Randomized Trial

The Value and Application of Personalized Needle Modification in Percutaneous Infrazygomatic Radiofrequency in Isolated Maxillary Nerve Pain through the Foramen Rotundum

Yajing Chen, MD1,2, Qiang Zhu, MD3, Bing Huang, MD2, Qianying Liu, MD1, Qiuli He, MD1, Yibing Yao, BS2, Kang An, MD4, Chunyan Zhu, MD2, Wei Chen, MD2, and Ming Yao, PhD2

Background: Percutaneous infrazygomatic radiofrequency (PIR) is a common approach used to block isolated maxillary nerve (V2) pain through the foramen rotundum (FR) in patients with trigeminal neuralgia (TN). Nevertheless, when using this method, there is a risk of accidental penetration of the superior orbital fissure (SOF) and the optic canal (OC) that may result in the injury of the vessels and nerves in that area, and in some severe cases may lead to blindness. According to the blocking of the external orifice of the FR and whether a curved needle was used, combined angle deviation from the path of percutaneous infrazygomatic approach, the FR to the SOF or the OC in the treatment of V2 pain, in which no research has reported the angle, we analyzed the value and application of personalized needle modification in PIR in isolated maxillary nerve pain through the FR.

Objectives: The following study examined the relationship between the FR and the SOF, and analyzed the clinical significance of personalized needle modification in computed tomography (CT)-guided PIR ablation of the maxillary nerve through the FR in patients with TN.

Study Design: Randomized, review, clinical research study.

Setting: Department of Anesthesiology and Pain Medical Center, Jiaxing, China.

Methods: Three-dimensional reconstruction was performed in 88 patients and 136 patients with PIR ablation in isolated maxillary nerve pain through the FR. According to the blocking of the external orifice of the FR and whether a curved needle was used, patients were divided into 4 groups: curved-needle blocking group (CB), straight-needle blocking group (SB), straight needle no-blocking group (SN), and curved-needle no-blocking group (CN).

Results: The results obtained revealed minimum H (shortest diameter of the FR) = 1.0 mm and minimum L (length of the FR tubes) = 3.7 mm. The distance between the external orifice of the FR and the SOF (FS) was 5.16 ± 1.33 mm. The angle A (between the radiofrequency needle and the sagittal plane) was 39 ± 3.95°; the angle between the canthomeatal line and the CT scan line (ACT) was 58.99 ± 6.23°; the puncture depth (LS) was 63.99 ± 4.24 mm; the deviation angle of the misplacement into the SOF (SAF) was 2.96 ± 0.71°; the deviation angle of the misplacement into the OC (OAF) was 4.95 ± 0.73°. In addition, the postoperative Numeric Rating Scale scores in the CB group were significantly lower compared with the SB group, whereas the probability of entering the SOF in the CB group was significantly lower compared with the SB group. The total number of punctures in the SN group was less than that in the CN group.

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

Conclusions: The distance between the FR and the SOF or the OC was only few millimeters, and slight angle error could lead to the SOF and the OC. For patients with blockage in the path, the treatment of radiofrequency with personalized needle modification could improve the curative effect and reduce the risk of accidental SOF penetration.

Key words: Trigeminal neuralgia, foramen rotundum, superior orbital fissure, radiofrequency, personalized needle modification


