

Randomized Clinical Trial

Efficacy and Safety of Radiofrequency Thermocoagulation with Different Puncture Methods for Treatment of V1 Trigeminal Neuralgia: A Prospective Study

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Background: Radiofrequency thermocoagulation through the supraorbital foramen with a different puncture method is a new approach for the treatment of ophthalmic division trigeminal neuralgia.

Objectives: To compare the efficacy of the vertical puncture method and the transverse puncture method in the treatment of ophthalmic division trigeminal neuralgia during radiofrequency thermocoagulation through the supraorbital foramen.

Study Design: Randomized, longitudinal prospective, clinical research study.

Setting: Department of Anesthesiology and Pain Medicine, Jiaxing, China.

Methods: A total of 57 patients with ophthalmic division trigeminal neuralgia were enrolled in the study between October 2011 and April 2018, and prospectively randomized into the vertical puncture group (n = 29) or transverse puncture group (n = 28). All these patients received computed tomography guided radiofrequency thermocoagulation through the supraorbital foramen. Patients in the vertical puncture group were treated with a vertical puncture method; patients in the transverse puncture group received a transverse puncture method. Facial pain was evaluated using the Numeric Rating Scale preoperatively and at 1 day, 6 months, 1 year, and 2 years after treatment; facial numbness degree was analyzed at 1 day and 2 years after the treatments were recorded. The short-term and long-term complications during the period of postoperative follow-up were recorded.

Results: All surgical procedures were successfully completed. The Numeric Rating Scale scores at 6 months, 1 year, and 2 years after the treatment were significantly lower in the transverse puncture group compared to the vertical puncture group ($P < 0.05$), while no difference was observed on day one after the treatment ($P > 0.05$). The numbness degree at 2 years was significantly decreased compared to day one in both groups ($P < 0.05$). The radiofrequency thermocoagulation for ophthalmic division trigeminal neuralgia in the transverse puncture group showed better long-term outcomes than those in the vertical puncture group ($P < 0.05$). No short-term or long-term postoperative complications were observed in any of the groups.

Limitations: Additional clinical data should be collected to preserve the results in future work.

Conclusion: The transverse puncture method during radiofrequency thermocoagulation through the supraorbital foramen had better efficacy and fewer complications in comparison with the vertical puncture method when treating ophthalmic division trigeminal neuralgia.

Key words: Trigeminal neuralgia, radiofrequency thermocoagulation, supraorbital foramen

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Trigeminal neuralgia (TN) is a facial neuropathic pain characterized by sudden and transient attacks, which can significantly affect the life quality of the patients (1). TN affects the trigeminal nerve through 3 major branches: the ophthalmic division (V1), the maxillary division (V2), and the mandibular division (V3) (2). If the V1 nerve is affected, the corneal sensation will be lost, which in turn, will affect the cornea and cause an inflammatory response, thus leading to corneal hypoesthesia and corneal ulcers (3). Therefore, the treatment of V1TN is relatively challenging. TN can be effectively treated with minimally invasive surgery, such as balloon compression (4), radiofrequency thermocoagulation (RFT), and gamma knife radiosurgery (5). However, in order to reduce recurrence, RFT at high temperatures should be selected when treating V1TN (6).

RFT with computed tomography (CT) guidance is an effective treatment method for neuralgia (7). RFT treatment of TN is safe and has fewer complications. Conventional Gasserian ganglion ablation with RFT through the foramen ovale is commonly used to treat V1TN (7,8). However, Gasserian ganglion ablation with high-temperature radiofrequency may cause corneal ulcers. In addition, RFT through supraorbital fissure (9) could reduce massive hemorrhage. Furthermore, RFT through the supraorbital foramina has been extensively used in the treatment of V1TN.

In our previous study, we used CT-guided RFT at 95°C through the supraorbital foramina to treat V1TN. Our data indicated good treatment efficacy and few complications (10). Although the supraorbital nerve is excised by RFT, V1TN is still relapsed in some patients, which makes the treatment difficult. The vertical puncture method is a conventional RFT puncture method for the treatment of V1TN, which may lead to a higher recurrence rate. Hence, we have developed a novel transverse puncture method to increase the destruction area by RFT through the supraorbital foramina. The aim of this study was to increase the duration of trans-supraorbital foramen RFT on V1TN and effectively reduce the relapse rate. We also compared the vertical puncture method versus the transverse puncture method in the RFT treatment of V1 trigeminal neuralgia.

