Observational Study

The Effectiveness and Safety of 42°C Pulsed Radiofrequency Combined with 60°C Continuous Radiofrequency for Refractory Infraorbital Neuralgia: A Prospective Study

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Background: Infraorbital neuralgia, one of the rare causes of facial pain, lacks systematic treatment guidelines because few studies on the topic have been published. We previously found that 42°C percutaneous nondestructive pulsed radiofrequency (PRF) treatment could achieve satisfactory pain relief for infraorbital neuralgia patients. However, patients who responded poorly to PRF had no other ideal treatment options until now. Recently, standard PRF combined with 60°C continuous radiofrequency (CRF) was successfully performed on trigeminal neuralgia patients and achieved a promising effective rate with mild complications. However, the efficacy of the combined therapy in the treatment of infraorbital neuralgia has not yet been reported.

Objectives: To evaluate the effectiveness and safety of 42°C PRF combined with 60°C CRF in infraorbital neuralgia patients who responded poorly to 42°C PRF and were reluctant to receive destructive therapies or nerve decompression surgery.

Study Design: Prospective, single-center, observational clinical trial.

Setting: The interventional pain management center in Beijing Tiantan Hospital.

Methods: We prospectively investigated the effects of 10 minutes of 3-dimensional computer tomography-guided 42°C PRF combined with 270 seconds of 60°C CRF in the treatment of 28 patients with refractory infraorbital neuralgia. The response criterion was a postoperative verbal pain numeric rating scale score reduction of > 50%. The response rates at different time points during a 2-year follow-up were calculated.

Results: The effective rates of combined PRF and CRF treatment were 95.5%, 86.4%, 81.8%, 72.7%, 72.7%, and 72.7% postoperative at 1 month, 3 months, 6 months, 1 year, 18 months, and 2 years, respectively. Except for 16 patients (72.7%) experiencing mild numbness that gradually disappeared within 1 week to 2 months after the operation, no obvious complications were observed.

Limitations: This study examined the therapeutic effectiveness over a period of only 2 years; no further follow-up was conducted. In addition, this study is a single-center observational clinical study with small sample sizes.

Conclusions: For patients with intractable infraorbital neuralgia, 42°C PRF combined with 60°C CRF is an effective and safe treatment. Prospective, double-blind randomized controlled trials with longer follow-up periods are needed to evaluate whether the combined treatment could become an alternative option for those who do not respond to conservative treatment, sparing those patients from destructive therapies or more invasive nerve decompression surgery.

Key words: Infraorbital neuralgia, effectiveness, safety, pulsed radiofrequency, continuous radiofrequency, combined therapy

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The infraorbital nerve is the terminal branch of the maxillary nerve, which in turn is the second branch of the trigeminal nerve. The path of the infraorbital nerve passes through the infraorbital groove, the infraorbital canal, and the infraorbital foramen to the facial area, where the nerve divides into several branches innervating the skin and mucous membrane of inferior eyelid, the ala nasi, and the upper lip (1). Infraorbital neuralgia, one of the rare causes of facial pain, is characterized by sudden, severe, paroxysmal stabbing pain in the infraorbital nerve distribution area (2), and it is usually evoked or aggravated by trigger factors such as washing, tooth brushing, and eating. As one of the most excruciating diseases, infraorbital neuralgia can cause anxiety, depression, and other psychological disorders in patients and seriously affect their quality of life (3). Causes of this type of neuralgia include trauma, herpes zoster, and maxillary sinusitis (3-5), and it can also occur with no apparent cause (2). The morbidity of infraorbital neuralgia has not been reported.

Currently, there are no systematic guidelines for the treatment of infraorbital neuralgia because few studies have been conducted on relevant therapies (5-8). As with trigeminal neuralgia (TN), the preferred first-line treatment for infraorbital neuralgia are antiepileptic drugs. Patients who respond poorly to drug treatment can be supplemented with other conservative treatments such as nerve blocks (5,9-11).

