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Citation

Published Version
doi:10.1097/MD.0000000000004940

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Percutaneous radiofrequency thermocoagulation for trigeminal neuralgia using neuronavigation-guided puncture from a mandibular angle

Weihua Ding, MD\(^a,b,c\), Shuping Chen, MD\(^b\), Rong Wang, BD\(^d\), Jun Cai, BD\(^b\), Yuan Cheng, MD\(^b\), Liang Yu, MD\(^b\), Qinghua Li, MD\(^b\), Fang Deng, MD\(^b\), Shengmei Zhu, MD, PhD\(^e\), \(^f\), Wenhua Yu, MD, PhD\(^e\), \(^f\)

Abstract
Percutaneous radiofrequency thermocoagulation (RFT) of the Gasserian ganglion is an effective treatment for primary trigeminal neuralgia (pTN). Current Hartel anterior approach is the most commonly used method to access the Gasserian ganglion. However, this approach is associated with high recurrence rate and technical difficulties in certain patients with foramen ovale (FO) anatomical variations. In the present study, we assessed the feasibility of accessing the Gasserian ganglion through the FO from a mandibular angle under computed tomography (CT) and neuronavigation guidance.

A total of 158 patients with TN were randomly divided into 2 groups (Group G and Group H) using a random number table. In Group H, Hartel anterior approach was used to puncture the FO; whereas in Group G, a percutaneous puncture through a mandibular angle was used to reach the FO. In both groups, procedures were guided by CT imaging and neuronavigation. The success rates, therapeutic effects, complications, and recurrence rates of the 2 groups were compared.

The puncture success rates in Group H and Group G were 52/54 (96.30%) and 49/54 (90.74%), respectively (P = 0.24). The 2 procedural failures in Group H were rescued by using submandibular trajectory, and the 5 failures in Group G were successfully reapproached by Hartel method. Therapeutic effects as measured by Barrow Neurological Institute (BNI) pain scale (P = 0.03) and quality of life (QOL) scores (P = 0.04) were significantly better in Group G than those in Group H at 36 months posttreatment.

Hematoma developed in 1/54 (1.85%) cases in Group H, and no cases of hematoma were observed in Group G (P = 0.33). In Group H, RFT resulted in injury to the unintended trigeminal nerve branches and motor fibers in 27/52 (51.92%) cases; in Group G, it resulted in the same type of injury in 7/49 cases (14.29%) (P < 0.01). In Group H, the 24- and 36-month recurrence rates were 12/51 (23.53%) and 20/51 (39.22%), respectively; in Group G, these recurrence rates were 7/49 (12.24%) and 9/49 (16.33%, P = 0.03), respectively.

CT- and neuronavigation-guided puncture from a mandibular angle through the FO into the Gasserian ganglion can be safely and effectively used to deliver RFT for the treatment of pTN. This method may represent a viable option to treat TN in addition to Hartel approach.

Abbreviations: BNI = Barrow Neurological Institute, CT = computed tomography, FO = foramen ovale, MVD = microvascular decompression, NRS = Numeric Rating Scale, pTN = primary trigeminal neuralgia, QOL = quality of life, REZ = root entry zone, RFT = radiofrequency thermocoagulation.

Keywords: mandibular angle, neuronavigation, radiofrequency thermocoagulation, trigeminal neuralgia

Editor: Helen Gharaei.

Funding: This work was supported by Hangzhou Science and Technology Plan (no. 201306333B02), Hangzhou Medical Science and Technology Plan (no. [HWS] 2011A012), Zhejiang Medical Science and Technology Plan (no. 2011KYB064), Traditional Chinese Medicine Administration of Zhejiang (2015ZSA128), and key project of Zhejiang Province Medicine & Health (NO. 2013ZDQ010).

Authors’ contributions: WD and SC designed the study protocol and WD wrote the draft of the manuscript. YC managed the literature searches. WY wrote the statistical analysis plan. SZ provided revision for intellectual content. JC and QL had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. FD, LY, and RW conduct of the study. WD revised the draft paper. WY and SZ finally approved of the manuscript.

The authors have no conflicts of interest to disclose.

WD, SC, SZ, and WY contributed equally to this work.

Supplemental Digital Content is available for this article.

