

## Retrospective Study

# Long-term Follow-up of the Effectiveness and Safety of High-voltage Pulsed Radiofrequency Treatment for Infraorbital Neuralgia: A Retrospective Study

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Disclaimer: Z Sun, L Liu, and T Wang contributed equally to this work. This research was supported by the Capital's Funds for Health Improvement and Research (No. 2020-2-2046) and the National Key Research and Development Program of China (No. 2022YFC3602203). ZS, LL and TW contributed equally to this work and should be considered co-first authors.

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

Article received: 12-12-2023  
Revised article received: 01-08-2024  
Accepted for publication: 04-16-2024

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**Background:** Infraorbital neuralgia is a refractory facial pain that may cause various psychological disorders. There is no optimal treatment for infraorbital neuralgia because few relevant studies have been conducted. Pulsed radiofrequency (PRF) is a minimally invasive procedure that has been proven effective in treating trigeminal neuralgia and other painful diseases. Our previous study demonstrated that high-voltage PRF was effective in patients with infraorbital neuralgia. However, there is little literature on the long-term follow-up of infraorbital neuralgia treated with high-voltage PRF with a large sample size.

**Objectives:** To explore the long-term effectiveness and safety of high-voltage PRF guided by computed tomography for patients with infraorbital neuralgia who failed conservative treatment.

**Study Design:** Monocentric, retrospective, observational study.

**Setting:** This study enrolled patients with infraorbital neuralgia who failed conservative treatment for infraorbital neuralgia and who underwent a high-voltage PRF procedure at the Department of Pain Management in Beijing Tiantan Hospital.

**Methods:** From January 2013 through June 2022, a total of 223 patients were included in this study; 16 were excluded according to the exclusion criteria. Finally, the medical records of 207 patients were extracted and analyzed including demographic data, intraoperative records, pain-related baseline, data and side effects. Treatment efficacy was evaluated using the Barrow Neurological Institute scores for pain. The Barrow Neurological Institute pain intensity score, onset time, perioperative complications and the time of recurrence were routinely followed up at month one, month 3, month 6 and every year postoperatively. Recurrence-free survival curves were presented by a Kaplan-Meier plot.

**Results:** The initial pain relief rate after the high-voltage PRF treatment was 86.0%. The cumulative recurrence-free survival rates were 85.5% (at month one), 82.6% (at month 3), 77.8% (at month 6), 65.7% (at month 12), 61.7% (at month 24), 55.8% (at month 48), 47.6% (at month 96) and 45.2% (at month 120) postoperatively. The median follow-up time of the 207 patients was 67.0 months (interquartile range, 38.0–93.0 months; range from 12 months to 125 months), with a median recurrence-free time of 80 months according to the Kaplan-Meier estimator.

**Limitations:** This was a retrospective observational study. Multicenter, prospective, randomized controlled studies should be conducted. In addition, the optimal parameters for PRF treatment of infraorbital neuralgia need to be further explored.

**Conclusion:** Computed tomography-guided high-voltage PRF treatment provides a minimally invasive and effective treatment option for patients with infraorbital neuralgia who fail conservative treatment, which could be considered as a preferred treatment before more invasive treatments.

**Key words:** Effectiveness, safety, high-voltage pulsed radiofrequency, infraorbital neuralgia

**Pain Physician 2024; 27:E751-E759**

**T**he infraorbital nerve is the main branch of the trigeminal nerve, which is distributed in the lower eyelid, nasal wing, and upper lip (1). The main symptom of infraorbital neuralgia is severe and irritating pain in the infraorbital nerve distribution area, especially during washing, brushing teeth, and eating (2-4). Studies have confirmed that herpes zoster and trauma can induce infraorbital neuralgia, but other causes are not yet clear (2-4). There is no research report on the incidence rate of infraorbital neuralgia. As a chronic and refractory facial pain, infraorbital neuralgia often seriously affects quality of life (3).

At present, there is no research report on the optimal treatment plan for infraorbital neuralgia (4-7). The preferred treatment for infraorbital neuralgia is oral medication such as antiepileptic drugs, which is similar to trigeminal neuralgia (5). However, many patients respond poorly to drug treatment and experience adverse reactions such as dizziness and drowsiness. de Vries and Smelt (4) described a nerve block using local anesthetic as the initial interventional procedure choice for post-traumatic infraorbital neuralgia as early as 1990, but repeated injections may be required (4,5,7).

