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Identification of Foramen Ovale With H-Figure Fluoroscopic Landmark Improves Treatment Outcomes in Idiopathic Trigeminal Neuralgia

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BACKGROUND: Because it is traditionally difficult and time-consuming to identify the foramen ovale (FO) with fluoroscopy, we recently developed the H-figure method to acquire fluoroscopic view of FO with shorter procedure time and less radiation. However, the impact of such an H-figure approach on the clinical outcomes of trigeminal ganglion radiofrequency thermocoagulation (RFT) in treating idiopathic trigeminal neuralgia (ITN) remains unclear.

METHODS: In a 12-month follow-up retrospective cohort study, patients with ITN had fluoroscopy-guided RFT of trigeminal ganglion via either classic approach (n = 100) or H-figure approach (n = 136) to identify FO. Data of continuous variables were analyzed with a Shapiro-Wilk test for normality and subsequently with a Mann-Whitney test, and the binary data were analyzed with a χ^2 test. The primary outcome was the facial pain measured by a Visual Analog Scale (VAS) 1 year after the treatment. The secondary outcomes included the quality of the fluoroscopic FO views, the threshold voltage to provoke paresthesia, the procedure time, the number of fluoroscopic images, and the facial numbness VAS.

RESULTS: Compared with the classic approach group, the H-figure approach group was associated with better long-term pain relief after the procedure, with significantly fewer patients had pain 3 months (6.6% vs 17.0%, $P = .012$) and 12 months (21.3% vs 38.0%, $P = .005$) after the procedure, and among patients who had pain after the procedure, patients in the H-figure group had significantly less pain 6 months after the procedure (VAS median [interquartile range (IQR)]: 3 [2–6] vs 6 [4–7], $P < .001$). Moreover, compared to the classic approach, the H-figure approach provided better fluoroscopic view of FO, lower threshold voltage to elicit paresthesia (median [IQR]: 0.2 [0.2–0.3] vs 0.4 [0.4–0.5] V, $P < .0001$), with shorter procedure time (median [IQR]: 7.5 [6.0–9.0] vs 14.0 [10.0–18.0] min, $P < .0001$), and required fewer fluoroscopic images (median [IQR]: 4.0 [3.0–5.0] vs 8.0 [6.0–10.0], $P < .0001$).

CONCLUSIONS: RFT of the trigeminal ganglion using the H-figure approach is associated with superior longer term clinical pain relief than the classic approach in treating ITN. (Anesth Analg 2022;00:00–00)

KEY POINTS

- **Question:** Does identification of foramen ovale (FO) with H-figure fluoroscopic landmark for radiofrequency thermocoagulation (RFT) of trigeminal ganglion lead to better clinical outcome in treating idiopathic trigeminal neuralgia (ITN)?
- **Findings:** RFT performed with H-figure approach was associated with superior long-term pain relief for ITN patients compared to RFT performed with classic approach.
- **Meaning:** H-figure is a faster and more effective approach to optimally visualize FO, and the approach may facilitate better long-term pain alleviation for ITN after RFT.

GLOSSARY

C = coronal angle; **FDR** = false discovery rate; **FO** = foramen ovale; **IQR** = interquartile range; **ITN** = idiopathic trigeminal neuralgia; **ns** = not significant; **RF** = radiofrequency; **RFG** = radiofrequency generator; **RFT** = radiofrequency thermocoagulation; **S** = sagittal angle; **S-P-T** = superior line of petrous ridge of temporal bone; **STROBE** = Strengthening the Reporting of Observational Studies in Epidemiology; **VAS** = Visual Analog Scale

Radiofrequency thermocoagulation (RFT) of trigeminal ganglion through foramen ovale (FO) is an effective way to manage idiopathic trigeminal neuralgia (ITN),^{1,2} one of the most common causes of persistent intense orofacial pain with

an incidence of 12.6 per 100,000 persons per year.³ However, the ambiguous fluoroscopic visualization of FO by existing approaches often leads to prolonged procedure time and suboptimal distance between the active RFT needle tip and target branches of

trigeminal ganglion. This ambiguity can also lead to inadvertent puncture of the jugular foramen and/or foramen spinosum that causes injury to the internal carotid artery or middle meningeal artery—both can be fatal complications.⁴⁻⁶

Recently, we developed the H-figure approach as a novel and easily recognizable fluoroscopic landmark that significantly facilitates the visualization of FO with fewer fluoroscopic shots and shorter procedure time.^{7,8} The H-figure landmark consists of 2 vertical lines from the medial border of mandible and lateral edge of maxilla and 1 horizontal line from the superior line of petrous ridge of temporal bone (S-P-T line). With H-figure fluoroscopic landmark, the FO fluoroscopic view can be easily optimized above the S-P-T line at the center of the H-figure when the medial end of the temporomandibular joint is located midpoint between the lateral and medial borders of mandible.⁷ Compared to the classic approach, RFT needle inserted by the H-figure method required lower electrical stimulation to elicit paresthesia in affected area after FO puncture,⁷ suggesting that the needle tip from the H-figure approach is closer to the target trigeminal ganglion branches. However, it remains unclear if RFT performed with H-figure has better clinical outcomes. We now report a 12-month follow-up retrospective cohort study to show that RFT with H-figure fluoroscopic approach is associated with better long-term therapeutic efficacy in managing ITN than the classic approach.

