrequency Techniques In Management of Refractory Trigeminal neuralgia

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ORIGINAL ARTICLE**Percutaneous Thermocoagulation Versus Pulsed Radiofrequency Techniques In Management of Refractory Trigeminal neuralgia****Abdalla Mohamed Goda Mohamed, Zaki Taha Saleh, Neveen Mahmoud El-Aaser, Khadeja Mahmoud Mohammed Elhossieny**

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ABSTRACT**Background:** Trigeminal neuralgia (TN) is a debilitating condition characterized by sudden, usually unilateral, severe, brief, stabbing recurrent episodes of pain in the distribution of one or more branches of the trigeminal nerve. The treatment of refractory trigeminal neuralgia is often a challenge in clinical practice. Nowadays, radiofrequency (RF) is one of the most effective options for treatment. this study aims to compare the effectiveness of percutaneous fluoroscopic-guided Thermocoagulation radiofrequency (TRF) versus pulsed radiofrequency (PRF) for management of patients with refractory trigeminal neuralgia.**Patients and methods :** A randomized comparative study was carried out in Zagazig university hospitals. Overall, 90 adult patients suffering from refractory TN were randomly assigned to two groups (45 in each). The TRF group was treated with TRF and the PRF group was treated with PRF.**Results :** There were significant improvements in both groups as regards Visual Analog Score which was higher in the TRF group at 12 months of follow up after that, pain began to return in the PRF group rather than in the TRF group.**Conclusion:** Both thermocoagulation radiofrequency and pulsed radiofrequency are effective in relieving pain associated with trigeminal neuralgia. Excellent pain relief and reduced consumption of analgesics for more than 12 months were observed in patients who received thermocoagulation radiofrequency compared with pulsed radiofrequency treatment of refractory trigeminal neuralgia.**Keywords:** Thermocoagulation, pulsed, radiofrequency, refractory, trigeminal neuralgia**INTRODUCTION****T**N is a debilitating condition characterized by agonizing, paroxysmal shooting, lancinating and often like an electric shock. It can be triggered by light touch in any area innervated by trigeminal nerve[1].

It has been recently shown that TN is the most frequent type of facial pain and that, among facial pain syndromes, the overall incidence of TN ranging from 12.6 to 28.9 per 100.00 patient / years[2].

It was demonstrate that a bidirectional relationship between poor sleep and pain, and craniofacial pain and sleep disturbance in a reciprocal manner and it is essential for clinicians to consider both aspects of treatment.. Other studies reported that patients with TN were found to have a 2.17 times greater risk of developing a sleep disorder[3][4][5].

Psychometric scores indicated mild to moderate depression, moderate to severe

anxiety, and moderate to severe functional limitation of daily life activities in TN patients[6][7].

The guidelines on TN management that have been agreed upon and jointly published by the American Academy of Neurology (AAN) and the European Federation of Neurological Societies (EFNS) were very clear as to the medical treatment as first line of treatment. If the patient reaches the therapeutic dosage without achieving the desired pain relief so interventional procedures should be proposed[8].

Hence, the definition of 'refractory trigeminal neuralgia' is easy: a patient with TN that is a non-responder to either of medical treatment or a patient that cannot take them because of specific counter indications or who cannot reach the therapeutic dosage because of excessive adverse effects[9].

By far, one of the most common procedures to treat pain is the use of radiofrequency (RF) lesioning. The main advantages of RF seem to be its effectiveness and high pain relief rate without the dangerous complications of surgical procedures and lack of secondary effects and reduction of oral medication[10].

Thermocoagulation RF (TRF) is the most common technique for treating refractory TN. It involves high-temperature effects of high-frequency current on the gasserian ganglia. The underlying mechanism was due to damaging the nerve's pain signal transmission by high temperature, as well as nonmyelinated fibers that conduct epicritic stimuli and block the transmission of electric activity [11].