Infraorbital neurotomy or avulsion, a conventional open procedure for the treatment of refractory infraorbital neuralgia, can achieve good pain relief by blocking the conduction of pain (4,12). Beigi et al (3) reported that 9 patients who had undergone infraorbital nerve decompression all experienced significant pain relief over a follow-up period of 3-37 months. However, the earlier mentioned procedures are more invasive than percutaneous techniques and are now rarely applied in clinical practice, having been largely supplanted by advances in minimally invasive interventional techniques.

In our previous studies, we found that the effectiveness rate of 42°C percutaneous nondestructive pulsed radiofrequency (PRF), especially with high output voltage, could reach 90% during a 1-year follow-up in the treatment of infraorbital neuralgia patients (6,13). However, some patients do not respond to PRF and are obliged to receive destructive continuous radiofrequency (CRF), which could result in bothersome dysesthesia for patients (14); this adverse effect hinders the widespread adoption of CRF clinically. Therefore, the search for more favorable treatments for refractory infraorbital neuralgia has become an urgent task for pain physicians.

In 2015, Ali Eissa et al (15) performed 45°CC PRF combined with 60°C-65°C CRF on 21 patients with primary TN and achieved a 66.7% effectiveness rate over 1 year, with mild complications such as facial dysesthesia and masseter weakness). In 2017, Elawamy et al (16) reported that 42°C PRF combined with 60°C CRF of the Gasserian ganglion was more effective than 42°C PRF alone for the treatment of idiopathic TN. Therefore, 42°C PRF combined with CRF at no more than 65°C may be a novel technique for relieving neuropathic pain (NP). However, the efficacy of the combined therapy in the treatment of infraorbital neuralgia has not yet been reported. This prospective study aims to evaluate the effectiveness and safety of 42°C PRF combined with 60°C CRF in patients with infraorbital neuralgia who responded poorly to 42°C PRF and are reluctant to receive destructive therapies or nerve decompression surgery.

Methods

Patient Population

The study protocol was approved by the ethics committee of Beijing Tiantan Hospital (No. kylw-2010-014). The study strategy has been registered in the XXX Clinical Trial Registry (NCT ChiCTRONRC-12002939). The objective, experimental procedure, benefits, and possible risks of the study were explained to the patients, and each patient signed an informed consent form.

The prospective study was conducted at the pain clinic of Beijing Tiantan Hospital between January 2011 and December 2016. We screened 28 patients with refractory infraorbital neuralgia who responded poorly to 42°C PRF and were unwilling to undergo destructive therapies or nerve decompression surgery for the moment; we ultimately enrolled 22 patients in this study, as 6 patients refused to participate.

Patients were included if they met the following criteria: 1) age of at least 18 years; 2) paroxysmal or persistent stabbing pain in the distribution area of the infraorbital nerve and a neurologic examination revealed hypersensitivity; and 3) numeric rating scale (NRS-11) (0 indicates no pain, 10 indicates the most severe pain imaginable) score > 7 after 42°C PRF treatment and still refusing to receive ablative treatment or decompression surgery. We excluded patients with any of the following conditions: 1) abnormal routine blood tests, liver and kidney insufficiency, coagulation

disorders, or abnormal electrocardiogram; 2) severe cardiopulmonary dysfunction; 3) infection at the puncture site; 4) history of mental illness; 5) history of anesthetic abuse; 6) allergy to local anesthetic drugs; and 7) neuralgia secondary to tissue damage around the infraorbital foramen from causes such as maxillary sinusitis or tumor.

Operation

Patients lay in a supine position with the neck slightly extended on the computed tomography (CT) scanner bed and were continuously monitored for blood pressure, heart rate, electrocardiogram, and pulse oximetry. The negative electrode of a Pain Management Generator PMG-230 (Baylis Medical Inc., Montreal, Canada) was attached to the patient's upper back. The puncture point was identified at the surface projection of the ipsilateral infraorbital foramen (the point where the connecting line from the external canthus to the midpoint of the upper lip crosses the vertical line through the pupil on the affected side) (Fig. 1). Local infiltration anesthesia with 1-2 mL of 1% lidocaine was conducted after skin disinfection. Then, a 10-cm-long insulated RF trocar needle with a 5-mm bare needle tip (PMF-21-100-5, Baylis Medical Inc.) was inserted upward, backward, and outward to reach infraorbital foramen.