METHODS

Ethical approval was obtained from the institution's Ethics Examining Committee of Human Research for this retrospective cohort study following the Strengthening the Reporting of Observational Studies

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The authors declare no conflicts of interest.

L.-L. He, W.-X. Zhao, and P.-Y. Paul Su contributed equally to the work as co-first authors.

L.-Q. Yang and Z. Guan contributed equally to the work as co-last authors.

Reprints will not be available from the authors.

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in Epidemiology (STROBE) guidelines.⁹ The clinical Research Ethics Committee agreed to waive written informed consent because all data were inquired retrospectively from the electronic medical record system and postoperative follow-up.

Patient Selection

The electronic medical records of ITN patients who underwent fluoroscopy-guided RFT of trigeminal ganglion with H-figure approach or classic approach from May 2015 to February 2020 were screened in the Department of Pain Management, Xuanwu Hospital, Capital Medical University, Beijing, China. All patients were diagnosed to have ITN according to the criteria of the International Classification of Headache Disorders-II (2004),¹⁰ and they did not have coagulopathy, infection, intracranial tumor, pregnancy, and allergy to local/general anesthetics. Patients who received microvascular decompression or who recorded incorrect contact information were excluded (Figure 1).

Procedure Management

In the H-figure group, patients were placed in supine position with 40° to 50° of head extension; the initial fluoroscope intensifier (General Electric OEC 9900 Elite C-Arm; Bluestone Diagnostics) was positioned with 15° of lateral rotation from midline toward the ipsilateral side and 15° of caudal tilt. The H-figure landmark was first identified following the medial border of the mandible and the lateral edge of the maxilla as the 2 vertical lines and the S-P-T line as the horizontal line. The FO was then identified above the S-P-T line between the mandible laterally and the maxilla medially (Figure 2). If the FO was superimposed by the maxilla or mandible, the fluoroscope was then rotated laterally or medially in coronal plane to locate the FO at the middle of H-figure. In addition, the FO is usually located close to the midpoint of H-figure when the medial end of the temporomandibular joint is aligned to the bottom of the mandibular notch, which is located at the midpoint between the coronoid and condylar processes of the mandible and on the lateral extension of S-P-T line (Figure 3A, B). On the other hand, if the FO was viewed as a narrow ovale or even a linear shape, then the fluoroscope was rotated in caudal or cephalad direction along the sagittal plane to acquire better visualization of the FO with greater width-to-length ratio.⁷ Once the FO view was finalized, the grade scale of FO view was assessed by grades 1 to 3 (grade 1 = width-to-length ratio $\leq 1:3$, Figure 3C; grade 2 = width-to-length ratio between 1:3 and 2:3; and grade 3 = width-to-length ratio $\geq 2:3$, Figure 3D).

The classic approach was previously described by Whisler and Hill.¹¹ Briefly, patients were placed in

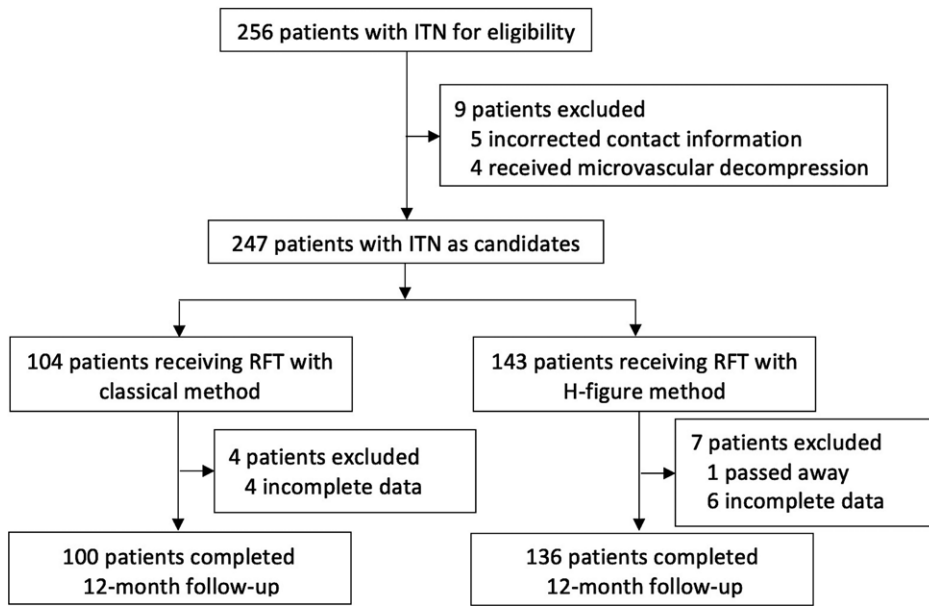


Figure 1. Flowchart of the study. ITN indicates idiopathic trigeminal neuralgia; RFT, radiofrequency thermocoagulation.