Neurolytic agents can be injected into the nerves, but the side effects and complications of neurolytic therapy, such as numbness in the innervated area and necrosis of the surrounding tissue, may occur (8,9). Similarly, as a neurologically damaging technique, radiofrequency thermocoagulation (RFT) may also lead to postoperative sensory deprivation by cutting off sensory pathways (10).

Surgeries—such as infraorbital nerve decompression, avulsion, and neurectomy—could be tried for patients with infraorbital neuralgia, but the clinical application is limited due to the massive trauma (3,11,12). Therefore, it is necessary to conduct relevant studies to explore an effective, safe, and minimally invasive treatment for infraorbital neuralgia.

Pulsed radiofrequency (PRF) is a minimally invasive procedure that has been proven effective in treating trigeminal neuralgia and other painful diseases (13). The case report by Kim, et al (14) showed that post-traumatic infraorbital neuralgia could be treated by infraorbital nerve block and PRF (14).

Our previous study (6) demonstrated that the effective rates were 69% (at postprocedure month one) and 50% (at postprocedure month 24) in standard-voltage PRF treatment for infraorbital neuralgia. Then we found that the effective rate of high-voltage PRF could reach 90% at one-year follow-up, which is signifi-

cantly higher than the standard-voltage PRF in patients with infraorbital neuralgia (15). Our further research showed that the effective rates were 95.5% (at postprocedure month one) and 72.7% (at postprocedure month 24) in PRF combined with 60°C continuous radiofrequency treatment; however, there was a certain degree of numbness left with this procedure (16). Therefore, there is a wide range of opportunities for high-voltage PRF treatment for infraorbital neuralgia. However, there is little literature on long-term follow-up with a large sample size. The aim of our study is to explore the long-term effectiveness and safety of computed tomography (CT) guided high-voltage PRF for patients with infraorbital neuralgia who failed conservative treatment.

## **METHODS**

### **Study Design and Ethical Approval**

This retrospective study was approved by the Beijing Tiantan Hospital Medical Ethics Committee and is in compliance with the Helsinki Declaration. Due to the characteristics of a retrospective study, waiving consent would not harm any patients' rights, so informed consent was exempted in this study.

We retrospectively reviewed the medical records of patients with infraorbital neuralgia who failed conservative treatment and underwent a high-voltage PRF procedure at the Department of Pain Management in Beijing Tiantan Hospital from January 2013 through June 2022. The follow-up period was through June 2023.

The inclusion criteria were as follows: 1) age  $\geq$  18 years old; 2) met the 8B 82.0 diagnostic criteria for infraorbital neuralgia in accordance with the 11th revised International Classification of Diseases (ICD-11) (17); 3) an effective diagnostic block (2% lidocaine, one mL) prior to a high-voltage PRF procedure (2,4); 4) failed conservative treatment and underwent a high-voltage PRF procedure.

The exclusion criteria were as follows: 1) incomplete medical records information; 2) secondary neuralgia caused by other diseases such as mass, zoster, or trauma; 3) previous infraorbital nerve decompression, resection, etc.

### **Procedure**

The CT-guided high-voltage PRF procedure was performed by pain physicians as follows. The patients were supine on a CT scanner bed. Monitored vital signs

including electrocardiogram, blood pressure, heart rate, and oxygen saturation. Negative plates (PMG-230, Baylis Medical, Inc.) were placed on the patients' skin.

The puncture site was the intersection of the vertical line of the affected pupil and the connecting line between the lower edge of the nasolabial sulcus and the external canthus. After disinfection and local anesthesia, the puncture was performed by an insulated RF trocar needle (10-cm-long, 5-mm bare needle tip) (PMF-21-100-5, Baylis Medical Inc.). The puncture was performed toward the infraorbital foramen under CT guidance (2 mm/layer, medical CT machine, model SOMATOM, SIEMENS Company) and 3-D reconstructed images (Fig. 1).