A thin-slice (2 mm) CT scan (Somatom, Siemens Company, Munich, Germany) of the maxillary sinus was performed to examine the relative positions of the puncture needle and the infraorbital foramen (Fig. 2). If it was confirmed that the trocar had entered the infraorbital foramen, then the depth of the needle was judged; if not, the puncture direction of the trocar was adjusted again with the assistance of CT imaging until it reached the infraorbital foramen. The plunger was pulled back to ensure that there was no blood or air. Then, the needle core was removed and a radiofrequency electrode (PMK-21-100, Baylis Medical Inc.) was inserted to test the resistance. A sensory test was performed by stimulating the nerve at 50 Hz, 0.1-0.2 V to induce a prickling pain sensation in the innervation area of the infraorbital nerve. The depth and direction of the trocar were slightly adjusted according to the patient's sensation to ensure the accuracy of the puncture location. Next, 0.5 mL of 1% lidocaine was injected; once the sensation from the infraorbital nerve on the affected side diminished, 42°C PRF was applied for 10 minutes in combination with 60°C CRF for 270 seconds (16). Patients who responded poorly to the combined therapy 1 month after the operation could choose to receive CRF as desired (parameters of CRF were set as 60°C, 75 seconds; 65°C, 75 seconds; 70°C, 75 seconds; 75°C, 75 seconds; and 80°C, 75 seconds) (13,17).

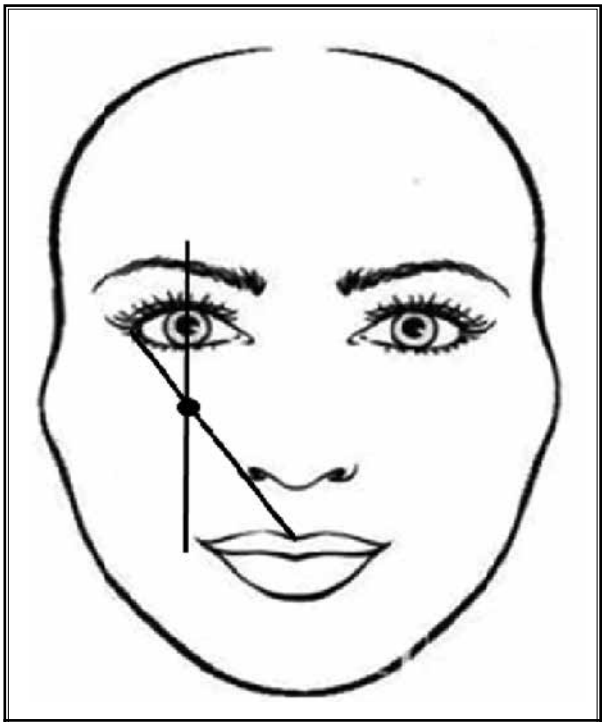

Fig. 1. *The puncture point (the point where the connecting line from the external canthus to the midpoint of the upper lip crosses the vertical line through the pupil on the affected side).*

Observations and Follow-Up

Before the operation, patients' clinical data were collected, including age (years), gender (male or female), duration of disease (months), pain laterality (left/right), the dosage of carbamazepine (milligrams per day), and NRS-11 score. The intraoperative data included the stimulus voltage during 50 Hz test positioning, the duration of the operation, the output voltage, and the local tissue resistance.

Patients were contacted by telephone 1 day, 3 days, 1 week, 2 weeks, 1 month, 3 months, 6 months, 1 year, 18 months, and 2 years after surgery to investigate outcomes.

The primary outcome was the 2-year response rate of infraorbital neuralgia patients to PRF combined with CRF (the criterion of response was a postoperative NRS-11 reduction of > 50%). The response rate was defined as follows: response rate = cases responding to