Pulsed radiofrequency (PRF) treatment is defined as the delivery of short pulses of radiofrequency via a needle tip, which does not result in an actual thermal lesion. There are mixed views regarding the use of PRF for trigeminal neuralgia (TN) [12].

Aim of the work: To compare the effectiveness of percutaneous fluoroscopic-guided Thermocoagulation radiofrequency (TRF) versus pulsed radiofrequency (PRF) for management of patients with refractory trigeminal neuralgia.

PATIENTS AND METHODS

This study was conducted in zagazig University Hospitals, from January 2015 to March 2018, The work has been carried out in accordance World Medical Association (Declaration of Helsinki) for studies involving humans before prospective collection of patient's data and after informed consent was obtained from patients.

Inclusion criteria

Ninety five subjects presenting with refractory facial neuralgia at Zagazig university hospitals, of either sex, average age 48 - 70 years old, undergo a multidisciplinary assessment, including complete neurological evaluation and magnetic resonance imaging (MRI)

Patients with refusal to procedure, local infection at the needle puncture, uncooperative patients and patients with coagulopathy were excluded from the study.

Sampling :

All patients who met the inclusion and exclusion criteria were included. 90 patients were included during the study period of 3 years (duration of the study). Patients were selected from among those presenting to the pain clinic at Zagazig university hospitals. Patients were randomly assigned to one of the two treatment groups (45 patients in each group). Patients in the TRF group were treated with TRF, whereas patients in the PRF group were treated with PRF.

All participants were subjected to the following:

- Pre-interventional evaluation:
 - History of personal data, onset, course, duration and severity of pain.
 - Concurrent medical illnesses.
- Investigations: Coagulation profile, MRI and fundoscopy to exclude papilledema or disc bulge due to intracranial lesions
- Clinical examination: general, local and neurological
- Baseline evaluative scale for pain: visual analogue scale assessment (VAS).

Procedure:

In the operating theater, standard monitors (ECG, noninvasive blood pressure monitoring

and pulse oximetry) were connected to the patient and O₂ was administered via a nasal prong. The patient was placed in the supine position with slight hyperextension of the neck to facilitate the submental view by fluoroscopy. Conscious sedation was complemented by use of 1 µg/kg fentanyl and 0.05mg/kg midazolam, after 5 min and 2 min; respectively, before local anesthesia infiltration at the site of puncture, and by 0.75 mg/kg propofol, shots during the needle journey through foramen ovale and during RF periods. After proper sterilization of the skin and draping, Fluoroscopy was adjusted in the submental view (caudocranial by 30°–50°) with slight obliqueness (10°–30°) to visualize the foramen oval at the inner side of the mandibular ramus of the affected side. The site of needle entry was 2–3 cm lateral to the angle of the mouth. The RF needle (Neurotherm, 100 mm, 22 gauge, 5 mm active tip, curved) was inserted after injection of lidocaine 1 % infiltration. The tunnel view technique for the needle path was tried, aiming at the pupil in anterior view and the mid-zigoma in lateral view. The needle passed end-on until a depth of 5–7 cm. Once the needle enters the foramen ovale into Meckel's cavity, the C-arm is then rotated laterally to ascertain the depth of penetration. The final position of the needle tip is just past the angle formed by the petrosal ridge of the temporal bone and the clivus. (Fig. 1) The propofol sedation is discontinued, the patient is allowed to awaken, and Trial stimulation: Firsts, sensory stimulation is carried out at 50 Hz. The definitive position of the electrode was verified by inducing paresthesia with sensory stimulation between 0.1–0.3 V in the affected painful area. As a second step, motor stimulation was performed using 2 Hz with 0.1–1 Volt, and the masseter muscle contractions were observed.

After sensory and motor stimulation, RF therapy was started by use of the RF generator (Neurotherm 1100) as:

In TRF group: RF lessoning was done at 60 °C for 60 s; 5 °C increments for 60 seconds up until we reach a maximum of 70 °C for 60

seconds; at each stage, the patient was allowed to recover from the I.V propofol, and we tested for reduction of response to pinprick stimulation.