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Trigeminal neuralgia (TN), a chronic neuropathic pain with unclear pathogenesis, is often described by recurrent electric shocks or sharp shooting pain caused by nonpainful facial movement or stimuli, such as speaking, brushing teeth, face washing eating, and similar tasks (1-5). TN always affects one or more branches of the trigeminal nerve, with V2 at 17%, V3 at 15%, V1 at 4%, and V2 + V3 approximately 32% (6) of the time. The attacks may be experienced for days, weeks, or months and in some cases may occur many times per day, seriously affecting the patient’s daily life. Oral antiepileptic drugs are the conservative treatment for TN. If this treatment approach is ineffective or intolerable, alternative invasive methods are used such as craniotomy microvascular decompression (7), percutaneous radiofrequency therapy of the Gasserian ganglion (8,9), balloon compression (10), injection of drugs that can induce chemical damage (11), and gamma knife (12,13). Radiofrequency treatment is a minimally invasive, low-risk method for treating TN with a high rate of initial efficacy and lower frequent side effects (8,9,14,15). Every approach has its own risk. Percutaneous trans-foramen ovale (FO) approach to the Gasserian ganglion is a typical method; however, approach to the FO is a difficult and time-consuming procedure that requires precision to place the needle near the Gasserian ganglion, and could lead to intracranial hemorrhage, subarachnoid injection, infection, and others (16). Percutaneous infrayzygomatic radiofrequency (PIR) is a common method used to block the isolated maxillary nerve (V2) through the foramen rotundum (FR) in patients with TN; PIR offers a higher rate of pain relief and higher safety and branch selectivity (15). Nevertheless, there is a risk of accidental entry into the superior orbital fissure (SOF) and the optic canal (OC), which may result in the injury of the vessels and nerves in the SOF and the OC, and in some extreme cases may result in blindness. Currently, there are no reports on the angle deviation from the path of PIR to the FR with the SOF or the OC. The aim of the present study was to examine the possibility of angle deviation from the path of percutaneous infrayzygomatic approach to the FR to the SOF or the OC in the treatment of V2 pain. We found that the puncture needle was blocked by the large wing of the sphenoid bone at the external orifice of the FR when some patients were punctured into the FR (17), which not only increased the puncture difficulty, but also forced the needle tip up into the SOF when it crossed the barrier. We collected clinical data on the blocking of the external orifice of the FR in relation to the puncture path and in relation to whether the curved needle technique was used or not. In addition, we examined whether there was any influence on the probability of entering into the SOF, to guide the clinical work and reduce the incidence of nerve and vascular injury in the SOF and the OC.

This is a randomized, review, clinical research study. The following study examined the relationship between the FR and the SOF, and analyzed the clinical significance of personalized needle modification in computed tomography (CT)-guided PIR ablation of the maxillary nerve through the FR in patients with TN.

**METHODS**

**CT Scan and Three-Dimensional Reconstruction**

A total of 88 (176 sides) CT (Siemens Somatom Sensation 64 spiral scanner) scans of nose and paranasal sinuses from adult patients and 3-dimensional (3D) reconstructions were collected from our hospital between January 2018 and June 2018. There were 28 male patients and 60 female patients aged 19-88 years with an average age of 48.73 years. The inclusion criteria were the following: 1) 64-row high-resolution CT (HRCT) scan and 3D reconstruction of the paranasal sinus; 2) the FR, the SOF, and the OC were clearly displayed and recognized; and 3) no previous history of traumatic fracture of skull base. Exclusion standards were: 1) structural deformation caused by malignant tumor invading the FR and its surrounding structure; 2) previous history of traumatic fracture of skull base; 3) the FR that was unclear or difficult to discern; and 4) CT scan that did not reach the planned point of puncture at the lower edge of the zygomatic arch. A flow chart of study patients and relevant data measurements and analyses are shown in Table 1.

Siemens Somatom Sensation 64 HRCT scanning was performed as follows: patient was in supine position; scanning range was supraorbital glabellar to superior alveolar. Scanning parameters were slice: 0.6 mm; kernel H41: medium +; window: sinuses 2; field of view: 178 mm; center X: 0 mm; center Y: –50 mm; mirroring: none; begin position: 127.5 mm; end position: 227.5 mm; image order: caudocranial; increment: 0.6 mm; number of images: 167. Next, the bone window was acquired, the 3D reconstruction was constructed, and finally, the image was analyzed. Measurements of 88 cases were analyzed using the software measuring.
Clinical Research Object

The study included patients with maxillary nerve pain who were diagnosed with primary TN according to the International Association for the Study of Pain criteria in our hospital from March 2015 to June 2018, and were expected to be treated under the guidance of CT half coronal scanning through percutaneous infraygomatic to FR radiofrequency ablation. Inclusion criteria were the following: 1) patients diagnosed with maxillary nerve pain; 2) those without mental illness who were able to cooperate with surgery and complete the Numeric Rating Scale (NRS) score (assessing pain levels over the last 24 hours; 0: painless; 1-3: mild pain, does not affect sleep; 4-6: moderate pain, unable to fall asleep or painful waking during sleep); 3) those who do not respond to oral antiepileptic drugs or cannot tolerate it; 4) duration ≥ 6 months, NRS score...
Fig. 1. Two-dimensional measurement. (A) Transverse position; L: the length of the FR. (B) Half sagittal position; A: preparation of puncture point; OAF: angle of deviation from the FR to the OC; SAF: angle of deviation from the FR to the SOF.