METHODS

Patients

The target sample size of participants was determined using the formula $N = (Z_{\alpha/2} + Z_{\beta})^2 \times \sigma^2 / \delta^2$, where α was 0.05, $Z_{\alpha/2}$ was 1.96, σ was 2.24, and δ was 1.78,

based on our preliminary experiment. After calculating, the resulting size was 7. For easier analysis, we amplified the sample size by 30% with a goal of at least 10 completed patients.

This longitudinal prospective randomized cohort study enrolled 57 patients with V1TN from the First Hospital of Jiaxing, Zhejiang, between October 2011 and April 2018. A random number table was used to randomize the patients into 2 groups: the vertical puncture (VP) group ($n = 29$) and the transverse puncture (TP) group ($n = 28$). Informed consent was obtained from the patients or their families. The Ethics Committee of the First Hospital of Jiaxing approved this study (approval no.: LS2019-292).

The inclusion criteria were the following: age > 40 years old; patients with only V1TN, or combined with V2/V3 trigeminal neuralgia; pretreatment Numeric Rating Scale (NRS) score of ≥ 5 ; disease course > 1 month; patients who were unable to achieve pain relief after a high dose of carbamazepine, gabapentin, or pregabalin, or with severe side effects. The exclusion criteria included patients who did not accept medical advice, those with local skin infection at the puncture site, psychiatric disorders or intellectual disability, severe organ disease, coagulation disorders, and allergic to local anesthetics.

Surgical Procedure with Different Puncture

The procedure was implemented with the patient lying in the supine position on the CT table. Noninvasive systolic blood pressure, diastolic blood pressure, blood oxygen saturation, and heart rate were continuously recorded. The point, depth, and route of puncture were measured by CT software. Then the puncture point on the body surface was marked. After local anesthesia was induced by 1% lidocaine, a 22-gauge radiofrequency puncture needle with 2 mm exposed segment length was used; the puncture point and puncture depth were measured before puncturing.

In the VP group, the puncture needle was vertically inserted into the supraorbital foramen. In the TP group, the puncture needle was laterally inserted from the skin near the supraorbital foramen. Then the puncture needle was adjusted according to the CT scan image results. The puncture was completed when the puncture needle tip reached the supraorbital foramen. After the puncture was completed, the puncture needle was fixed, the needle core was pulled out, and the radiofrequency electrode was inserted for electrical impedance test and high-low frequency sensorimotor electrophysiological test. If 0.5 mA or less current was enough to induce pain symptoms in the original lesion area in sensory

tests (high frequency, 50 Hz, 0.1 V) and muscle twitch in the ipsilateral supraorbital area in the movement test (low frequency, 2 Hz, 1.0V), the RFT target was accurate. Anesthesia was induced by intravenous injection of 1.5 – 2.0 mg/Kg propofol before RFT. After that, continuous standard RFT (95°C, 120 seconds) was conducted. After the patient was awakened, the sensory changes in the region supplied by the ipsilateral V1 trigeminal nerve were tested. If there was still residual pain, the position of the needle tip was readjusted, and RFT was performed again until the pain disappeared. After the completion of RFT, the patient was laid in the supine position and observed for 30 minutes. If there was no discomfort, the patient could return to the ward.

Observations and Follow-up

The primary outcomes included facial pain scores and facial numbness degrees. Secondary outcomes were effective pain-free rates and complications. Additionally, age, gender, disease course, division of the trigeminal nerve, times of CT scanning, and side effects were also recorded. The investigators executing the follow-ups were blinded to the treatment of puncture methods and patients. Information on pain relief, degree of numbness, patients' need for medication to relieve pain, complications, and patient satisfaction were recorded.