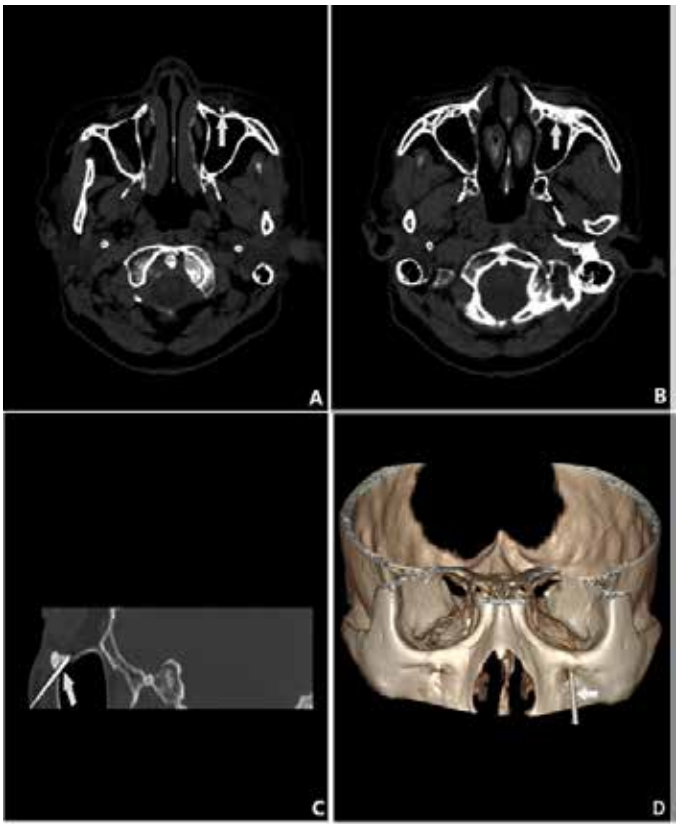

Fig. 2. *Operative puncture of the infraorbital foramen. (A) Axial CT scan of maxillary sinus showing the tip of the trocar was entering the ipsilateral infraorbital notch. (B) Axial CT scan of maxillary sinus showing the tip of the trocar was entering the ipsilateral infraorbital foramen. (C) Sagittal CT scan of maxillary sinus showing the needle was entering the ipsilateral infraorbital foramen. (D) 3-D reconstruction of spiral CT shows the needle was entering the ipsilateral infraorbital foramen.*

treatment/total number of cases*100%. The secondary outcome parameters included time to take effect (the day on which that patients' NRS-11 reduction was >50%); NRS-11 score; dosage of carbamazepine at each follow-up time point within 2 years; postoperative response rates at 1 month, 3 months, 6 months, 1 year, and 18 months after combined PRF and CRF treatment; intraoperative and postoperative complications; and data regarding refractory patients who switched to other treatments. The complications included facial numbness, facial swelling, facial hematoma, and others. The degree of facial numbness was scored as follows: 0, no numbness; 1, mild numbness (tolerable, with no significant impact on life or work); 2, moderate numbness (with some impact on life); and 3, severe numbness (intolerable) (18).

Statistical Analysis

All data analyses were performed with SPSS Version 22.0 (IBM Corporation, Armonk, NY). Normally distributed data were expressed as mean ± standard deviation, and non-normally distributed data were expressed as the median (minimum-maximum). The characteristic variables were performed by descriptive analysis. NRS-11 score and drug dosage were compared between different time points with the 2-sided Wilcoxon signed-rank tests. A P value < 0.05 was considered statistically significant.

Results

Patients' Clinical Data and Intraoperative Parameters

We included a total of 22 patients in the study. All the patients underwent successful puncture under the guidance of 3-dimensional CT (3D-CT) and completed the treatment and follow-up (Fig. 3). General information regarding the patients are listed in Table 1.

Treatment Effects and Additional Drugs

After combined PRF and CRF treatment, effective cases (effective rate) were 21 (95.5%), 19 (86.4%), 18 (81.8%), 16 (72.7%), 16 (72.7%), and 16 (72.7%) cases at postoperative 1 month, 3 months, 6 months, 1 year, 18 months, and 2 years, respectively. The NRS-11 scores of responsive patients showed significant reduction at all time points after treatment compared to the pretherapy baseline (Fig. 4). The mean time to take effect was 3 (1-7) days. One patient who failed to respond to the treatment at 1 month and 5 patients who suffered from pain recurrence at 69 days, 3 months, 4 months, 6 months, and 1 year, respectively, finally had no choice but to undergo destructive CRF; all patients' pain was relieved after this treatment.