After the trocar needle was inserted into the infraorbital foramen, the stylet was removed and no blood or air was confirmed, then an RF treatment electrode was placed (PMK-21-100, Baylis Medical, Inc.) Electrical stimuli of 0.1-0.2 V at 50 Hz and 2 Hz were used to test sensory and motor threshold, respectively. The direction and depth of the trocar needle were

adjusted to ensure accurate puncture. The parameters of high-voltage PRF were set as manual pulsed mode (maximum temperature 42°C, rotated the UP knob to reach the maximum output voltage [which was bearable and without causing pain in patients]; 120 seconds, 2 times) (15).

### Outcomes

The Barrow Neurological Institute (BNI) pain intensity (Table 1) (18) was used to evaluate the procedure's effect. Satisfactory pain relief referred to BNI I to BNI IIIb. The initial pain relief referred to the first satisfactory pain relief post the high-voltage PRF procedure; the onset time was recorded. Complete pain relief referred to being pain free without drugs (BNI I) postprocedure. The BNI grade that reached I-IIIb at one month postprocedure was considered effective. Recurrence was defined as patients whose BNI increased to IV-V post effective treatment (BNI I-IIIb). The effective rate referred to:  $([BNI\ I+II+IIIa+IIIb] \text{ number of patients} / \text{total number of patients}) \times 100\%$ .

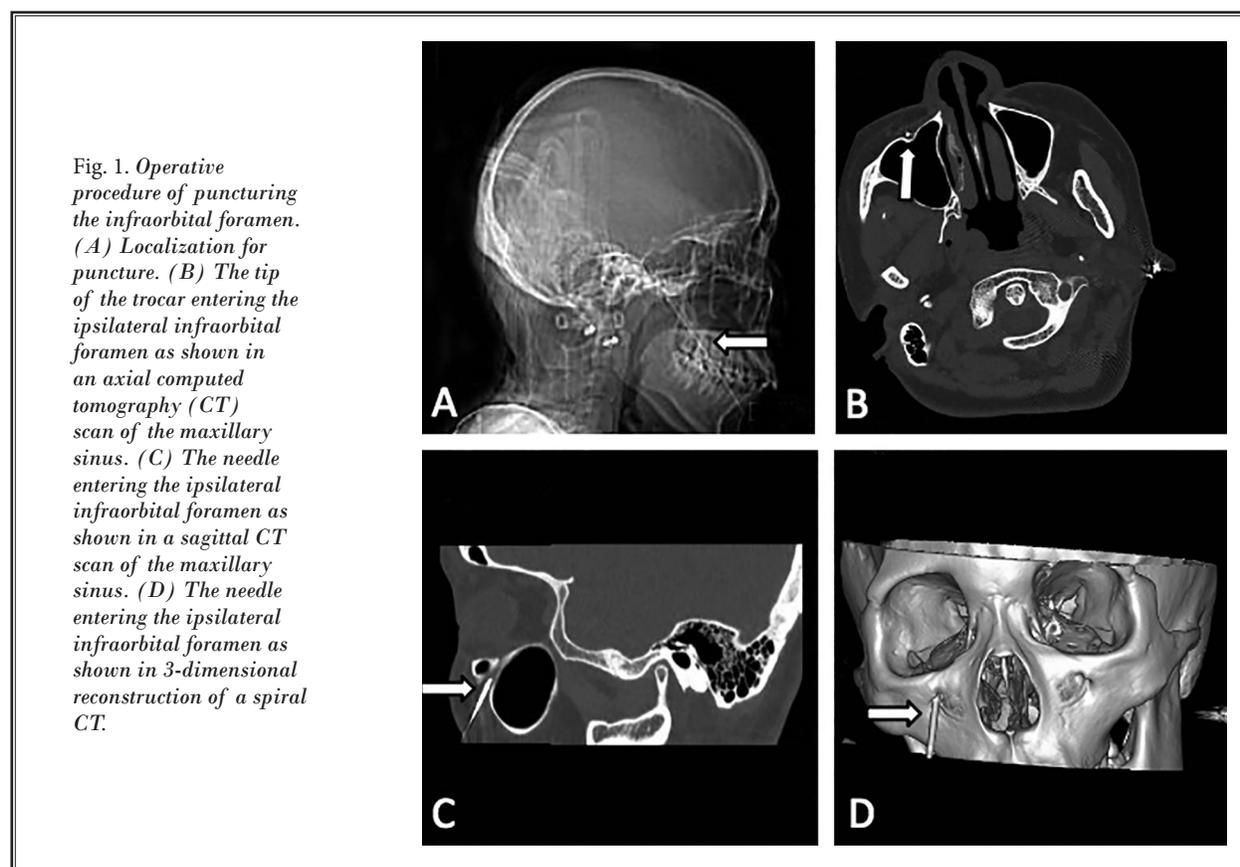


Table 1. Modified Barrow Neurological Institute (BNI) pain intensity criteria.