Facial pain was evaluated using NRSs (NRS, range from 1 to 10) (11), and effective pain relief was evaluated as NRS \leq 1. Facial pain was recorded before the treatment and on one day, 6 months, one year, and 2 years after the treatment. Facial numbness degree was evaluated using the BNI facial numbness scale (12), as follows: Grade I, no facial numbness; Grade II, mild facial numbness, which was not annoying; Grade III, moderate facial numbness, which was occasionally annoying; Grade IV, severe numbness, which was very annoying. Facial numbness degree was recorded on one day and 2 years after the treatment. Trigeminal neuralgia was classified into 3 types (13). Type 1: idiopathic trigeminal neuralgia that occurred without apparent cause. Type 2: classical trigeminal neuralgia that

was caused by vascular compression of the trigeminal nerve root. Type 3: secondary trigeminal neuralgia that resulted as the consequence of a major neurologic disease, such as tumor of the cerebellopontine angle or multiple sclerosis. The short-term and long-term follow-up after the treatment was conducted by telephone.

Statistical Analysis

Statistical analyses were performed using SPSS 24.0 (SPSS Inc., Chicago, IL) software. The quantitative data of normal distribution were described as means and standard divisions ($\bar{x} \pm s$). The independent t-test was used for comparisons between groups, while the paired t-test was used for comparisons between different batches. Qualitative data were presented as frequencies and percentages (%) and were compared using the Chi-square (χ^2) test. A *P* value < 0.05 was considered to be statistically significant.

RESULTS

Patients' characteristics

A total of 70 patients undergoing RFT were recruited in this study, and 57 were included in the final analysis. There were 29 in the VP group and 28 in the TP group. A flow diagram of patient enrollment is summarized in Fig. 1. There was no significant difference in gender, age, preoperative NRS scores, disease course,

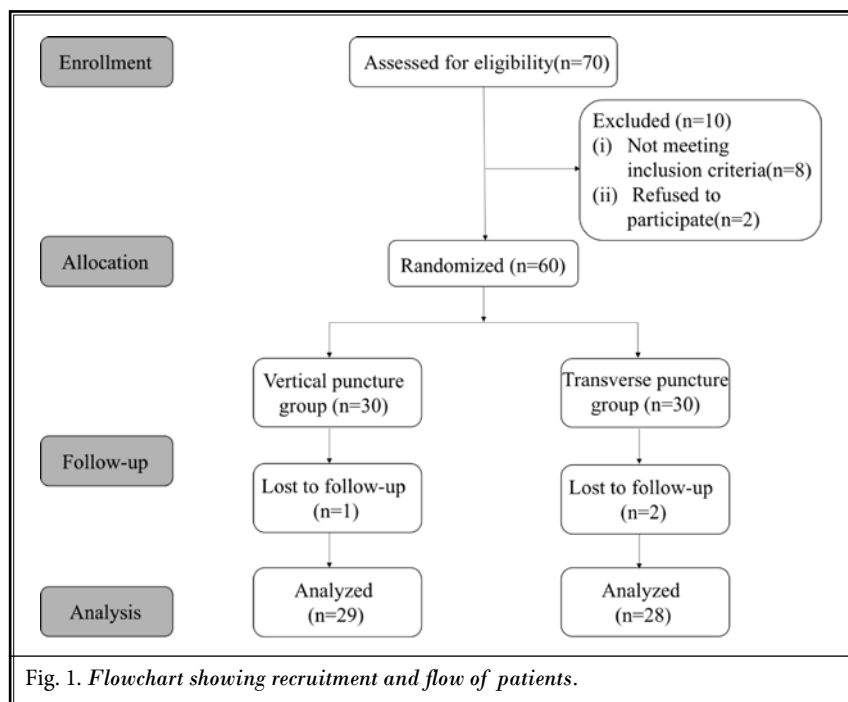


Fig. 1. Flowchart showing recruitment and flow of patients.

operation times, the types of V1TN, and the types of supraorbital foramen variations between groups ($P > 0.05$). However, the time of CT scanning in the VP group was shorter than in the TP group ($P < 0.05$, Table 1). All surgical procedures were successfully completed in 57 patients. The successful diagram of the VP group and TP group is shown in Figs. 2 and 3, respectively. Moreover, the CT 3-dimensional reconstruction of the transverse puncture method is shown in Fig. 4.

Table 1. Comparison of patients characteristics in the two groups.