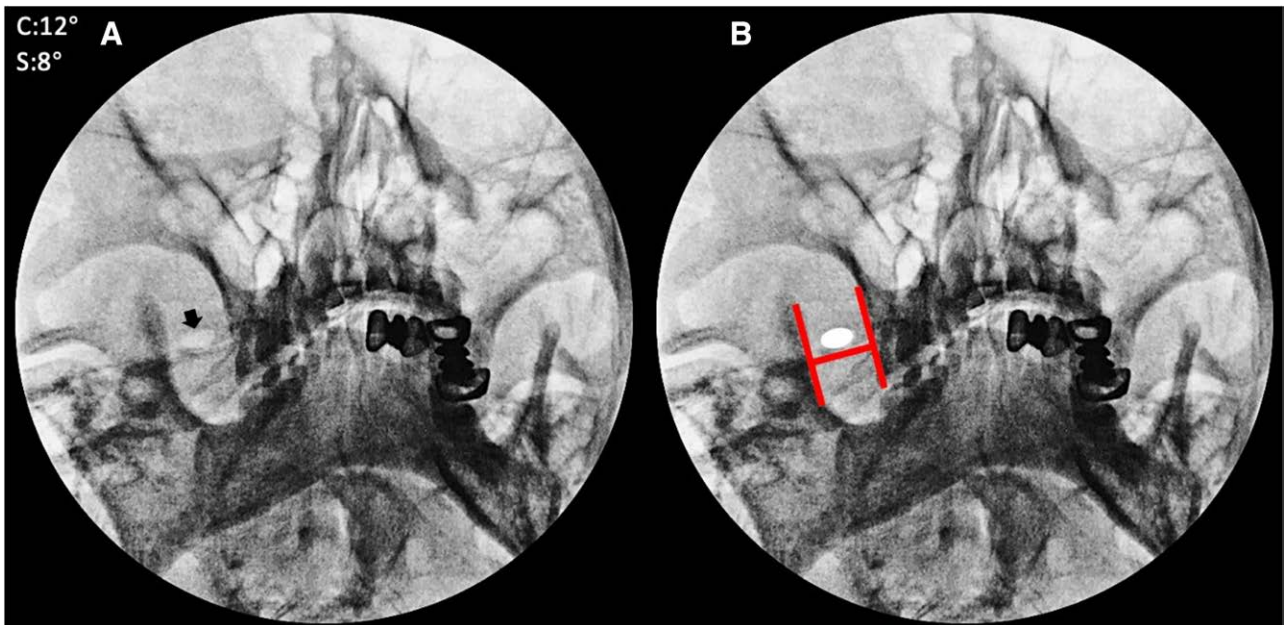


Figure 2. The fluoroscopic landmark of the H-figure to identify FO. A, The fluoroscopic view of FO, which is indicated by the black arrow. B, The H-figure composes of 2 vertical lines that are the medial border of mandible and lateral edge of maxilla and 1 horizontal line that is the S-P-T line. The FO marked by the white ovale. C indicates coronal angle; FO, foramen ovale; S, sagittal angle; S-P-T, superior line of petrous ridge of temporal bone.

supine position with their head extension of 40° to 50°. The fluoroscope was initially set to be approximately 15° off the midline away from lesion side in a submental and oblique view. The fluoroscope angulations were then adjusted in the coronal and sagittal planes, or patients’ heads were turned laterally or medially to midline until the boundaries of FO were visualized above the petrous ridge.

After visualization of FO, a 150-mm 22-G straight radiofrequency (RF) needle (Cosman Medical) with a 5-mm active tip was inserted through the sterilized skin in the “Haertel” approach¹² after local tissue

infiltration with 5- to 10-mL 0.5% lidocaine and intravenous injection of 50-µg fentanyl and 0.5-mg atropine. In a transfacial and oblique projection, the needle tip was advanced through the FO, and the depth of the needle tip did not extend beyond the clivus in the lateral projection (Figure 4). The position of needle tip was adjusted to elicit the paresthesia or masticatory responses within 1.0 V of sensory (50 Hz) or motor (2 Hz) electrical stimulations with Cosman RF lesion generator, model RFG-4 (Cosman Medical). Under intravenous anesthesia with propofol (1–2 mg/kg), ganglion neurotomy with RFT was performed at 65