BNI degrees	Explanations
BNI I	No pain, no medication
BNI II	Occasional pain, not requiring medication
BNI III <sup>a</sup>	No pain with medication
BNI III <sup>b</sup>	Controlled pain with medication
BNI IV	Improved pain that is inadequately controlled by medication
BNI V	Persistent pain that is inadequately controlled by medication

### Data Collection

All medical records—including preoperative baseline characteristics, intraoperative records, and postoperative follow-up data—were extracted in our hospital's information system and the follow-up database. Preoperative baseline characteristics including gender, age, body mass index, the disease's course, BNI pain intensity, and concomitant diseases were collected. Intraoperative records—including sensory and motor stimulation voltage, output voltage, tissue resistance, and operation time—were extracted. Perioperative side effects and complications—including ecchymosis, hematoma, facial numbness, and infection—were also collected.

In order to improve the quality of medical care, the patients were routinely followed up at postprocedure month one, month 3, month 6, and every year. The follow-up outcomes measured were BNI pain intensity, onset time, perioperative complications, and the time of recurrence. If patients experienced pain recurrence or other abnormal conditions, they could come to our pain clinic for further examination and treatment, or consult by phone or online using the WeChat application (Tencent Holdings, Ltd.)

### Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics 23.0 (IBM Corporation). Continuous variables with normal distribution were represented as mean  $\pm$  SD, and statistically analyzed using one-way analysis of variance. Continuous variables with nonnormal distribution were represented as median and interquartile range (IQR), and statistically analyzed using the Mann-Whitney U test. However, for discontinuous data, categorical variables were represented as frequency and percentage. Recurrence-free survival curves were presented by a Kaplan-Meier plot. The standard for statistically significant difference was a *P* value  $< 0.05$ .

## RESULTS

A total of 223 patients with infraorbital neuralgia who underwent a CT-guided high-voltage PRF procedure were reviewed at the Department of Pain Management in Beijing Tiantan Hospital from January 2013 through June 2022. Due to 16 patients meeting the exclusion criteria being excluded, the final study included 207 patients. The median follow-up duration for this study was 67.0 months (IQR, 38.0 months–93.0 months; range from 12 months to 125 months).

### Patient Characteristics

The basic data of the patients with infraorbital neuralgia are listed in Table 2. This study included 116 men, accounting for 56.0%. The median age was 64.0 years (IQR, 58.0–71.0 years; range from 37 years to 88 years). The median duration of disease was 56.4 months (IQR, 44.4–69.6 months; range from 18 months to 112 months). All patients had unilateral onset; 110 of them (53.1%) were left-sided. All patients suffered severe pain (BNI IV-V), of which 82 (39.6%) reported BNI V.

The median sensory and motor stimulation voltage were both 0.1 V (IQR, 0.1 V–0.2 V) and the median output voltage was 95 V (IQR, 90 V–99 V). The mean tissue resistances before and after high-voltage PRF treatment were 390  $\Omega$  (IQR, 375  $\Omega$ –418  $\Omega$ ) and 390  $\Omega$  (IQR, 375  $\Omega$ –421  $\Omega$ ), respectively. The mean operation time was 28 minutes (IQR, 24 minutes–33 minutes).

### Treatment Effect

The initial pain relief rate post high-voltage PRF treatment was 86.0%. The median onset time of high-voltage PRF treatment was 4 days (IQR, 1–18 days; range from 0 to 30 days). A total of 178 patients (86.0%) experienced satisfactory pain relief; 81 (39.1%) experienced complete pain relief at one month postprocedure. A total of 29 patients (14.0%) failed high-voltage PRF treatment at one month postprocedure; 14 of them received a second high-voltage PRF combined with 60°C RFT treatment, while the other 15 directly received RFT treatment.