Variable	VP Group (n=29)	TP Group (n=28)	t/ χ^2	P Value
Age (years)	69.76±8.75	73.64±13.62	-1.276	0.209
Gender (M/F)	15/14	13/15	0.160	0.739
Preoperative NRS	5.03±0.50	5.2±0.53	-1.833	0.072
Disease course (months)	50.71±59.95	31.30±55.05	1.271	0.209
Operation Times	1.14±0.35	1.17±0.39	-0.414	0.681
Scanning Times	4.17±2.47	3.04±1.53	2.101	0.04
Types of V1 TN (1/2/3)	16/5/8	14/5/9	0.255	0.937
Types of SFV (H/N)	15/14	15/13	0.019	0.889

VP: vertical puncture; TP: transverse puncture; TN: trigeminal neuralgia; M/F: male/female; SFV: supraorbital foramen variations; H/N: hole type/notch type; Types of V1 TN(1/2/3): Idiopathic /Classical / Secondary TN



Fig. 2. CT image of vertical puncture.

NRS Score of Facial Pain

The NRS scores before the treatment and at one day after the treatment showed no significant differences between the 2 groups ($P > 0.05$). However, the NRS scores at 6 months, one year, and 2 years after the treatment in the TP group were significantly lower than in the VP group ($P < 0.05$). The NRS scores of D-value between pre-operation and at the remaining time points showed significant differences between the 2 groups ($P < 0.05$). At the same time, a comparison of preoperative NRS scores and at the remaining time points showed a significant decrease in each group ($P < 0.05$, Table 2).

Facial Numbness Degree

The degree of facial numbness on day one after the treatment showed no significant differences between the 2 groups ($P > 0.05$). At the same time, the results were the same at 2 years post-treatment ($P > 0.05$). Yet, comparison of the numbness degree at 2 years after the treatment and on day one post-treatment showed a significant decrease in both groups ($P < 0.05$, Table 3).

Effective Rate for Pain-free

In the VP group, pain-free survival rates on 1 day, 6 months, 1 year, and 2 years after RFT were 72%, 45%, 41%, and 38%, respectively. In the TP group, pain-free survival rates on one day, 6 months, one year, and 2 years after RFT were 93%, 82%, 75%, and 64%, respectively. Kaplan-Meier curves for pain-free survival are shown in Fig. 5. Kaplan-Meier survival curves illustrate pain-free survival among patients who achieved excellent pain outcomes after percutaneous RFT in each treatment group. Pain recurrence tended to occur in patients from the VP group. The RFT for V1TN in the TP group had better long-term outcomes than those in the VP group ($P < 0.05$).

Postoperative Complications

Different degrees of swelling at the puncture point were found in both groups. All these symptoms were resolved within 1 to 3 days. In addition, in the VP group, one case developed puncture-point ulcer (Fig. 6), and one case developed optic nerve damage and diplopia during the RFT period, which was caused by unsuccessful treatment (the puncture needle slipped into the back of the eyeball during treatment) (Fig. 7). There were no other short-term or long-term postoperative complications in both groups, such as decreased corneal reflex or masticatory weakness.