Fig. 2. Three-dimensional reconstruction. (A) SOF: superior orbital fissure; FR: foramen rotundum. The anatomic structure of the yellow dotted line is magnified by the image shown in B. (B) H: the shortest diameter of the FR; FS: the distance between the SOF and the FR.

≥ 5; 5) patients with no severe systemic disease and those able to tolerate radiofrequency thermocoagulation surgery; and 6) radiofrequency thermocoagulation surgery was performed by the same experienced physician. Exclusion criteria were: 1) V2 TN caused by tumors, cysts, infections, and similar; 2) severe systemic disease; 3) use of narcotic drugs and alcohol dependence or allergies; 4) skull base malformation in which it was not
possible to recognize the FR, the SOF, and the OC; and 5) patients with mental illness who were not capable of cooperating with surgery or completing the NRS score.

**Clinical Case Grouping and Data**

According to inclusion and exclusion criteria, 136 patients were enrolled in this study. The male/female ratio was 40/96, aged 36-95 years, with an average age of 66.6 ± 12.7 years. According to the blocking of the external orifice of the FR and whether the curved needle was used or not, patients were divided into 4 groups: curved-needle blocking group (CB), straight-needle blocking group (SB), straight needle no-blocking group (SN), curved-needle no-blocking group (CN). The following statistical analyses and comparison of the data were performed for all 4 groups: preoperative NRS score (pre-NRS), postoperative NRS score (post-NRS), angle between the canthomeatal line and the CT scan line (ACT) (Fig. 3A), radiofrequency needle puncture depth (LS) (Fig. 3B), if the external orifice of the FR was blocked, and the angle between the tube axis of the FR and the puncture path was measured (Fig. 3B). Also, the radiofrequency of bent needle to the angle, which was shown in Fig. 3B, was measured with the

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**Fig. 3.** Measurement of clinical data. (A) ACT: the angle between the canthomeatal line and CT scan line (the angle between green line and red line). (B) P: positioning bars; LS: the depth of inserting the needles. The magnifying structure of the yellow solid line is the yellow dashed line in the picture. (C) The individual radiofrequency needle bending device. (D) Curved needle puncture. A: the angle between the needle and the sagittal plane. (E) The puncture needle was blocked by the large wing of the sphenoid bone at the external orifice of the FR, the straight radiofrequency needle cannot enter the FR, only radiofrequency in the external orifice of the FR.
individual radiofrequency needle bending device (Fig. 3C). Then, angle A between the radiofrequency needle and sagittal plane was measured (Fig. 3D), and finally, puncture with a curved personalized needle modification and radiofrequency (Fig. 3D), the total number of puncture N (the total adjustment time that reflects the time-consuming procedure), the ratio of not entering into the FR (Fig. 3E), and the probability of the puncture needle entering into the SOF (Fig. 4).

**Preoperative Preparation**

Before operation, patients underwent the following examination: coagulation function analysis, liver and kidney function analysis, electrolytes testing, brain magnetic resonance imaging, paranasal sinus CT, and electrocardiogram. Elimination of secondary TN and contraindications were also analyzed. In addition, patients fasted for 8 hours and did not consume any liquid 4 hours before the operation. Additionally, all patients were informed about potential risks and complications. We prepared related operating instruments, such as the radiofrequency therapy apparatus (Baylis Inc., Beijing, China), No. 7 radiofrequency needle (Zhejiang Volt Medical Device Co., Ltd., Zhejiang, China), positioning bars (unlabeled products), the individual radiofrequency needle bending device (Zhejiang Volt Medical Device Co., Ltd.), and obtained intravenous access, among others.