The cumulative recurrence-free survival of the 207 patients post high-voltage PRF treatment is shown as a Kaplan-Meier actuarial curve (Fig. 2). The cumulative recurrence-free survival rates were 85.5% (at one month postprocedure), 82.6% (at 3 months postprocedure), 77.8% (at 6 months postprocedure), 65.7% (at 12 months postprocedure), 61.7% (at 24 months postprocedure), 55.8% (at 48 months postprocedure), 47.6% (at 96 months postprocedure), and 45.2% (at

120 months postprocedure). The median follow-up duration was 67.0 months (IQR, 38.0–93.0 months; range from 12 months to 125 months), with a median recurrence-free time of 80 months according to the Kaplan-Meier estimator (Fig. 2).

A total of 69 patients (33.3%) experienced recurrence after high-voltage PRF treatment; the median recurrence time was 48.0 months (IQR, 23.3–72.8 months; range from 4 months to 118 months). Among 69 patients who experienced recurrence, 14 patients (20.3%) were willing to receive a second high-voltage PRF treatment with the same parameters, while 29 patients (42.0%) received a second high-voltage PRF combined with 60°C RFT treatment. Among the 43 patients who received the second high-voltage PRF treatment, the median follow-up time was 48.0 months (IQR, 22.0–72.5 months; range from 4 months to 118 months), of which 33 patients (76.7%) and 8 patients (18.6%) experienced satisfactory pain relief and complete pain relief, respectively.

Ten patients failed to respond to the second high-voltage PRF treatment and subsequently received RFT treatment. Nine patients who underwent a second high-voltage PRF treatment received a third high-voltage PRF treatment due to pain recurrence. Four patients failed to respond to the third high-voltage PRF treatment and subsequently received RFT treatment; one patient received a fourth high-voltage PRF treatment due to pain recurrence. According to the last postoperative follow-up database, the only patient was followed up for 24 months without pain recurrence (Fig. 3).

### Perioperative Side effects and Complications

No serious perioperative complications, including eye injury and blindness, occurred in this study. Among 207 patients, 15 patients (7.2%) experienced facial ecchymosis; 6 (2.9%) experienced local hematoma, but all absorbed spontaneously within 2–3 weeks (Fig. 4). Among them, 130 (62.8%) experienced mild numbness that gradually returned to normal within one month.

### DISCUSSION

Our study retrospectively reports the long-term effectiveness and safety of 207 patients with infraorbital neuralgia who underwent high-voltage PRF treatment from January 2013 through June 2022, with a median follow-up duration of 67.0 months (IQR, 38.0 months–93.0 months). Our previous study (15) only reported the efficacy of high-voltage PRF treatment in 30

Table 2. Patient characteristics.

Patients	Total (n = 207)
Gender, men, n (%)	116 (56.0%)
Age (years, median [IQR])	64.0 (58.0–71.0)
BMI (median [IQR])	24.2 (23.1–25.6)
Comorbidities, n (%)	
Hypertension	65 (31.4%)
Diabetes mellitus	39 (18.8%)
Coronary disease	31 (15.0%)
Stroke	18 (8.7%)
Duration of disease (months, median [IQR])	56.4 (44.4–69.6)
Affected side, left, n (%)	110 (53.1%)
Preoperative BNI pain intensity	
BNI IV	125 (60.4%)
BNI V	82 (39.6%)
Median sensory stimulation voltage	0.1 (0.1–0.2)
Median motor stimulation voltage	0.1 (0.1–0.2)
Output voltage	95 (90–99)
Mean tissue resistances before PRF treatment	390 (375–418)
Mean tissue resistances after PRF treatment	390 (375–421)
Operation time (min, median [IQR])	28 (24–33)
Follow-up duration (months, median [IQR])	67 (38–93)
Onset time (days, median [IQR])	4 (1–18)
Recurrence time (months, median [IQR])	48 (23.3–72.8)

IQR, interquartile range; BMI, body mass index ( $\text{kg}/\text{m}^2$ ); BNI, Modified Barrow Neurological Institute pain intensity criteria; PRF, pulsed radiofrequency