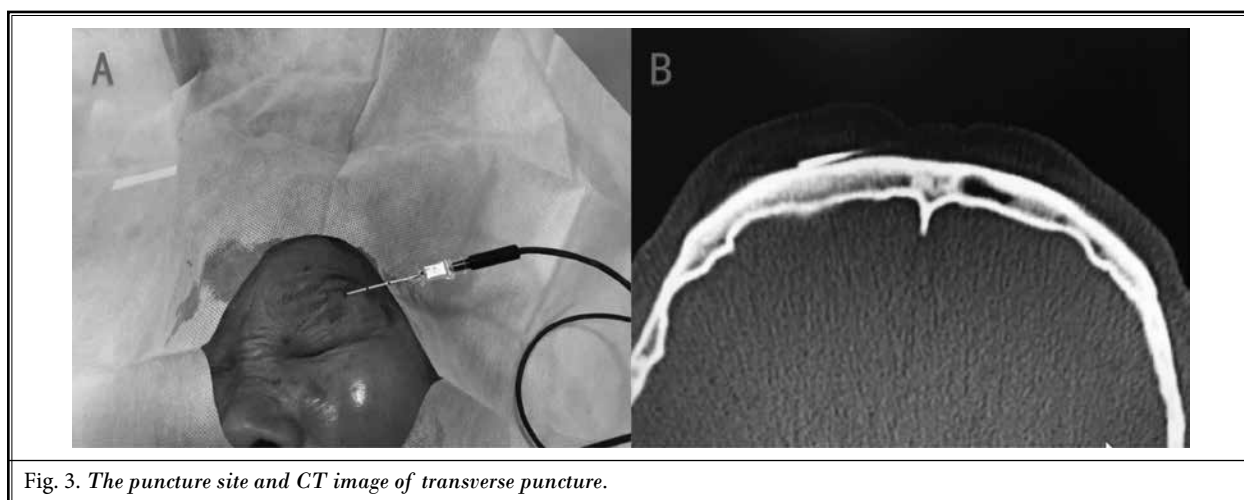


Fig. 3. The puncture site and CT image of transverse puncture.

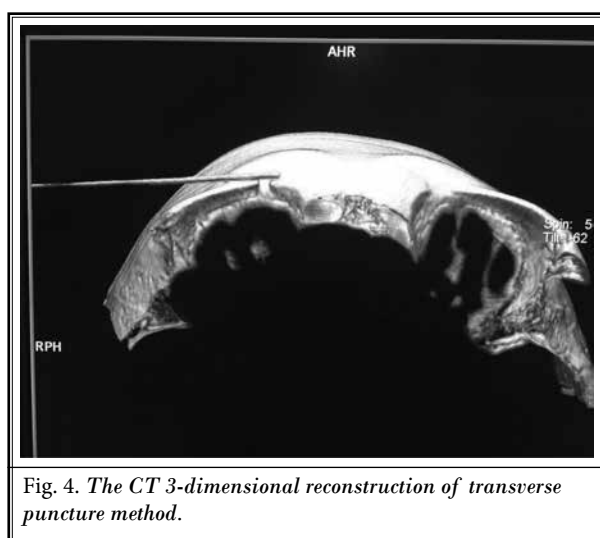


Fig. 4. The CT 3-dimensional reconstruction of transverse puncture method.

Table 2. Comparison of NRS score in the 2 groups

Group	VP Group (n = 29)	TP Group (n = 28)	t	P
Before operation	5.03 ± 0.50	5.29±0.54	-1.833	0.072
1 day	1.62 ± 0.98	1.32±0.54	1.417	0.162
6 months	2.34 ± 1.47	1.07±0.66	4.239	< 0.001
1 year	2.55 ± 1.52	0.86±0.85	5.206	< 0.001
2 year	2.79 ± 1.82	1.11±1.34	3.989	< 0.001
D-value 1 day	3.41 ± 0.90	3.96±0.74	-2.500	0.015
D-value 6 months	2.69 ± 1.41	4.21±0.83	-4.973	< 0.001
D-value 1 year	2.48 ± 1.48	4.43±1.14	-5.582	< 0.001
D-value 2 year	2.24 ± 1.79	4.18±1.59	-4.322	< 0.001

D-value 1 day= Before operation - 1 day; D-value 6 months= Before operation - 6 months; D-value 1 year= Before operation - 1 year; D-value 2 year= Before operation - 2 year

DISCUSSION

In this study, we adopted the transverse puncture method in RFT for the treatment of V1TN. This method was then compared to a traditional vertical puncture method. The transverse puncture was performed at the lateral point of the skin near the supraorbital foramen, while the vertical puncture was performed by vertical insertion from the skin surface above the supraorbital foramen. Overall, satisfactory results were achieved by both methods. The NRS score after the treatment was significantly lower than that before surgery in both groups. However, in the long term, the NRS score in the TP group was lower than that in the VP group ($P < 0.05$). Also, Kaplan-Meier curves suggested that patients in the VP group experienced pain

recurrence ($P < 0.05$). The recurrence of V1TN after the RFT treatment was mainly caused by nerve regeneration and incomplete destruction of the V1 nerve fibers. After RFT is applied, the V1 nerve mainly causes neuropathological changes, such as Wallerian degeneration and axonal regeneration. During the early phase, the nerve fiber rapidly disassembles. However, the nerve fiber can regenerate, although the neurons are unable to regenerate, or they tend to regenerate extremely slowly (14). In this study, we found that the recurrence rate was significantly different in the 2 groups ($P < 0.05$). This may be because the transverse puncture method makes the contact area between the puncture needle and the nerve tissue larger, thus cutting off the nerve tissue more completely, while the vertical method only contacts the nerve tissue with