In PRF group:PRF current is applied for 6 minutes at 45 V, with a pulse width of 10 ms and a pulse frequency of 4 Hz. The cut-off needle tip temperature was set at 42 °C.

All patients were transferred to the recovery room, vital signs were monitored, and ice packs were applied to the patients' faces to reduce facial ecchymosis. Age, sex, VAS and consumption of analgesics (pre-procedure and post-procedure) at 1st day, 1st week 1st month, , 3th month, 6th month and 12th months were recorded as a part of our routine clinic follow-up. Less than 50 % improvement in VAS was regarded as unsatisfactory block; 50–80 % improvement of VAS was regarded as satisfactory block; more than 80 % improvement in VAS was regarded as excellent pain relief. Adverse effects, for example anesthesia dolorosa, moderate headache, facial numbness, mastication muscle weakness, facial swelling, nausea and vomiting, CSF leakage, pain at entry site and facial dyesthesia were recorded.

Statistical analysis

The data were tabulated and analyzed using Statistical Package of Social Science program, (SPSS version 20.0) software Qualitative data were expressed as number and percentage and analyzed using The chi square (χ^2) test Quantitative data were expressed as mean \pm SD and analyzed by using the *t*-test as P value >0.05 not statistically significant , P value <0.05 statistically significant and P value <0.01 highly statistically significant.

RESULTS

Patients' demographic data of two studied groups:

Statistically, there were no significant differences between the demographic data of two studied groups (Table 1)

Age was distributed as 55.91 \pm 6.29 and 53.35 \pm 6.51 between studied groups respectively with no statistically significant

difference between both groups, also there was no statistically significant difference between groups regarding to gender as female were represent about two thirds of both groups, regarding duration of medical treatment and duration of intervention there was no statistically significant difference between both groups.

Pain severity before and at different times of measurements after treatment of the two studied groups:

Statistically, the baseline (pretreatment) VAS values of both TRF and PRF groups were comparable. VAS values of both TRF and PRF groups at 1st day, 1st week and 1st month after treatment were comparable with each other but they highly significant below the corresponding pretreatment value. The VAS values of TRF group at 3rd month and at both 6th and 12th months after treatment were significantly and highly significant lower than the corresponding VAS values of PRF and these value of both groups were highly significant below the corresponding pretreatment value (Table 2) (Figure 2).

Results of the present study demonstrated that there was a statistically statistically highly statistically significant difference as regards VAS at different stages of follow up after TRF when compared with pretreatment stage (Table 3). Moreover, there was a highly statistically significant difference in VAS between different stages of follow up after PRF when compared with pretreatment stage (Table 3).

The incidence of the various associated side effects in the two studied groups:

Statistically, the incidence of facial numbness in TRF group was highly significant higher than in PRF group . Also the incidence of anesthesia dolorosa , moderate headache, mastication muscle weakness and facial dyesthesia, in TRF group were significantly higher than those in PRF group (Table 4).

The incidence of facial numbness in TRF group was 33.3% (15 patients) in the 1st day reduced to 22.3%(10 patients) at first month and reduced significantly to 6.7% (3 patients) at 3rd month and to 0.0% at 6th and 12th months (Figure 3).

Table (1): patient characteristics and duration of medical treatment and interventionof the two studied groups

Data	TRF group n = 45		PRF group n = 45		P
	N	%	N	%	
Gender					
Male	14	31.1%	16	35.6%	0.65
Female	31	68.9%	29	64.4%	
Age (years)					0.062
X ± SD	55.91±6.29		53.35±6.51		
Range (ys)	48.2 - 62.2		47.84 - 66.9		
Duration of medical treatment (years)	2.17±0.88		2.16±0.7		0.947
Duration of intervention (min.)	24±0.59		22±0.79		0.08

Data are presented by mean standard deviation or number (%)

n= total numberof paients in each group

N= number of femal and male patient in each group

P<0.05 means non significant difference

Age was distributed as 55.91±6.29 and 53.35±6.51 between studied groups respectively with no statistically significant difference between both groups, also there was no statistically significant difference between groups regarding to gender as female were represent about two thirds of both groups, regarding duration of medical treatment and duration of intervention there was no statistically significant difference between both groups.