**Operation Steps**

With a thin pillow on the shoulder of the patient, the head was tilted back approximately 30° (Fig. 3A), rotating the CT machine for half-coronal scanning, selecting the appropriate slices and position by the positioning bars, and marking puncture point (Fig. 3B). The puncture path was designed, and if the puncture path was blocked by a large sphenoid wing, the angle of the circular axis of the FR to the puncture direction was measured (Fig. 3B), and the individual radiofrequency needle bending device was used to bend the radiofrequency needle (Fig. 3C) for percutaneous subzygomatic FR puncture. High (50 Hz) and low (2 Hz) frequency electrophysiological stimulation tests were performed after reaching the puncture target. If the numbness and muscle fibrillation of the V2 innervation region could be induced in 0.5 mA, then, given appropriate propofol, radiofrequency thermocoagulation was applied (the parameters for thermocoagulation is 95°C, last 120s, repeat 2 or 3 times).

**Statistical Methods**

SPSS Version 17.0 software (IBM China Software Development Lab, SPSS Inc., Beijing, China) was used to analyze the data, and GraphPad Prism 6.0 (GraphPad Software Inc., La Jolla, CA) was used to map the analysis. The data were all expressed as mean ± standard deviation (X ± s) or percentage (%). The right and left sides of the same patient were paired using a sample t test. The t test was used for independent samples between 2 groups, whereas the probability of the puncture needle entering into the SOF, the ratio of entering into the FR, and ex ratio were tested by the chi-square test between groups. \( P < 0.05 \) was considered significantly different. Institutional review board and ethics com-
committee approval was obtained from the institutional review board of the Jiaxing First Hospital (2017-188). The patients have consented to the submission of the study results.

**RESULTS**

**Imaging Data**

Two- and 3D anatomies of paranasal sinuses were analyzed in 88 cases. The shortest diameter of the FR (H) was 1.71 ± 0.36 mm; the minimum diameter was 1 mm and the maximum diameter was 2.9 mm. The length of the FR tubes (L) was 6.41 ± 1.44 mm; the maximum diameter was 10.9 mm and the minimum was 3.7 mm. The diameter between the external orifice of the FR and the SOF (FS) was 5.16 ± 1.33 mm; the minimum diameter was 2.8 mm and the maximum was 10.7 mm. A paired sample t test on the left and right sides showed no significant difference in H, L, FS, deviation angle of the misplacement into the SOF (SAF), and deviation angle of the misplacement into the OC (OAF) \((P > 0.05)\); therefore, descriptive statistical analysis was performed.

The angle A (between the radiofrequency needle and the sagittal plane) was 39 ± 3.95°; the maximum was 51° and the minimum was 31°. The ACT was 58.99 ± 6.23°; the maximum was 75° and the minimum was 41°. The LS was 63.99 ± 4.24 mm; the maximum was 73 mm and the minimum was 52 mm. The SAF was 2.96 ± 0.71°; the minimum was 2°. The OAF was 4.95 ± 0.73°, the minimum was 3° (Table 2).

**Clinical Data Results of the 4 Groups**

The pre-NRS scores in the SB, SN, CB, and CN groups were 5.12 ± 0.83, 5.14 ± 0.53, 5.27 ± 0.78, and 5.29 ± 0.58, respectively, and the difference between scores was not statistically significant \((P > 0.05)\). Moreover, the post-NRS scores in the CB group \((1.65 ± 0.49)\) and the SB group \((2.56 ± 1.00)\) were significantly lower compared with pre-NRS scores of the CB and the SB group, respectively \((P < 0.001)\). In addition, the post-NRS scores in the CB group were significantly lower compared with post-NRS of the SB group \((P < 0.001)\) (Fig. 5A). The post-NRS scores in the SN group \((1.71 ± 0.46)\) and the CN group \((1.68 ± 0.59)\) were significantly lower compared with pre-NRS scores in the same groups \((P < 0.001)\), whereas no significant difference in post-NRS scores were observed between the SN group and the CN group (Fig. 5B). Furthermore, the total number of punctures \((4.47 ± 1.55)\) was significantly lower in the SN group compared with the CN group \((5.24 ± 1.53)\) \((P < 0.05)\), whereas the total number of punctures in the SB group \((5.56 ± 1.39)\) was not significantly different compared with the CB group \((6.5 ± 2.1)\) (Fig. 5C). Additionally, the probability of misentry into the SOF in the SB group \((40\%)\) was higher than that in the CB group \((11.5\%)\) \((X^2 = 5.436; P = 0.02)\), whereas the probability of misentry into the SOF in the SN group \((3.9\%)\) was lower compared with the CN group \((14.7\%)\) \((X^2 = 3.139; P = 0.076)\) (Fig. 5D). Also, the ratio of entering the FR in the SB group \((40\%)\) was significantly lower compared with the CB group \((100\%)\) \((P < 0.05)\), whereas the ratio of entering the FR in the SN group \((100\%)\) was not different from that in the CN group \((100\%)\) (Fig. 5E).