The carbamazepine dosage of responsive patients showed significant reduction beginning 1 week after combined PRF and CRF treatment (Fig. 5). The discontinuation cases (discontinuation rates) of carbamaze-

pine were 0 (0%), 1 (4.5%), 3 (13.6%), 4 (18.2%), 2 (9.1%), 2 (9.5%), 6 (33.3%), 6 (35.3%), 4 (25%), and 6 (37.5%) postoperative at 1 day, 3 days, 7 days, 14 days, 1 month, 3 months, 6 months, 1 year, 18 months, and 2 years, respectively.

Treatment Safety

A total of 16 (72.7%) patients experienced mild postoperative numbness, which were scored as 1, in the area innervated by the infraorbital nerve. All cases of numbness gradually subsided within 1 week to 2 months. One patient had postoperative facial swelling, which subsided within 2 weeks. However, all 6 of the patients who finally underwent standard CRF treatment suffered from severe facial numbness (2 patients were scored as 2 and 4 patients were scored as 3) immediately after the procedure, and it gradually subsided beginning 3-6 months after treatment.

Discussion

The object of the study was patients with infraorbital neuralgia who responded poorly to 42°C PRF treatment; in the past, the only options for such patients would be neurodestructive CRF (6,13) or more invasive treatments such as infraorbital neurotomy, nerve avulsion, or nerve decompression (3,4,12). However, this study achieved very promising efficacy with a combination of 42°C PRF and 60°C CRF. The effective rate 1 month after treatment reached 95.5%, and the effectiveness rate at 6 months was over 80%; furthermore, over 70% of the patients attained pain relief for the entire 2-year follow-up period. Compared to the pretherapy baseline values, NRS-11 scores showed a significant postoperative reduction, and the drug dosage decreased significantly as well; these improvements reveal that PRF combined with CRF is an effective treatment for patients with intractable infraorbital neuralgia. PRF may relieve pain by exerting a neuromodulatory but not neurodestructive effect; thus, it is expected to be an ideal technique for the treatment of NP. However, the effectiveness of PRF against NP remains to be improved. A series of clinical studies have been performed to improve the analgesic effect of this novel technique; in particular, the combination of PRF and CRF has become a focus for researchers in recent years. After Ali Eissa et al (15) and Elawamy et al (16) reported that the combination of PRF and CRF could significantly reduce both pain intensity and carbamazepine dosage with minimal complications in patients with