Table (2): VAS values in TRF group versus PRF group at different times of measurements

VAS score	Thermocoagulation Radiofrequency group (TRF) n = 45	Pulsed Radiofrequency group (PRF) n = 45	P
pretreatment	8.82±0.77	8.88±0.68	0.666
1 st Day	3.61±0.66	3.87±0.58	0.115
1 st week	2.29±0.80	2.40±0.66	0.192
1 st Month	1.43±0.65	1.52±0.51	0.289
3 rd Month	1.0±0.35*	1.38±0.34	0.008
6 th Month	0.62±0.23**	2.51±0.82	<0.001
12 th Month	0.57±0.16**	3.64±0.91	<0.001

* Statistically Significant

** highly statistically significant

There was no significant difference between both groups as regard pretreatment, 1st day, 1st week, 2nd week, 3rd week and 1st month after treatment.

Thermocoagulation radiofrequency group was significantly lower VAS score at 3rd month and was highly significantly at 6th and 12th months after treatment than pulsed radiofrequency group.

Table (3): Comparison of VAS values at different times of measurements after treatment of the two studied groups with their corresponding pretreatment VAS value.

Group	VAS score	Mean	Standard Deviation	P
TRF Group n=45	Pre treatment	8.82	0.78	<0.001**
	1 st day	2.51	0.66	
	Pre treatment	8.82	0.78	<0.001**
	1 st Month	1.42	0.69	
	Pre treatment	8.82	0.78	<0.001**
	3 th Month	1.04	0.35	
	Pre treatment	8.82	0.78	<0.001**
	6 th Month	0.62	0.23	
	Pre treatment	8.82	0.78	<0.001**
12 th Month	0.58	0.16		
PRF Group n=45	Pre treatment	8.89	0.68	<0.001**
	1 st day	2.47	0.58	
	Pre treatment	8.89	0.68	<0.001**
	1 st Month	1.52	0.52	
	Pre treatment	8.89	0.68	<0.001**
	3 th Month	1.38	0.52	
	Pre treatment	8.89	0.68	<0.001**
	6 th Month	2.51	0.87	
	Pre treatment	8.89	0.685	<0.001**
12 th Month	3.64	0.91		

n= total number of patients in each group.

P> 0.001 means highly significant differences

Table (4): The incidence of various associated side effects in the two studied groups

Complication	TRF Group n = 45		PRF Group n = 45		P
	N	%	N	%	
Anesthesia dolorosa	5*	11.1*	0	0.0	0.01
Moderate headache	5*	11.1*	1	2.2	0.01
Facial numbness	15**	33.3**	0	0.0	<0.001
Mastication Muscle weakness	5*	11.1*	0	0.0	0.01
Facial swelling	10	22.2	8	17.7	0.42
Nausea vomiting	6	13.3	8	17.7	0.48
CSF Leakage	2	4.4	1	2.2	0.39
Pain at entry site	8	17.7	7	15.5	0.72
Facial dysthesia	3*	6.7*	0	0.0	0.02