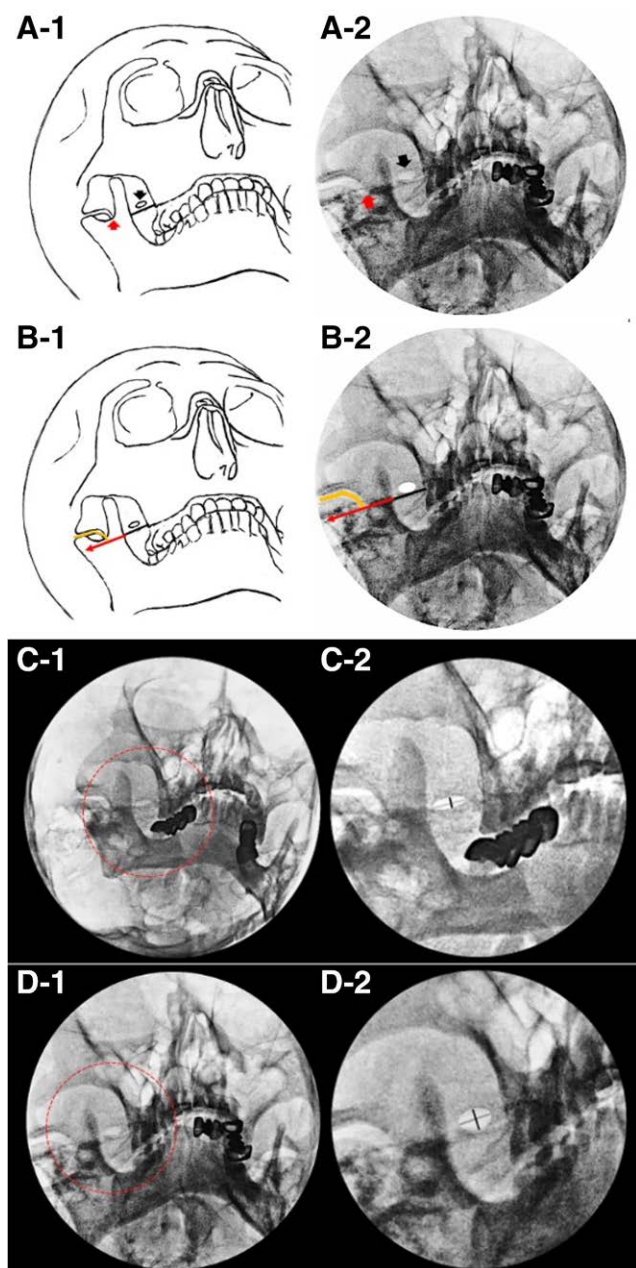


Figure 3. Identification of FO with medial end of temporomandibular joint and S-P-T line and the grades of FO view with different width-to-length ratios. A-1 and A-2, FO is at the center between the medial border of mandible and lateral edge of maxilla when the medial end of temporomandibular joint is aligned at the midpoint of the mandibular notch. The red arrow indicates the medial end of temporomandibular joint, and the black arrow indicates FO. B-1 and B-2, The medial end of the temporomandibular joint is on the lateral extension of the S-P-T line. The red arrow indicates the lateral extension of the S-P-T line, the yellow arc marks the medial end of temporomandibular joint, and the white ovale marks FO. C, Grade 1 FO view (C-1) with the width-to-length ratio of 1:3, and C-2 is the amplified image of red circle in C-1. D, Grade 2 FO view (D-1) with the width-to-length ratio of 2:3, and D-2 is the amplified image of red circle in D-1. The black line indicates width, and the grey line indicates length. FO indicates foramen ovale; S-P-T, superior line of petrous ridge of temporal bone.

°C for 90 seconds to treat V1 or 75 °C for 120 seconds to treat V2 and V3.

All patients were blinded for the procedure approaches. Three medical providers performed H-figure approach and 4 medical providers performed classic approach, and they all had similar clinical experience in fluoroscopy-guided trigeminal RFT.

Data Collection and Outcomes

All data were collected, respectively, through the electronic medical record system up to 12 months after the procedure. The primary outcome was assessed with pain Visual Analog Scale (VAS) (0–10, with 0 as no pain and 10 as the worst pain) at 12 months after the procedure.

The secondary outcomes included the VAS score at different time points after the procedure (1 week and 1, 3, and 6 months), grade scale of FO visualization, the number of fluoroscopic images as a proxy for radiation exposure needed to visualize FO, the procedure duration to visualize FO, the threshold voltage to elicit paresthesia of target branches, and the facial numbness VAS (0–10, with 0 as no numbness and 10 as the worst numbness) at different time points after the procedure. Postdural puncture headaches, diplopia, and other adverse reactions were identified in the medical records.