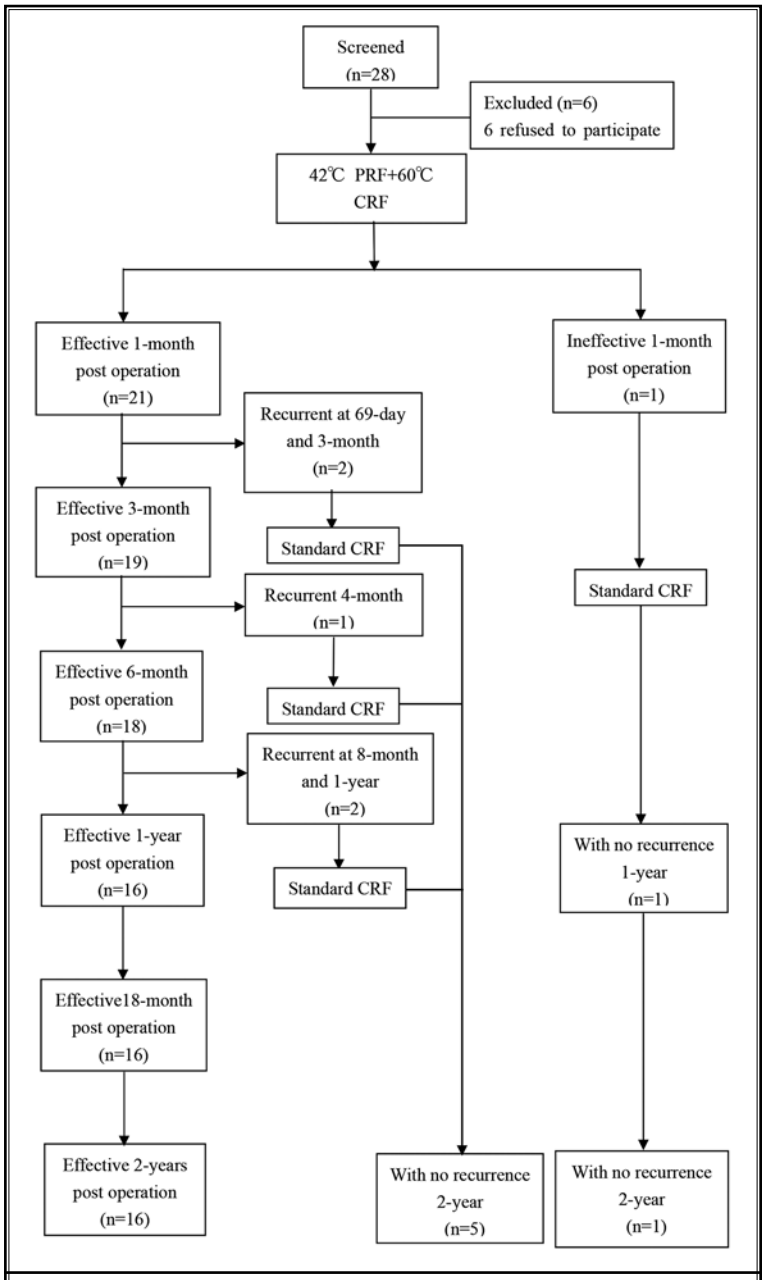

Fig. 3. *Flow chart and outcomes of the study.*

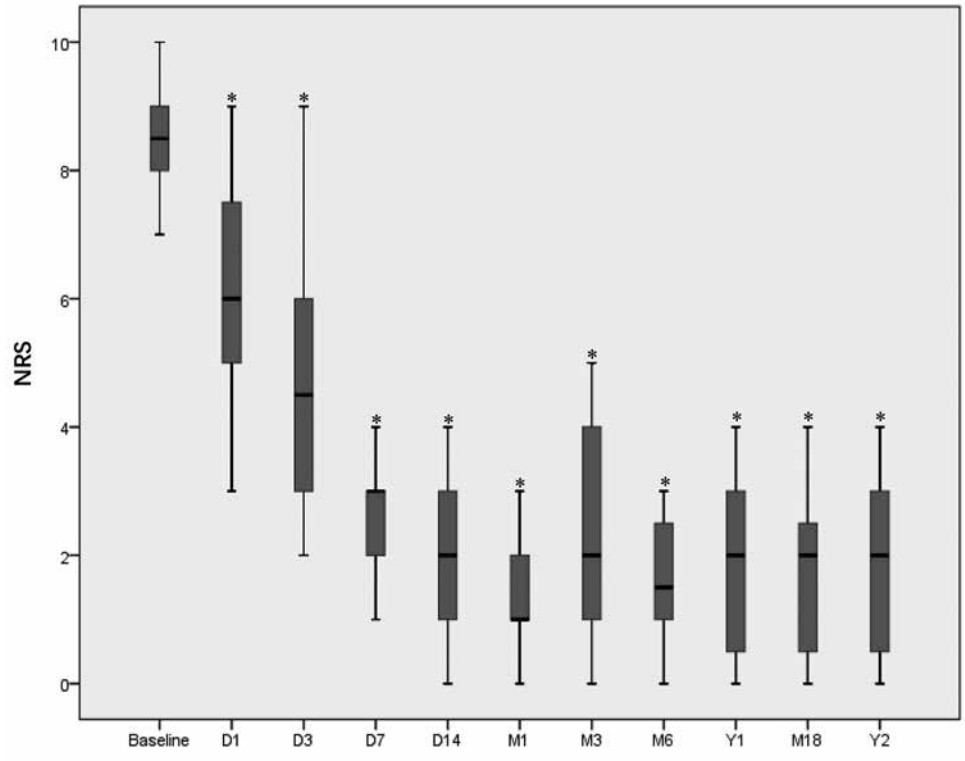

Fig. 4. *Evolution of pain intensity values of NRS-11 score at preoperation and postoperation. *Significant compared to preoperation.*

Table 1. *Clinical data and intraoperative parameters.*

Variable	Value (n = 22)
Age	64.4 ± 10.3
Gender	
Male	9
Female	13
Duration of disease (yrs)	5.2 ± 2.8
Pain laterality	
P Left	7
Right	15
Dosage of carbamazepine drugs (mg/day)	300 (100-600)
NRS-11 score	8.5 (7-10)
50 Hz stimulating voltage (v)	0.1 (0.1-0.2)
Operation time (min)	29 ± 3
Output voltage (v)	45.8 ± 3.2
Tissue resistance (Ω)	358.38 ± 25.7

Data are shown as mean ± SD, median (minimum-maximum), or number.