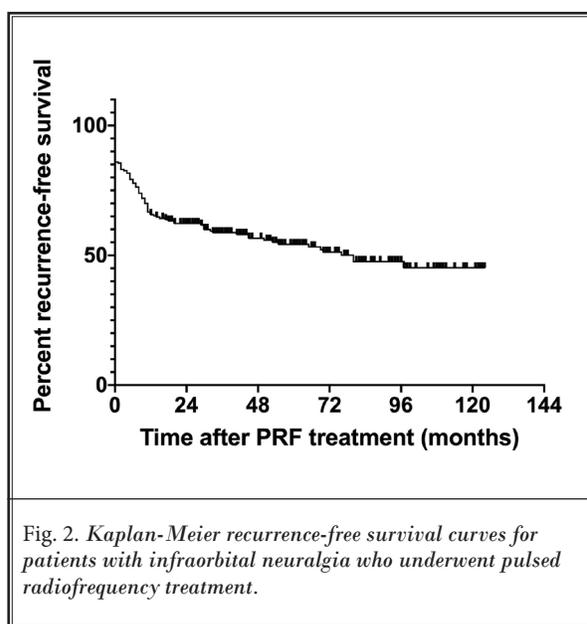


Fig. 2. Kaplan-Meier recurrence-free survival curves for patients with infraorbital neuralgia who underwent pulsed radiofrequency treatment.