Table 3. The case of facial numbness between the 2 groups

Numbness degree	VP Group (n = 29)	TP Group (n = 28)	χ^2	P1
1 day after the treatment				
Grade I	0 (0%)	0 (0%)	0.189	0.414
Grade II	3 (10.3%)	5 (17.9%)		
Grade III	26 (89.7%)	23 (82.1%)		
Grade IV	0 (0%)	0 (0%)		
2 year after the treatment				
Grade I	11 (37.9%)	8 (28.6%)	3.413	0.352
Grade II	15 (51.7)	13 (46.4%)		
Grade III	3 (10.3%)	4 (14.3%)		
Grade IV	0 (0%)	3 (10.7%)		
χ^2	37.241	28.796		
P2	< 0.001	< 0.001		

P1: Comparison of facial numbness between the 2 groups; P2: Comparison of facial numbness between 1 day and 2 year after the treatment in each group.

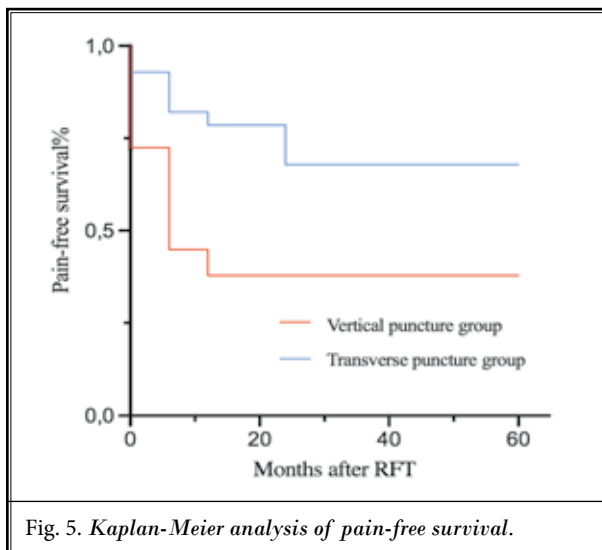


Fig. 5. Kaplan-Meier analysis of pain-free survival.

the needle tip, while the part of the exposed segment remains exposed to the surface of the skin, eventually resulting in the formation of ulceration on the skin surface of the puncture point, as shown in Fig. 6.

For the patients of V1TN with a notch type supra-orbital foramen, the supraorbital nerve may not travel through the normal supraorbital foramen. The course of the notch type supraorbital nerve might show some variation, such as inner or outer deviation (15). Therefore, the anatomic variations may lead to deviations between the target puncture point and the actual nerve position for RFT with a vertical puncture method, and

eventually lead to a relatively higher recurrence rate, which, in turn, may affect the clinical curative effect. During the operation, the transversal puncture needle is more easily fixed than the vertical puncture needle, which cannot be completely fixed on the supraorbital foramen. The movement caused by pain stimulation or the patient's unconscious movement may increase the risk of puncture needle movement, thus affecting the clinical efficacy. In this experiment, there was a case of ocular injury caused by the slide of the puncture needle during the RFT in the VP group, which eventually led to diplopia (Fig. 7). This all suggests that transverse puncture is safer and more suitable for the treatment of V1TN.

One of the radiofrequency related complications is facial numbness. The success of the surgery in reducing pain depends on the achievement of numbness (16). Nie et al (17) reported that 93.3% of patients developed facial numbness after 90°C RFT for trigeminal neuralgia. In our study, the incidence rates of facial numbness one day after the treatment were 100% in each group. The incidence of facial numbness in our study was higher than that in the study of Nie et al (17), which may be because we chose a different treatment method, i.e., supraorbital foramen instead of Gasserian ganglion. Although the patients suffered to certain degree of facial numbness, most people claimed that they would prefer the numbness to the pain. Moreover, over time, the incidence of facial numbness was decreased. Two years after the treatment, the incidence rates were 62.1% in the VP group and 71.4% in the TP group. Our study found that over time, the incidence of numbness in the TP group was higher than that in the VP group, indicating that the duration of analgesia in the TP group was longer than that in the VP group.