TN, the current well-designed prospective study demonstrated for the first time that the combination of PRF and CRF was also effective in patients with refractory infraorbital neuralgia. Nevertheless, the specific analgesic mechanism of standard PRF combined with 60°C CRF remains unclear.

In contrast to previous studies on the efficacy of PRF combined with CRF for patients with TN (15,16), the patients in this study did not achieve satisfactory results immediately after treatment but required a short recovery period. The mean time for the treatment to take effect in our study was 3 (1-7) days, and one patient even needed a full week to achieve a satisfactory effect; this duration was consistent with our previous studies on PRF for the treatment of patients with infraorbital neuralgia and supraorbital neuralgia, who needed a recovery period of 4 (1-21) and 7 (1-30) days, respectively (13,17). This recovery period might be the reason why the antiepileptic drug dosage did not decrease until 1 week after the intervention procedure in this study. The reason for the existence of a post-PRF recovery period is not clear; we hypothesized that PRF could cause plas-

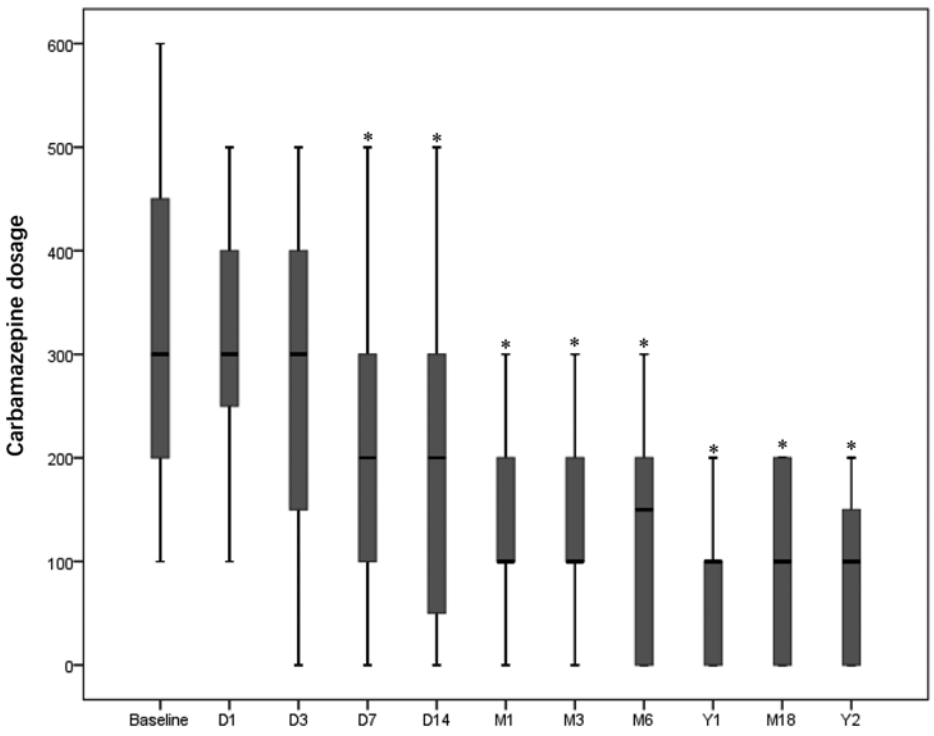

Fig. 5. *Evolution of carbamazepine dosage at preoperation and postoperation. *Significant compared to preoperation.*

tic changes in pain transmission pathways and result in slow neuromodulation, which would require some time to take effect (13); however, the mechanism of the combined PRF and 60°C CRF is not clear. Because the combined PRF and CRF treatment did not work immediately, pain physicians should apply individualized treatment schedules that accommodate the variability of patients' responses to treatment to help each patient successfully experience the recovery period and achieve optimal results; for example, the continuation of antiepileptic drugs should be individualized according to treatment response.