* statistically significant

** highly statistically significant

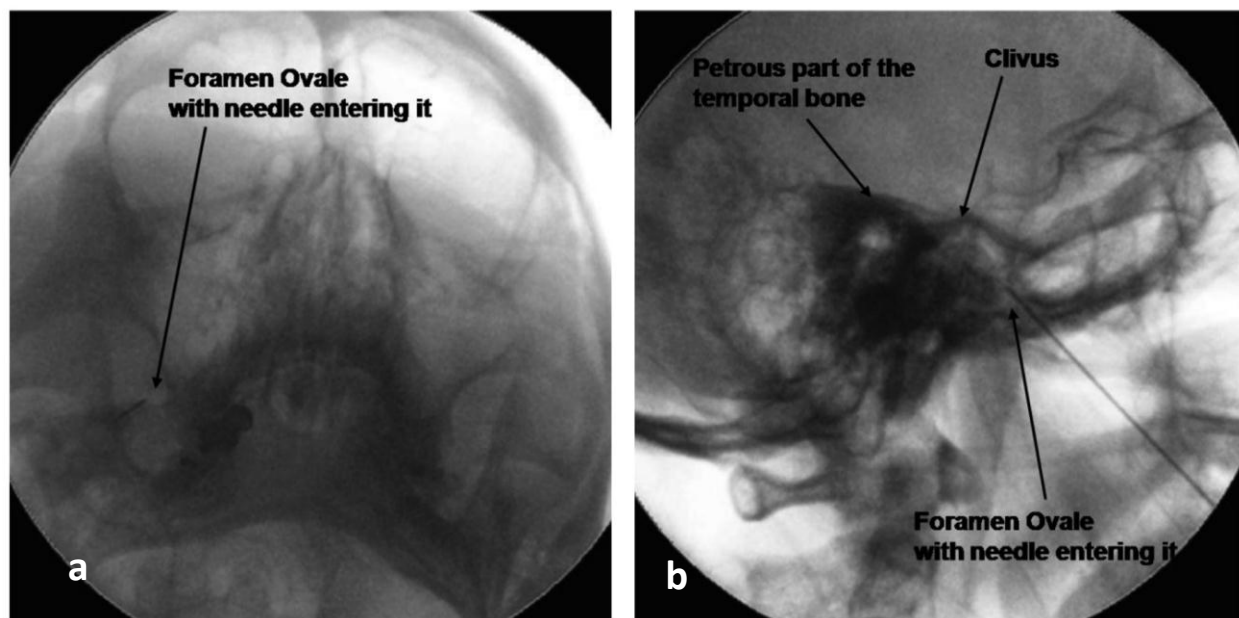
n= total number of patients in each group

N= number of patients with each side effect

P> 0.001 means highly statistically significant

P< 0.05 means non statistically significant

Data were expressed as number and percentage



Fig(1): a. submental and b. Lateral view of the Foramen Ovale)