At the same time, multiple adjustments of the needle position could increase the risk of intracranial neurovascular injury during RFT. In this experiment, the time of CT scanning in the TP group was significantly shorter than that in the VP group ($P < 0.05$). This indicates that the transverse puncture method could greatly reduce the adjustment times and the operation time.

Lopez et al (18) found that RFT provides a higher rate of complete pain relief compared with balloon compression, glycerol rhizolysis, and stereotactic radiosurgery. Liu et al (19) have also reported that RFT is an effective and safe therapy for patients with persistent or recurrent trigeminal neuralgia. RFT temperatures ranging from 60 to 95°C are usually used for the treatment

of trigeminal neuralgia (20-22). These studies suggest that RFT with higher temperature is safe and effective in the treatment of trigeminal neuralgia and could reduce the recurrence rate of trigeminal neuralgia. Therefore, in this study, the 95°C temperature was selected for the RFT of the V1TN with the aim of achieving a complete pain block and improved therapeutic outcomes. Xie et al (22) reported that RFT through the supraorbital foramen was a safer method than through the Gasserian ganglion since it could reduce corneal injury and other complications. Therefore, in this study, we adopted the RFT method through the supraorbital foramen for the treatment of V1TN. The potential mechanism of RFT in the treatment of trigeminal neuralgia with high-temperature is the impairment of the nerve's pain signal transmission (23), and the destruction of non-myelinated fibers to conduct epicritic stimuli and block the transmission of electrical activity (24). Devor et al (25) found that the ignition hypothesis could interpret the pathogenesis of trigeminal neuralgia; the treatment could reduce abnormal neurotransmitter transmission of the demyelinated trigeminus. Therefore, in this study, our team chose RFT technology to treat V1TN. Compared with the preoperative NRS, the postoperative NRS showed a significant decrease in each group ($P < 0.05$).

Limitations

This study has a few limitations. First, the sample size is small, which may lead to bias. Second, RFT was performed with CT guidance, which requires radiographic knowledge.

CONCLUSIONS

RFT with the transverse puncture method through the supraorbital foramen has better efficacy and fewer complications in comparison with RFT with the vertical puncture method in the treatment of V1TN. The transverse puncture method was also associated with significantly shorter operation time. Our study suggests that the transverse puncture method is a good treatment option for V1 trigeminal neuralgia.

Authors' Contributions

TTW conducted the majority of the experiments

and wrote the manuscript. SJX and QLH conceived and designed the study. JCT and HDN performed the data analysis. JJZ and GL collected the data. JF reviewed the final draft and KYX coordinated and supervised the experiments. All authors read and approved the final manuscript.

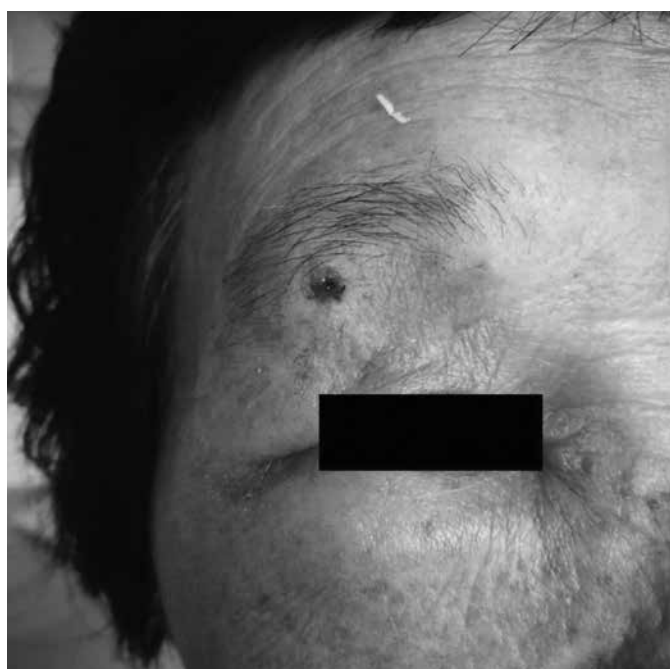


Fig. 6. Puncture point ulcer that occurred in the vertical puncture group.



Fig. 7. CT image of the puncture needle slipped into the back of the eyeball.

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