Statistical Analyses

Sample size was calculated based on our pretest, which contained 20 patients in each group, which illustrated a true difference of mean (Group H Mean-Group C Mean) of 2.05 in pain VAS score at 12 months after RFT procedure. The total sample size of 95 patients per group was required to achieve an effect size of 90% power type I error of 2.5% using a superiority margin of 1. Data of continuous variables were analyzed with a Shapiro-Wilk test for normality and were presented as median (interquartile range [IQR]: 25th–75th percentile). Because of the nonnormal distribution of these data, they were analyzed with a 2-tailed unpaired Mann-Whitney test. The comparison of pain and numbness VAS scores at multiple time points after the procedure (Figure 5B, D) was further analyzed with a 2-stage step-up multiple comparison of Benjamini, Krieger, and Yekutieli after a Mann-Whitney test, with a false discovery rate (FDR) set as 1%. Binary data were presented as percentage and were analyzed with a 2-sided χ^2 test. All analyses were processed by GraphPad Prism software version 9.3.1 (GraphPad Software), and $P < .05$ was deemed to be statistically significant.

RESULTS

Participants

A total of 256 patients with ITN were admitted from May 2015 to February 2020 (Figure 1). Among them, 9 patients were excluded for incorrect contact

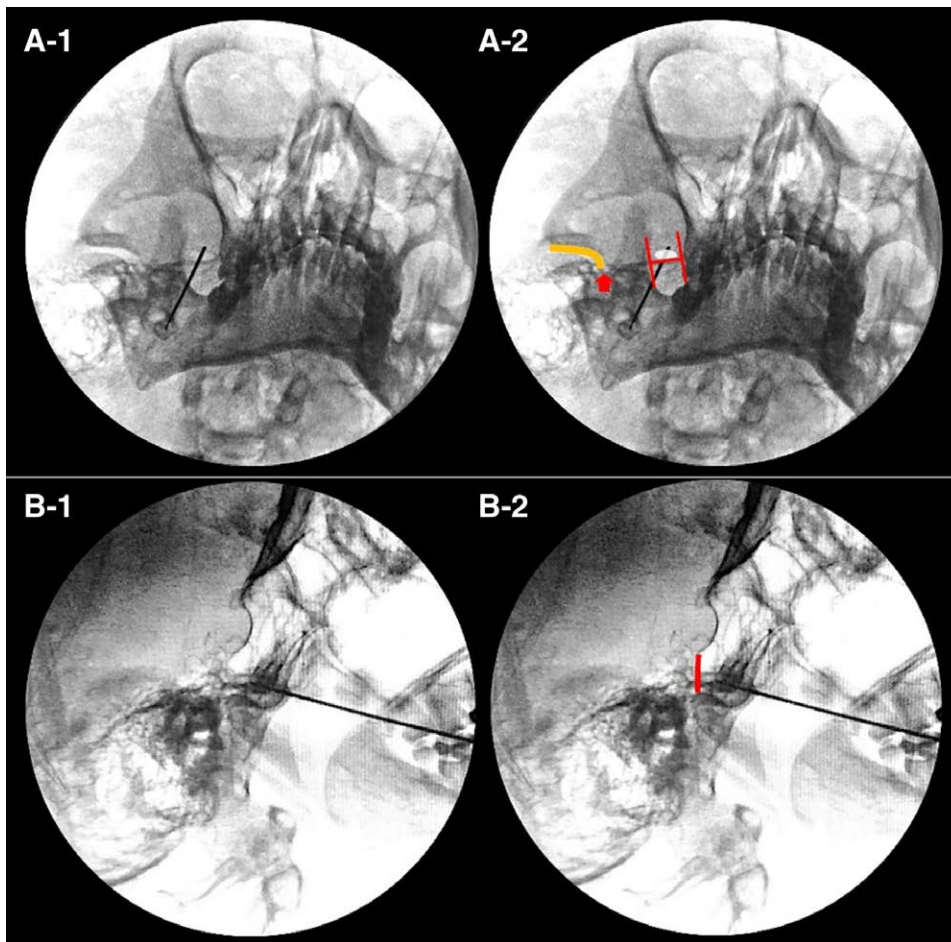


Figure 4. Punctuation of FO with H-figure approach. A, The image of FO punctuation (A-1) with highlighted H-figure (A-2) in oblique projection. The white ovale marked FO, the yellow arc shape indicates the temporo-mandibular joint, and the red arrow indicates the midpoint of mandibular notch. B, The image showing the position of the needle tip (B-1) with highlighted clivus (B-2) in lateral projection. The red vertical line indicates the clivus. FO indicates foramen ovale.

information (5 patients) and microvascular decompression surgery (4 patients). In the remaining 247 patients, 104 patients underwent fluoroscopy-guided with classic approach and 143 patients underwent fluoroscopy-guided with H-figure approach. Four patients in the classic approach group were excluded from analysis because of incomplete data, and 7 patients in the H-figure approach group were excluded because of incomplete data or patient passed away unrelated to RFT procedure. Eventually, the analysis was performed in 236 patients, including 100 patients in the classic group and 136 patients in the H-figure group (Figure 1).