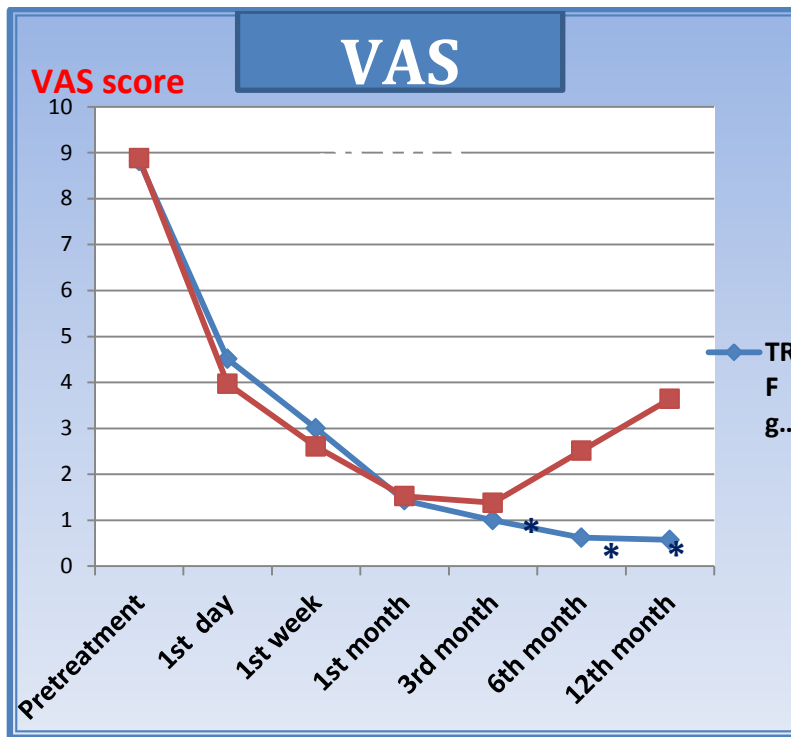


Figure (2): VAS at the different times of measurements in the studied groups

VAS score decreased in both groups until 1st month after intervention but VAS score increases in PRF group and recurrence of pain by the time in follow up. So TRF group was significantly lower VAS score at 3rd month and was highly significantly at 6th and 12th months after treatment than pulsed radiofrequency group.

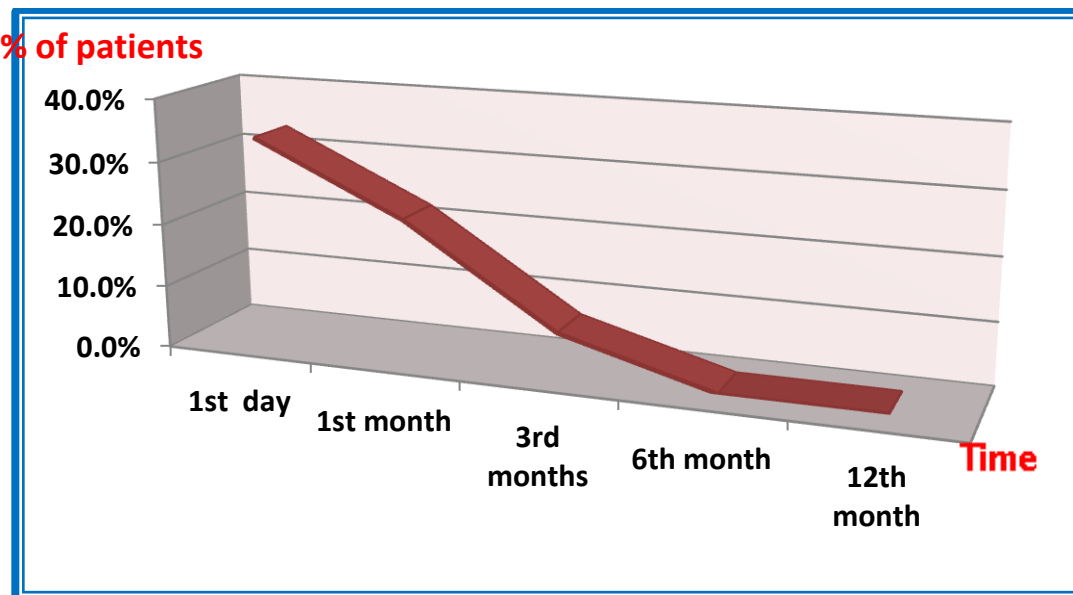


Figure (3): Incidence of facial numbness in different times of measurements in TRF group. Facial numbness decreased by the time in TRF group and disappeared from 6th month.

DISCUSSION

TN is described as the most irritating pain known to humanity [2]. Various drugs and surgical procedures have been used for treatment. Despite numerous available approaches, the results are not completely satisfying.[13] The treatment of patients with refractory TN is often a challenge in clinical practice. By far, one of the most common procedures to treat pain is the use of radiofrequency lesioning (RF). The main advantages of radiofrequency seem to be its effectiveness and high pain relief rate [1].

Interventional procedures include glycerol injection, percutaneous balloon microdecompression, rhizotomy, thermocoagulation with RF, microvascular decompression, and gamma knife radiosurgery, they have numerous advantages including being minimally invasive, quick and having a low incidence of adverse events: these advantages are balanced with a risk of recurrence, which increases over time.all of which may be necessary when other treatments fail[14].