PRF exerts its analgesic effect via radiofrequency not exceeding 42°CC to provide a neuromodulatory effect instead of neuroabalative effect (15). However, the underlying mechanism of CRF by temperature > 60°C destroys the unmyelinated fibers (Aδ-fibers and C-fibers), thereby interrupting the transmission of pain signals (18). In 2006, Heavner et al (19) evaluated the ability of radiofrequency to thermocoagulate egg whites in vitro and found that CRF > 60°C could cause visible coagulation of egg whites. Lower temperature would certainly be less capable of causing nerve tissue damage. Therefore, in contrast to the Ali Eissa et al (15) study (temperature of CRF was at 60°C-65°C), the temperature of CRF was set at 60°CC in this study to reduce unwanted thermal tissue destruction. Accordingly, in this study, the incidence of numbness in the innervation area of infraorbital nerve (72.7%) was lower than that of the Ali Eissa et al (15) study (85.7%). However, the incidence of numbness in this study was significantly higher than in patients who received only 42°C PRF (27%) (13), which indicated that CRF created a long-lasting blockade of synaptic transmission and was more destructive than PRF even at a lower temperature (16,20). Fortunately, the numbness was mild and reversible, which indicated that the combined 60°C CRF treatment might cause only minor tissue injury and less nerve degeneration, and was therefore a safe interventional treatment worthy of widespread clinical application. However, the no-effect and recurred patients in this study undergoing conventional (80°C) CRF experienced significant sensory loss and severe numbness.

Over the years, radiofrequency treatment of patients with TN has usually been performed under the guidance of fluoroscopy or a C-arm device (16,21,22), which has the risk of causing additional tissue injury for patients due to inaccurate or repeated punctures. In this study, all of the procedures on patients were performed under 3D-CT guidance (Fig. 2), which increases the rate of successful punctures (the successful puncture rate was 100% in the present study) and decreases the incidence of adverse events caused by puncture inaccuracy (0% in this study) because of the intuitive and clear 3D-CT images. Moreover, the increased rate of successful puncture under 3D-CT guidance would decrease the number of puncture attempts needed, which could further reduce radiation exposure. However, exposure to radiation energy still remains a problem that needs to be considered. Lim et al (23) performed 42°C PRF on a 60-year-old man with facial herpes zoster in the left infraorbital nerve under ultrasound guidance for the first time, and the pain relief has been maintained for over 1 year with no additional medication. Ultrasound seems to be an ideal imaging modality that can protect patients from direct radiation exposure (24). Therefore, the effectiveness and safety of ultrasound-guided PRF in patients with infraorbital neuralgia need to be studied in the future.

Limitations

This study has several limitations. First, the study evaluated the effectiveness and safety of combined 42°C PRF and 60°C CRF for only 2 years after the operation; a longer follow-up duration is needed to examine the long-term outcome of the novel combined therapy. Second, the study recorded only the subjectively reported degree of facial numbness and did not include quantitative sensory testing to examine the degree of destruction by the operation. Third, the cost of 3D-CT scanning is comparatively high, and patients are inevitably exposed to radiation energy, which would restrict clinical access. Ultrasound seems to be a safer and more economical imaging modality with which to guide the operation in future research. Fourth, parameters measuring the effectiveness of the procedure, such as the treatment duration, waveform, pulse width, and frequency, need to be further studied. Finally, this study is a single-center observational clinical study with small sample sizes; multicenter, double-blind randomized controlled trials with larger sample sizes are needed to provide a higher level of evidence of the efficacy of PRF combined with CRF.

Conclusions

For patients with intractable infraorbital neuralgia, 42°C PRF combined with 60°C CRF is expected to be a preferred option. Prospective, double-blinded randomized controlled trials with longer follow-up duration are needed to evaluate whether the combined treatment could become an alternative option for those who have failed to respond to conservative treatment, sparing those patients from destructive therapies, or more invasive nerve decompression surgery.

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