Baseline of Patients’ Demographic Data

All 236 subjects received RFT of trigeminal ganglion through FO. The sex, age, pain duration, side of the pain, affected division of trigeminal nerve, and pain level before RFT were all similar among the H-figure group and the classic group (Table).

The Primary Outcome

Compared with the classic approach group, the H-figure approach group was associated with better pain relief after the procedure (Table), with

significantly fewer patients H-figure approach group who had facial pain 3 months (6.6% vs 17.0%, $P = .012$) and 12 months (21.3% vs 38.0%, $P = .005$) after the procedure (Figure 5A). Among patients who had facial pain after the procedure, patients in the H-figure group had significantly less pain 6 months after the procedure (VAS median [IQR]: 3 [2–6] vs 6 [4–7], $P < .001$) (Figure 5B).

The Secondary Outcomes

Facial numbness is the most frequent accompanying adverse effect after RFT of trigeminal ganglion. Compared with the classic approach group, the H-figure group had similar incidence of facial numbness at different time points after the procedure (Figure 5C), and among patients who had facial numbness, the numbness VAS scores were similar between 2 groups (Figure 5D). Compared to the control classic approach group, the H-figure approach group took almost half the procedure time (median [IRQ]: 7.5 [6.0–9.0] min H-figure group versus 14.0 [10.0–18.0] min classic group, $P < .0001$) (Figure 5E) with approximately half number of fluoroscopic shots (median [IRQ]: 4 [3–5] H-figure group versus 8 [6–10] classic group, $P < .0001$) (Figure 5F) to obtain more high-grade scale