The present study revealed that the ratio of males to females complaining from TN was 1:2, it is closely twice as common in women. A similar pattern of results was obtained in previous studies [15] [16] [17].

This can be due to the posterior fossa volume in males was larger than posterior fossa volume in females. This finding, along with the higher incidence of TN in females, suggests that smaller posterior fossa volume might be an independent factor in the pathophysiology of TN [18].

In the present study, a comparison was made between the TRF and PRF groups in the treatment of refractory TN. As regards pain relief, there was a significant improvement in VAS in both groups throughout the follow-up period; follow-up was scheduled on the first day, at first month, at 3 months, at 6 months and at 12 months after treatment. This improvement continued up to 12 months. PRF patients showed a higher rate of recurrence of pain at 3rd month of follow up. It was stated that thermocoagulation offers the highest rates of

complete pain relief; this is in agreement with the present study, as we found a highly significant difference in VAS scores at different time points of follow-up compared with pretreatment results [19].

In agreement with our results A similar pattern of results was obtained that complete pain relief was found immediately after the procedure in all patients up to the third month follow-up; after that, pain began to return in the PRF group rather than in the TRF group [20].

In agreement with our results, It was illustrated that thermocoagulation of the gasserian ganglion is achieved with a technical success of 98–100%. [21] Also, Immediate pain relief is described as high as 90–95% in multiple studies [20][22][23].

In contrast, it was demonstrated that after TRF treatment pain relief can be achieved in 98% patients but 15%–20% of patients may experience recurrence of pain in 12 months [10] and It was reported that pain recurrence rates are between 25% and 60% after TRF with high incidence of side-effects [24].

It was demonstrated that Pulsed RF is effective and safe technique for TN patients resistant to conservative management.[17] with increase gradually in VAS score with the time in follow up [25].

Trigeminal neuralgia has been treated by TRF of gasserian ganglion effectively. However, it has postoperative side effect such as facial numbness, anesthesia dolorosa, facial dysethesia and masseter muscle weakness [26].

Anesthesia dolorosa may also occur following a trigeminal rhizotomy, it is referred to as a deafferentation pain syndrome [27] Complications like anesthesia dolorosa, though considered rare by some, are regarded to be worse than the initial pain of TN. It was perhaps for this reason that PRF was explored as a less risky alternative [27][28].

In agreement with our observations, The intensity of facial dysethesia was mildest in the TRF group on the seventh day after the procedure and was improved in most cases by the sixth month [29].

There was a statistically significant difference in the incidence of facial numbness between groups I and II. facial numbness can be relieved over short time as it was observed in 15 patients in group. The time to recovery from facial numbness was 4.4 ± 1.9 (3–6) months, by the end of the 3 months there were only 3 patients complaining from facial numbness and by end of 6 month all patients recovery from numbness; no severe facial numbness occurred. In agreement with our results, the incidence of facial numbness was lower in TRF group as previous studies [30][31]. The lower incidence might be accounted for by the lower temperature (60 °C) used for TRF in our study. The incidence of complications after TRF is directly correlated with the temperature of TRF [26].

Patients undergoing TRF plus PRF had decreased recurrence; reduced complications, including corneal hypoesthesia; and shortened time to recovery compared with patients undergoing TRF only. recently reported that PRF reduced the complications and shortened the recovery time after TRF [22][31].

It was demonstrated that a combination of TRF with PRF could help eliminate postoperative complications of trigeminal neuralgia but not increase the pain relief [32].

Limitations of the present study: few number of cases of trigeminal neuralgia

CONCLUSION

Under the condition of the present study we can conclude thermocoagulation radiofrequency is more effective than in pulsed radiofrequency in relieving pain associated with refractory trigeminal neuralgia but associated with more side effects.

RECOMMENDATION

Larger scale, prospective work encompassing combined TRF and PRF, separate PRF and separate TRF groups may yield more solid and clear data.

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