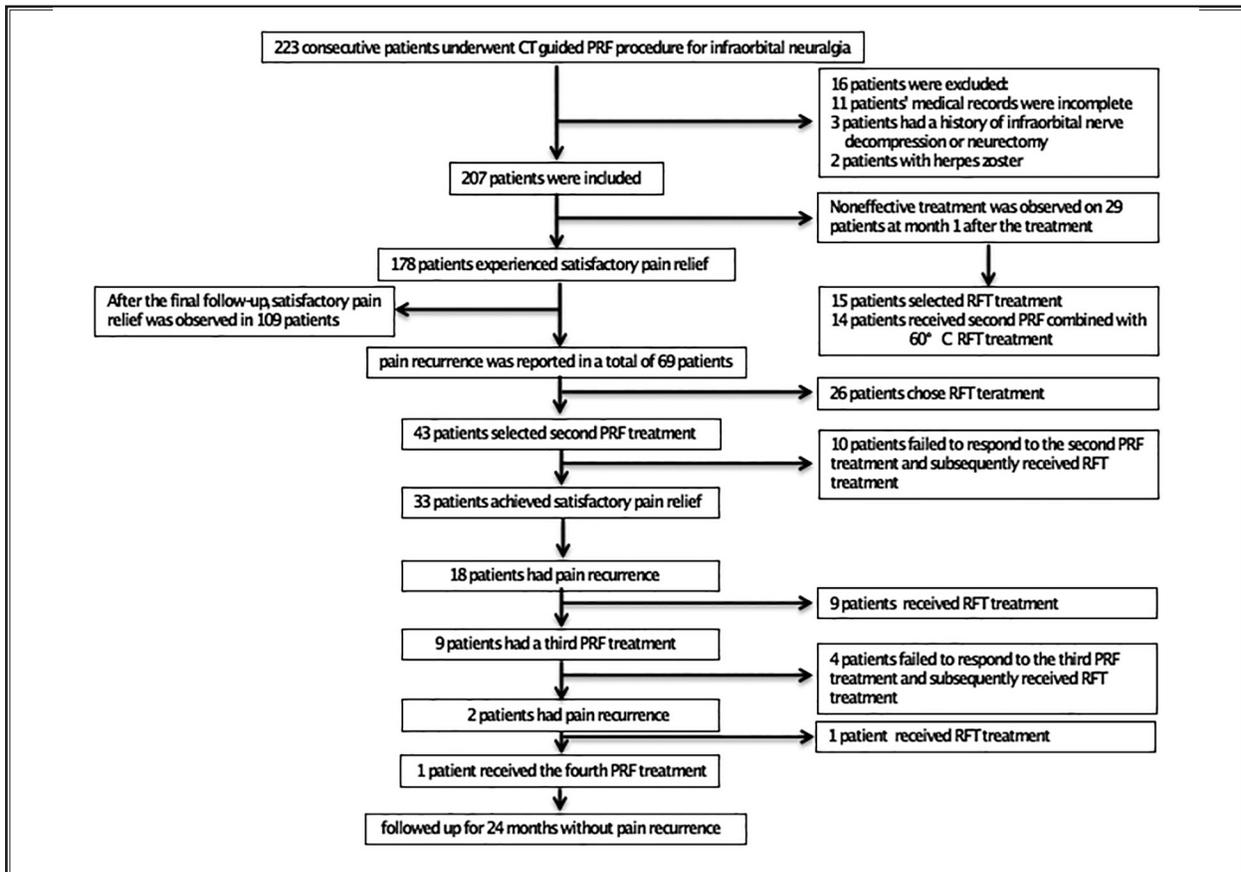


Fig. 3. Flow chart of the study populations.

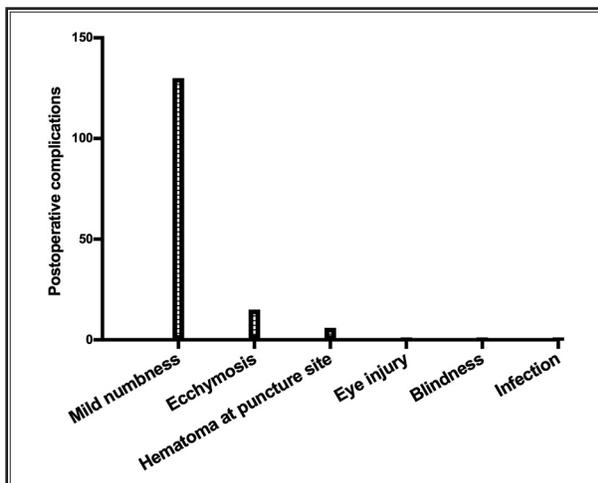


Fig. 4. Perioperative side effects and complications.

patients with infraorbital neuralgia within 2 years post-procedure. As far as we know, the research reported here has the longest observation time and the most number of patients.

The initial pain relief rate (86.0%) in our study is similar to the initial pain relief rate (90%) in the treatment of infraorbital neuralgia with high-voltage PRF reported previously (15); both were higher than the initial pain relief rate of standard voltage PRF reported previously (16). The median onset time of high-voltage PRF treatment was 4 (1–18) days; this is also consistent with our previous studies (15,19). Therefore, high-voltage PRF treatment is expected to be a therapeutic option for patients with infraorbital neuralgia. However, its initial pain relief rate was still lower than that of PRF combined with low-temperature RFT treatment (95.5%). Further research is needed to explore PRF parameters that can improve its efficacy without increasing side effects and complications.

The cumulative recurrence-free survival after a single high-voltage PRF treatment was 61.7%, 55.8%, 47.6% and 45.2% at postprocedure months 24, 48, 96 and 120, respectively. Recurrence-free survival decreased gradually with the prolongation of treatment time, which was consistent with Jia, et al's research (20) about treating trigeminal neuralgia with gasserian ganglion PRF.

In our study, after the first high-voltage PRF treatment, a total of 69 patients (33.3%) experienced recurrence with a median recurrence time of 48.0 months, of which 43 patients (43/69, 62.3%) were willing to receive a second high-voltage PRF procedure. After the second procedure, 33 patients (33/43, 76.7%) experienced satisfactory pain relief. Nine patients (9/43, 20.9%) received a third procedure due to pain recurrence. After the third procedure, one patient received a fourth procedure due to pain recurrence and finally got satisfactory pain control. A similar conclusion was reached in the study of Chua, et al (21), which might be due to the exponential decrease in electric field strength, with most target tissues subjected to low and moderate electric fields. However, due to the minimally invasive and safe nature of high-voltage PRF treatment, many patients were willing to undergo repeated procedures; some patients had already received 4 treatments (21).

Whether the recurrence rate of PRF procedures can be further reduced remains to be studied. At present, there are no research reports on the long-term efficacy of other minimally invasive techniques, such as RFT, for infraorbital neuralgia treatment. Previous neurodestructive techniques—such as chemical drugs, RFT, surgical decompression, or avulsion—are characterized by short maintenance time, a high recurrence rate, and repeated treatments (8-11). PRF treatment may have great advantages in relieving pain by exerting neuromodulation.