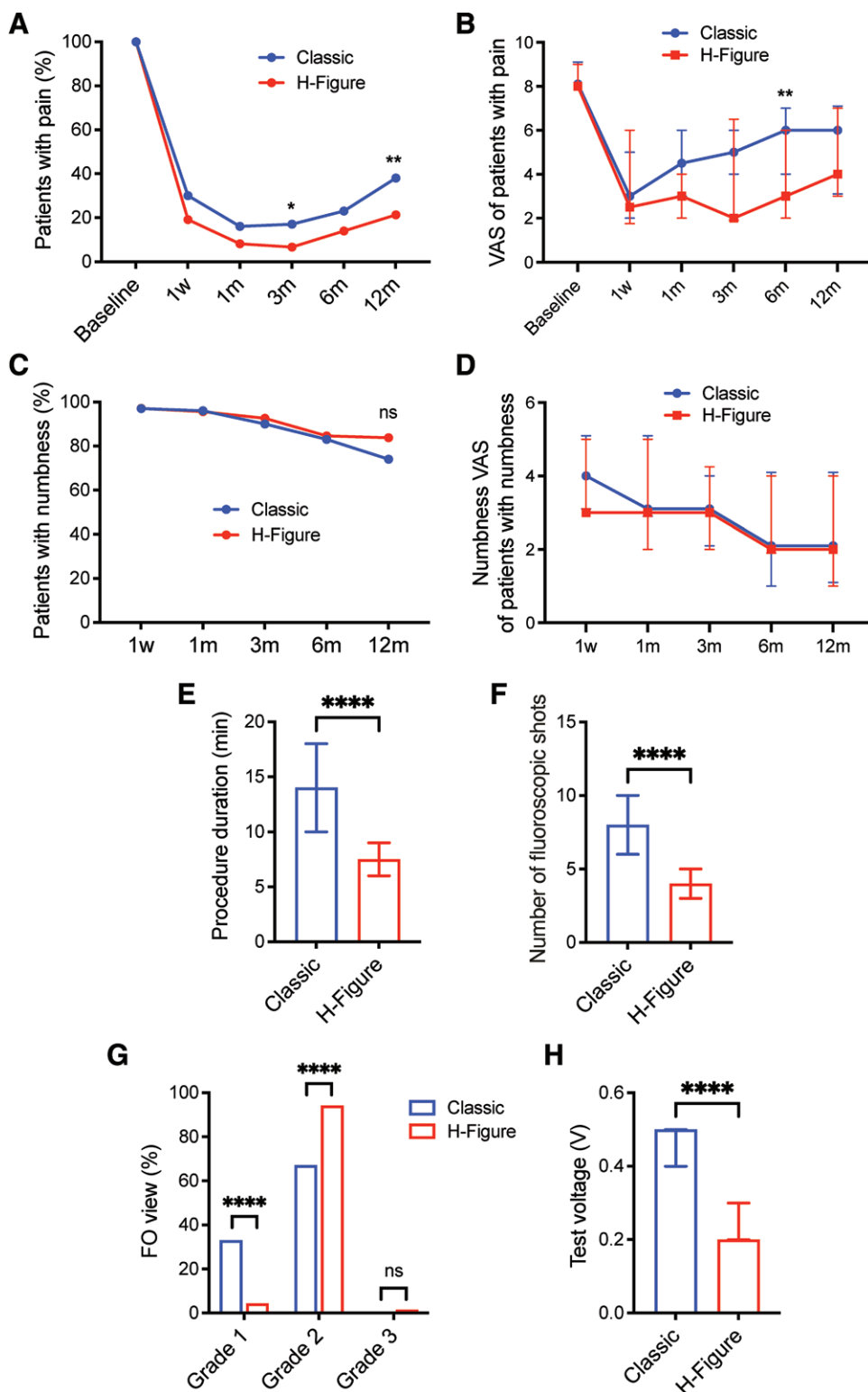


Figure 5. H-figure method is superior to the classic method in treating ITN with RFT. A, Compared to the classic method group, fewer patients in the H-figure method group had facial pain 3 and 12 mo after RFT. B, Among patients who had facial pain after RFT, patients in the H-figure method group reported less pain 6 mo after the procedure. C, Similar percentage of patients in both groups reported facial numbness at different time points after RFT. D, Among patients who had facial numbness after RFT, patients in both groups reported similar numbness VAS scores. The H-figure method took about half the procedure time (E), with approximately half the number of fluoroscopic shots (F) to obtain a better view of FO (G), and it required roughly half of the testing voltage to evoke paresthesia (H). Data are presented as percentage and are analyzed with a 2-tailed χ^2 test in (A), (C), and (G), or as median (IQR) and are analyzed with a 2-tailed Mann-Whitney test in (B), (D)–(F), and (H). * $P < .05$, ** $P < .01$, and **** $P < .0001$. FO indicates foramen ovale; IQR, interquartile range; ITN, idiopathic trigeminal neuralgia; ns, not significant; RFT, radiofrequency thermocoagulation; VAS, Visual Analog Scale.

of FO visualizations (4.4% grade 1 view versus 33% grade 1 view, $P < .0001$; 94.1% grade 2 view versus 67% grade 2 view, $P < .0001$; 1.4% grade 3 view versus 0% grade 1 view, $P = .2233$) (Figure 5G). Compared with the control classic group, the threshold voltage to elicit paresthesia was significantly lower in the H-figure approach group (median [IRQ]: 0.2 [0.2–0.3]

V H-figure group versus 0.4 [0.4–0.5] V classic group, $P < .0001$) (Figure 5H) to elicit paresthesia in the target branch after successful puncture of the FO.

Complications

No serious complications were noted, except for 5 cases of postdural puncture headaches, which self-resolved

Table. Patient Demographic Data and Pain Characteristics

| Variables | H-figure (n = 136) | Classic (n = 100) | P value |
|---|--------------------|-------------------|---------|
| Sex, M/F | 59/77 | 42/58 | .8320 |
| Age, years, median (IQR) | 66 (56–70) | 62 (54–71) | .2268 |
| Pain duration, years, median (IQR) | 4 (3–6) | 5 (3–8) | .2058 |
| Side affected, R/L | 84/52 | 56/44 | .3730 |
| No. of divisions of trigeminal nerve, n (%) | | | |
| V1 | 2 (1.4) | 3 (3.0) | .4201 |
| V2 | 37 (27.2) | 27 (27.0) | .9720 |
| V3 | 42 (30.9) | 29 (29.0) | .7554 |
| V1 + V2 | 8 (5.9) | 6 (6.0) | .9698 |
| V1 + V2 + V3 | 5 (3.7) | 5 (5.0) | .6179 |
| V2 + V3 | 42 (30.9) | 30 (30.0) | .8843 |
| Baseline pain, VAS, median (IQR) | 8 (8–9) | 8 (8–9) | .1894 |
| Pain after RFT, VAS, median (IQR) | | | |
| 1 wk | 0 (0–0) | 0 (0–0) | .0528 |
| 1 mo | 0 (0–0) | 0 (0–0) | .0372 |
| 3 mo | 0 (0–0) | 0 (0–0) | .0065 |
| 6 mo | 0 (0–0) | 0 (0–0) | .0304 |
| 12 mo | 0 (0–0) | 0 (5–0) | .0031 |

Abbreviations: IQR, interquartile range; RFT, radiofrequency thermocoagulation; VAS, Visual Analog Scale.

within 1 week (2.2% in the H-figure group and 2.0% in the control classic group, *P* = .9136).

