Evaluation of the Effectiveness of Using Pulse Dose Radiofrequency for Treatment of Trigeminal Neuralgia

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Abstract- Trigeminal neuralgia has an incidence of 4-13 per 100000 people per year. The incidence of this disease increases in the elderly, and it is known to cause severe shock-like pain. Pharmacological therapy is the first-line treatment of trigeminal neuralgia. If pharmacological therapy fails, then different procedures are available. Pulse-dose radiofrequency is one such procedure. In this study, we evaluated Pulse dose radiofrequency's efficacy as a method in which pulse amplitude and width are considered essential variables. This research was conducted as a cross-sectional study on trigeminal neuralgia patients referred to the pain clinic of Amir A'lam Hospital in 2020. Conservative therapy has failed; therefore, the clinician decided to use pulse dose radiofrequency to reduce their pain. Among the 29 patients registered during this period, 15 (51.8%) were women and 14 (48.3%) were men. The mean (±SD) age of the patient was 57.07(±14.26) years. The tow route was interrupted in 7 (24.1%) patients. A significant difference was observed between the pain scores before and after the operation (P<0.001). Pulse-dose radiofrequency is a safe and effective therapy for treating trigeminal neuralgia and can be considered a new way to develop the pulse radiofrequency method.

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Keywords: Trigeminal neuralgia; Pulse dose radiofrequency

Introduction

Trigeminal neuralgia (TN) is characterized by recurrent brief episodes of electric shock-like pain the trigeminal nerve, with an incidence of 4-13 in 100000 per year (1,2). Treatment of trigeminal neuralgia is challenging, and there are different methods such as pharmacological therapy, microvascular decompression(MVD), and radiofrequency ablation (RF) (3). Pharmacological therapy is the first choice of treatment. If pharmacological therapy fails, surgical therapy may be considered the second choice. After pharmacological therapy fails, the treatment can be different depending on the type of TN, For the classic type of TN, MVD is the second choice, but neuroablation can be considered the second choice for the idiopathic type (1). Effectiveness and significant rate of pain relief are the greatest advantages of RF procedures (4). This technique employs the thermal energy effect on target nerves that involves the pathological transmission of painful stimuli. RF devices use high-frequency electromagnetic radiation to generate oscillations between molecules that produce heat (5).

There have different subtypes for RF such as conventional radiofrequency (CRF), pulse radiofrequency (PRF), and pulse dose radiofrequency (PDRF). The CRF procedure uses high temperature to denature and necrose tissue in an area that has different and severe adverse effects such as numbness, corneal hypesthesia, masticatory atonia, and blindness during the PRF procedure to maintain the temperature below 42° C thus; PRF tries to avoid thermal damage (6).

PDRF is a PRF subtype. Both these methods try to keep the temperature below the limit of tissue thermocoagulation, but the difference between these two procedures is about how to achieve this goal. In the PRF

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procedure, if the temperature in the tissue increases, the device attempts to modify the next pulse amplitude and width; however, in the PDRF procedure, if the temperature increases, the device waits until the temperature decreases and the next pulse generated with the same amplitude and width. Hence, the difference in this method is not related to temperature but to the pulse and time of silence (7-8).

This study aimied to assess the effectiveness of PDRF in treating trigeminal neuralgia to determine its merits and usefulness. Considering the high morbidity associated with trigeminal neuralgia, we evaluated this method.

Materials and Methods

This retrospective cross-sectional study investigated the different aspects of the Pulse dose radiofrequency (PDRF) procedure conducted in the Department of Anesthesiology and Pain Medicine at Amir A'lam Hospital of Tehran University of Medical Sciences over a period of one year (April 2021-April 2022). The convenience approach was used for sampling, and the Numeric Analog Scale (NRS) was used as a standard questionnaire to evaluate pain. NRS questionnaires scale from 0 to 10, with 0 indicating no pain and 10 representing the worst pain in the patient's life. The inclusion criteria were: 1-patient with a diagnosis of TN and an NRS score of more than seven, known as severe pain, at the beginning 2-The the pharmacological method must be failed or not tolerated by the patient. According to the declaration of Helsinki, patients who met these criteria signed an informed consent from and were registered for the study. Thirty patients registered for the study initially, but one was excluded due to dissatisfaction with participation.

Procedure

At the beginning of the diagnostic block, the trigeminal ganglion was blocked with the guidance of a fluoroscope for each patient. If the patient's pain decreases by more than 50%, the patient is considered a candidate for PDRF. The PDRF procedure was executed in three periods of pulses at 42° C for 120s and under fluoroscopy guidance. We used a Diros RF needle gage22 and an active tip of 5 millimeters (blunt).