Different parameters of PRF treatment, that is, "PRF dose," may lead to different therapeutic effects for neuropathic pain (21). Tanaka, et al (22) confirmed that the antihypersensitivity effect of PRF was enhanced after the procedure time was increased from 2 minutes to 6 minutes in an animal model of neuropathic pain. Han, et al (23) reported that proper increase of voltage was more effective and safe for the PRF treatment of postherpetic neuralgia.

We doubt that the poor therapeutic effect of PRF treatment confirmed in some studies may be due to insufficient "PRF dose." Wang, et al (24) suggested that long-duration and high-voltage PRF provided sig-

nificant pain relief (at least 12 weeks) for patients with pudendal neuralgia. Therefore, the "PRF dose," including voltage and duration, needs to be investigated in further clinical studies.

PRF's therapeutic mechanism remains unknown. It may be related to temperature and neuromodulation (25,26). The molecular structure changes caused by the electric field, regulation of early gene expression, and transient inhibition of synaptic activity are possible mechanisms (27,28). Vallejo, et al (29) suggested that anti-inflammatory cytokines expression, including GABAB-R1 and 5-HT<sub>3r</sub>, were increased and the pro-inflammatory cytokines expression such as tumor necrosis factor (TNF)- $\alpha$  and interleukin (IL)-6 returned to baseline values post-PRF (29). Park and Chang (30) reported that PRF could act on pain afferent fiber axons of small myelinated A $\delta$  and unmyelinated C fibers (30), thereby inhibiting the conduction of nerve impulses. Jin et, al (31) demonstrated that PRF alleviates neuropathic pain by upregulating the transcription and translation of glial cell-derived neurotrophic factors in rats with a compressed sciatic nerve. Previous studies have suggested that PRF might achieve its analgesic effect by enhancing noradrenergic and serotonergic descending pain inhibitory pathways (32), and might be effective in relieving neuropathic pain via NaV1.7 upregulation inhibition (33).

In our study, due to CT guidance, all punctures were successful and no puncture-related serious adverse events occurred. The 3-dimensional reconstruction images of CT, especially spiral CT, are intuitive and clear, and the puncture learning curve for pain physicians is significantly shortened. However, there is a disadvantage due to patients' radiation exposure, and can only provide guidance for the next puncture direction instead of real-time assisted guided puncture. There are other guidance methods, such as ultrasound, for infraorbital nerve puncture. As a safe, simple and noninvasive guidance method, ultrasound can identify the infraorbital foramen, although the infraorbital nerve may not be identified due to its small size and imaging artifacts (34).

Fifteen patients (7.2%) experienced ecchymosis and 6 patients (2.9%) reported hematoma at the puncture; all of them recovered spontaneously within 2 to 3 weeks without treatment. A total of 130 patients (62.8%) experienced mild postprocedure numbness but did not require any treatment. The mild numbness might have been caused by mild nerve injury due to the puncture trocar entering the infraorbital foramen. Consistent with previous studies of high-voltage PRF treatment

for neuropathic pain, so long as the temperature does not exceed 42°C, increasing the intraoperative output voltage would not cause serious nerve damage (15,24). However, there is a lower incidence of facial numbness with the PRF procedure than the RFT procedure. Our results are consistent with Huang's research (35), which demonstrated that PRF treatment could play a role in neuromodulation without causing significant structural damages. In summary, PRF is a safe treatment for infraorbital neuralgia. Several studies have confirmed that PRF is a safe and effective procedure (36,37). As a minimally invasive and microdestructive technique, PRF is easily accepted by patients when compared with more invasive and destructive treatment.

### Limitations

There are several limitations in our study due to of its being a retrospective study. Multicentric, pro-

spective, randomized and controlled studies should be conducted. In addition, the optimal parameters for PRF treatment of infraorbital neuralgia need to be further explored.

### CONCLUSION

CT-guided high-voltage PRF treatment provides a minimally invasive and effective treatment option for patients with infraorbital neuralgia who failed conservative treatment., It should be considered as a preferred treatment before traumatic treatments.

### Ethical Approval

Ethics approval was obtained from the Ethics Committee of Beijing Tiantan Hospital. The application for a waiver of informed consent for this study was approved.

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