DISCUSSION

Because fluoroscopic visualization of FO with classic approach is difficult and time-consuming, which contributes to risk of mispunctures,^{11,13–18} we recently developed H-figure as easily recognizable fluoroscopic landmark to view FO in clinical practice.⁷ In this 12-month follow-up retrospective cohort study, we showed that the H-figure approach was not only associated with substantially accelerated identification of FO with less fluoroscopic radiation, but also provided a better view of FO. More importantly, RFT performed utilizing the H-figure approach was associated with closer needle placement to the nerve targets as detected by lower paresthesia threshold voltages and was associated with better long-term pain alleviation across the entire 12-month follow-up period.

Although Vance et al¹⁴ described that the FO can be viewed when the top of the petrous ridge (S-P-T line) bisects the mandibular ramus, no detail was described on how to acquire the FO visualization with greater width-to-length ratio. On the other hand, Lee et al¹⁸ considered that the petrous ridge (S-P-T line) is too difficult to identify as a reliable anatomic landmark. To overcome the difficulty in finding the S-P-T line, we suggested to use the medial end of temporomandibular joint as an easily recognizable fluoroscopic landmark to identify the S-P-T line because the lateral extension of S-P-T line usually crosses through this landmark independent of angulation

of the fluoroscopy C-arm.⁷ In fact, the greater width-to-length ratio of FO visualization can be achieved when the S-P-T line is moved down in the “H-figure” through sagittal adjustment of an X-ray tube. Indeed, in this study, almost all the final views of FO were at least grade 2 with H-figure approach.

For acquiring the better therapeutic efficacy under fluoroscopy-guided RFT of trigeminal ganglion, 4 elements are essential: optimized FO view,⁷ accurate FO puncture,¹⁷ proximity to target branch, and appropriate thermocoagulation settings.^{1,2,19} As the first element, the optimized FO view can be easily adjusted close to maximum width-to-length ratio using fluoroscopic H-figure landmark.⁷ Many anatomical studies of human FO parameters suggested that the maximum width-to-length ratio of FO is around 2:3,^{20–22} while other studies suggest that the width-to-length ratio of FO ranges from 1:3 to 2:3.^{23–25} As it is impractical to measure the size of FO with fluoroscope, we relied on the width-to-length ratio of FO as a proxy for the quality final fluoroscopic view of FO. A width-to-length ratio >1:3 was considered as a good visualization of FO.

The reasonable thermal temperature in our practice, we use 65 °C for 90 seconds to treat V1 and 75 °C for 120 seconds to treat V2 and V3 as the RFT protocol for both H-figure and control groups. We chose 65 °C in treating V1 to avoid corneal anesthesia and ulceration or abducens nerve thermal injury,^{26,27} and 75 °C in treating V2 and V3 for effective pain relief and to minimize facial numbness.¹⁹ Because RFT of V1–V3 is more effectively achieved by inserting the needle in the medial third, middle, and lateral third of the FO, respectively,¹⁷ a good visualization of FO is critical for directing the RF needle piercing with accuracy. As the H-figure approach provided more high-grade FO views, the RF needle inserted by H-figure approach was closer to target branch to require lower electric test voltage, and we suspect that this translates to a better long-term pain alleviation with similar RF temperature.

Several limitations should be acknowledged. As a retrospective study, the classic approach or H-figure approach as medical providers’ preference in clinical practice might cause provider’s bias. In addition, the clinical significance of the H-figure approach in the RFT of the trigeminal ganglion in treating ITN is observed in Chinese patient population and, thus, may limit the generalizability to other populations. However, there is little reason why H-figure approach for RFT treatment of INT cannot be applied to other ethnic groups.

CONCLUSIONS

In conclusion, RFT performed with H-figure approach is associated with superior long-term clinical pain

relief compared to RFT performed via classic approach in treating ITN patients. ■■

DISCLOSURES

Name: Liang-Liang He, MD.

Contribution: This author helped develop the method, manage the patients, conduct the analysis, and write the manuscript.

Name: Wen-Xing Zhao, MD.

Contribution: This author helped develop the method and manage the patients.

Name: Po-Yi Paul Su, MD.

Contribution: This author helped analyze the data and write the manuscript.

Name: Qin-Ran Sun, MD.

Contribution: This author helped contribute to the procedures.

Name: Gui-Li Guo, RN.

Contribution: This author helped contribute to assess the grade of FO images.

Name: Jian-Ning Yue, MD.

Contribution: This author helped contribute to the procedures.

Name: Jia-Xiang Ni, MD.

Contribution: This author helped contribute to patient management.

Name: Li-Qiang Yang, MD.

Contribution: This author helped organize the study.

Name: Zhonghui Guan, MD.

Contribution: This author helped design the study, supervise the analysis, and write the manuscript.

This manuscript was handled by: Honorio T. Benzon, MD.

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