To evaluate the efficacy of the PDRF procedure, we compared the scores of the NRS pain questionnaire before surgery, 1 hour, seven days, one month, and three months after the procedure and recorded any adverse effects in this period and the location and side of pain. We describe pain relief of more than 50% as effective pain relief.

For data analysis, descriptive statistics (e.g., mean, SD…) were used to describe the variable. For infer the relationship between variables, inferential statistics such as Kruskal-Wallis ANOVA, Wilcoxon, and Mann-Whitney tests were used. Only *P* less than 0.05 were considered significant.

Results

We identified 29 patients who met our inclusion criteria. The mean (±SD) age was 57.07(±14.621) years (range 25-85), and the highest frequency was for middle-age (44-60 years) patients. This study included 15 female (51.7%) and 14 male (48.3%). Route involvement included the orbital nerve (n=4, 13.8%), mandibular nerve (n=11, 37.9%), maxillary nerve (n=7, 24.1%), and two rout involvement (n=7, 24.1%). The frequency on the right side (n=19, 65.5%) was higher than the one on the left side (n=10, 34.5%).

The NRS score three months after the procedure significantly decreased ($P<0.001$) (Wilcoxon test). The mode and median of the NRS score before surgery were 10 and reported in 23 patients, and the mean pain was 9.52. Complete pain relief (NRS score=0) was observed in 11 patients an hour after the procedure (mean NRS score, 3.28), 12 patients seven days after the procedure (mean=3.34), 14 patients one month after the procedure (mean=3.69), and 13 patients three months after the procedure (mean=4.14, median=3). Effective pain relief (decrease in NRS score of more than 50%) was observed after three months (58.6%). There were no significant differences between the age of the patient and decrease in the pain (Sig2-tail=0.283). (Mann-Whitney test).

The Kruskal-Wallis ANOVA test was used to investigate the difference between the decreased pain relief and the route involved in TN, and no significant differences were found between them (Sig-2tail=0.179).

Side effects were reported in 13 patients (44.8%), including paresthesia [n=11] and swelling of the surgical site [n=5]. We observed masticatory atonia, infection, numbness, decreased corneal reflex, and other side effects, but no patient reported other side effects. The side effects of different routes are summarized in Table 1.

Table 1. Frequency of side effects in different routes

Routes	**V1**	side effect	have not	4
			have	0
	V2	side effect	have not	6
			have	1
	V3	side effect	have not	5
			have	6
	Two routes	side effect	have not	1
			have	6

V1: orbital route, V2: maxillary route, V3: mandibular route

Discussion

Trigeminal neuralgia is a condition characterized by severe shock-like pain, and different medications and surgical therapies are available. Pharmacological therapy is the first choice for different medical treatments such as Carbamazepine, Oxcarbazepine, Baclofen, Lamotrigine, Phenytoin, and Topiramate. If pharmacological therapy is fails, invasive methods such as MVD, stereotactic radiosurgery (SRS), percutaneous radiofrequency rhizotomy (PRR), percutaneous glycerol rhizotomy (PGR), and percutaneous balloon compression (PBC) are available (9,10). In this step, clinicians may suggest different methods according to their center's patient preferences, side effects, and clinical specialists. MVD is the most common surgical method used for the treatment of classic TN. Although MVD provides 70-80% pain relief, it has serious adverse effects such as cerebrospinal fluid leak (1.6%), hearing loss (13.4%), vascular complications (0.7%), incisional infection (1.3%), and facial numbness (9.1%). (11-15). Therefore, some clinicians prefer to use other methods as a first step. A systematic review of ablative neurosurgical techniques for TN found that PRF provided the highest long-term complete pain relief (16).

Although many studies have defined the main mechanism involved in PRF as not temperature, there are many studies on CRF and PRF methods, and the effect of different temperatures on the rate of pain relief and adverse effects. Still, we found a defect in the study of the PDRF method; as a method, the amplitude and width of the pulse are considered essential variables (17,18).

Almost half (44.8%) of our patients in three months after PDRF had complete pain relief, whereas other studies reported complete pain relief for CRF, approximately 33.7%-95%, and PRF, about 0%-85.7% (19-22).

The most common adverse effects of RFT treatment include masticatory atonia, numbness, and decreased corneal reflex. However, facial numbness has been seen in 85-100% of patients in other studies, only 33.8% of our patients reported paresthesia, and any major adverse effect has not been seen in any patient, so we can say that PDRF is a safe method (any adverse effect, even minor adverse effect, not reported by V1 TN) (23-29).

PDRF is a safe and effective therapy for treating trigeminal neuralgia and can be considered a new way to develop pulse radiofrequency.

Limitations

In this study, due to the COVID-19 pandemic and the lack of proper follow-up by patients, there was some interruption in the follow-up of the patient that was solved with a phone call; therefore, recall bias may occure in this process.

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