**DISCUSSION**

Proficiency in the anatomic structure related to the FR can help to avoid complications in CT-guided PIR ablation of the maxillary nerve through the FR employed to treat V2 TN. Three-dimensional (3D) reconstruction has definite guiding significance for clinical work (18,19). Through the 3D reconstruction and measurement of the FR and the SOF, the structural characteristics of the FR and the SOF can be better understood. According to previous studies, in percutaneous Hartel approach FO, balloon compression, and percutaneous radiofrequency thermocoagulation semilunar ganglion, the needle passes during the puncture through the inferior orbital fissure into the SOF and the external orifice of the OC, which can damage the optic nerve and lead to blindness (20,21). It has been reported that with these approaches it is possible to enter into the OC at an angle of 16.5 ± 2.9° (22). In the present research, we found that the tip of the needle only needs to deviate from the normal trajectory 2.96 ± 0.71°, and minimally 2°, to enter into the SOF and to cause damage of the

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Fig. 5. Comparison of data in the 4 groups. (A) The post-NRS scores in the CB group and the post-NRS scores in the SB group were lower compared with preoperative data (###P < 0.001). The post-NRS scores in the CB group were significantly lower than those in the SB group (###P < 0.001). (B) The post-NRS scores of the SN group and the post-NRS scores of the CN group were lower than those preoperative (P < 0.001). There was no significant difference in post-NRS scores between the SN group and the CN group. (C) The total number of punctures in the SN group (4.47 ± 1.55) was lower than in the CN group (5.24 ± 1.53) (P < 0.05). The total number of punctures in the SB group (5.36 ± 1.39) was not significantly different from those in the CB group (6.5 ± 2.1). (D) The probability of misentry into the SOF in the SB group (40%) was higher than that in the CB group (11.5%) (X² = 5.436; P = 0.02, there are statistical differences). The probability of entering the SOF in the SN group (3.9%) was lower than that in the CN group (14.7%) (X² = 3.139; P = 0.076, there was no statistical difference). (E) The ratio of entering the FR in the SB group (40%) was significantly lower than that in the CB group (100%) (the difference was statistically significant). The ratio of entering the FR in the SN group (100%) was not different from that in the CN group (100%).
important vessels and nerves in the SOF. Also, when the upward deviation was 4.95 ± 0.73°, and minimally 3°, the tip may enter into the OC and cause optic nerve injury or even blindness (23,24). The complications related to the optic nerve and nerve and blood vessels in the SOF more easily occur when the PIR ablation of the maxillary nerve is performed through the FR than with the percutaneous Hartel approach FO. Therefore, in clinical work, this issue should be properly addressed. Because the zygomatic nerve and other small branches may separate from the maxillary nerve in the inner FR (25), if the radiofrequency therapy is only applied at the external orifice of the FR, this can lead to partial neurologic branch missing and can cause radiofrequency thermocoagulation damage, thus leaving the treatment incomplete.

The analysis and comparison of clinical data revealed that for the patients with the blocking of the FR external orifice, the curved needle, which is personalized needle modification, can reduce the probability of entering into the SOF during the puncture, and increase the ratio of entering into the FR, thus achieving a definite therapeutic effect. For patients without blocking by the sphenoid wing, straight needles can reduce the number of needle adjustments, which in turn can reduce the total number of punctures, thereby reducing radiation exposure. In clinical work, we also found that even if the tip of the needle goes into the orbital fissure, with no radiofrequency thermal coagulation performed, it will not cause diplopia, strabismus, keratitis, mild vision loss, and other ocular complications. Nevertheless, if the SOF is mistaken for the FR during radiofrequency thermocoagulation treatment, it can certainly cause injury of the ophthalmic nerve, oculomotor nerve, trochlear nerve, and abducent nerve in the SOF, and even optic nerve injury in the OC (24) that can cause obvious damage to the patient’s vision. Consequently, it is very important for the operator to distinguish the FR from the SOF. When it is established that the needle tip deviates from the intended puncture direction and points to the SOF through the external orifice of the FR, it is necessary to immediately stop the needle entry, to correct the puncture direction, or to use the curved needle technique to make the needle tip turn into the FR, and thus prevent serious ocular complications after radiofrequency. The FR and its adjacent structures are very much complex, which is why it is necessary to fully understand the adjacent structure of the FR that can help to design the puncture path and reduce the risk of surgery and the incidence of related complications.

This study measured the angle of deviation from the FR to the OC and angle of deviation from the FR to the SOF in CT-guided PIR ablation of the maxillary nerve through the FR to treat V2 TN. It has certain guiding significance for clinical workers. CT-guided PIR ablation of the maxillary nerve through the FR to treat V2 TN is an innovative technique for the treatment of TN (15). Our results suggested that for the patients with blocking of the external orifice in the puncture path, the personalized needle modification can increase the probability of entering the FR, obtaining better therapeutic effect, reducing the probability of entering into the SOF, and reducing the probability of orbital neurovascular injuries.

Limitations

This study has few limitations. The clinical data that included the number of cases whose external orifice of the FR was blocked by the large wing of the sphenoid bone was relatively small. Although the chi-square test statistical data were meaningful, the interval between cases was longer. The accidental error caused by the operator during clinical operation may not be eliminated. More clinical data should be collected to preserve the results in future work.

Conclusions

Because the H is 1.71 ± 0.36 mm (1-2.9 mm), the diameter of the radiofrequency needle should be < 1.0 mm so that the radiofrequency needle can enter into the FR. The length of the FR was 6.41 ± 1.43 mm (3.7-10.9 mm), and the depth of the needle should be < 3.7 mm after reaching the external orifice of the FR to avoid the puncture tip into the middle cranial fossa. The distance from the SOF to the FR is 5.16 ± 1.33 mm (2.8-10.7 mm). When the tip of the needle points to the SOF, if the reentry depth is < 2.8 mm after reaching the external orifice of the FR, the SOF can be avoided.

In CT-guided PIR ablation of the maxillary nerve through the FR used to treat V2 TN, the angle between the CT scan plane and canthus ear line plane is 58.99 ± 6.23°, which can make the puncture point, puncture target, and puncture path at the same CT plane. The average depth of radiofrequency needle puncture is 63.99 ± 4.24 mm, the maximum is 73 mm, and the minimum is 52 mm. The average of angle between needle and sagittal plane is 39 ± 3.95°, maximum is 51°, minimum is 31°. The angle of deviation into the SOF is 2.96 ± 0.71° and the minimum is 2°, much smaller than A and ACT. An inexperienced physician is very likely to enter the
SOF, causing vascular and nerve damage in the SOF. When the tip of the needle deviates from $4.95 \pm 0.73^\circ$, the minimum is $3^\circ$, it may enter the OC and cause optic nerve injury or even blindness.

In CT-guided PIR ablation of the maxillary nerve through the FR used to treat V2 TN in patients with blockage in the path of puncture FR, the treatment of radiofrequency thermocoagulation with personalized needle modification can improve the ratio of entering into the FR (100%/40%), the curative effect (1.65 ± 0.49/2.56 ± 1.00), and can reduce the probability of the puncture needle entering into the SOF (11.5%/40%); for the patients without blockage in the path of puncture FR, the total number of punctures (4.47 ± 1.55/5.24 ± 1.39) and the radiation dose of the patients and medical staff can be reduced by using a straight needle.

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