*Department of Anesthesia & Pain Medicine, The First Affiliated Hospital of Medical School of Zhejiang University, \(^\text{b}\) Pain Clinic, Hangzhou First People’s Hospital, Nanjing Medical University, Hangzhou, Zhejiang, P.R. China, \(^\text{c}\) Pain Medicine, Massachusetts General Hospital, Harvard Medical School, Boston, MA, \(^\text{d}\) Department of Radiology, \(^\text{e}\) Department of Neurosurgery, Hangzhou First People’s Hospital, Nanjing Medical University, Hangzhou, Zhejiang, P.R. China.

Correspondence: Shengmei Zhu, Department of Anesthesia & Pain Medicine, The First Affiliated Hospital of Medical School of Zhejiang University, No. 79, Qingchun Road, Hangzhou, P.R. China (e-mail: smzhu20088@163.com); Wenhua Yu, Department of Neurosurgery, Hangzhou First People’s Hospital, Nanjing Medical University, No. 261, Huashan Road, Hangzhou, P.R. China (e-mail: powerdwh@163.com).

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Medicine (2016) 95(40):e4940

Received: 28 March 2016 / Received in final form: 17 August 2016 / Accepted: 18 August 2016

http://dx.doi.org/10.1097/MD.0000000000004940
1. Introduction
Primary trigeminal neuralgia (pTN) is one of the most common causes of persistent severe facial pain, especially in the elderly. The symptoms of pTN have been described as pain characterized by feelings of piercing, tormenting electric shock. Such pangs or pain are felt cursorily in the skin or buccal mucosa and are elicited by perfunctory interactions over a relatively circumscribed location. The pain is often momentary and followed by refractory interludes lasting a few minutes. In short, paroxysms of pain occur in regular intervals and may succeed each other almost endlessly. Many studies have suggested that microvascular compression and demyelination of the trigeminal nerve at the root entry zone (REZ) are the underlying causes of pTN. Thus, microvascular decompression (MVD) is a common procedure for managing the condition. Besides MVD, percutaneous radiofrequency thermocoagulation (RFT) of the Gasserian ganglion through the foramen ovale (FO) has emerged as an effective treatment for TN. RFT is a minimally invasive procedure that is commonly performed using Hartel anterior approach. More specifically it involves cannulating through the FO in combination with electrophysiological testing to identify the target followed by RFT. However, anatomic variations of the FO can lead to unsuccessful cannulation. Using the Hartel approach, FO cannulation has a failure rate of 5.17% (9 of 174 patients) due to anatomic variations in FO morphology, despite the use of neuronavigation technology with computed tomography (CT) imaging. Additionally, recurrence and complications are commonly reported using this approach. Therefore, we sought to establish an alternative to Hartel anterior approach that is suitable to variations in FO anatomy and provides clinically acceptable safety and efficacy profiles. In the present study, we report a novel percutaneous approach to the Gasserian ganglion with neuronavigation-guided RFT through the FO. The postoperative success and complication rates associated with this approach were compared with those produced by Hartel anterior approach.

2. Methods
2.1. Selection criteria
A total of 108 patients from the medical pain unit at Hangzhou First People’s Hospital who were diagnosed with pTN and successfully managed by Gasserian ganglion RFT from 2011 and 2014 were evaluated. The research was approved by the Ethics Committee of Hangzhou First People’s Hospital (approval #: 2011-023-01; Principal Investigator: Weihua Ding; date of registration: March 1, 2010). Preoperatively, all patients were given information about the procedure and its possible complications, and written informed consent was obtained.

The following inclusion criteria were used to enroll patients with pTN: aged between 20 and 75 years; previous administration of gastroretentive carbamazepine or gabapentin for at least 6 months with a lack of efficacy or poor tolerance; no previous surgical treatment to manage pTN, such as MVD or radiosurgery, that potentially resulted in other types of pain; no indication of secondary TN induced by the presence of a tumor or other disorders based on brain magnetic resonance imaging (MRI); preoperative Numeric Rating Scale (NRS) score greater than 7; and normal cognitive abilities. Additionally, all enrolled patients complied with treatment. The following exclusion criteria were applied: known bleeding disorder (e.g., hemophilia); anticoagulation therapy (e.g., Coumadin, Plavix, or Lovenox); uncontrolled high blood pressure (>170/100); unstable cardiovascular disease; contraindications to MRI scanning (e.g., presence of a cardiac pacemaker or pacemaker wires, metallic particles in the body, vascular clips in the head from previous neurosurgery, prosthetic heart valves, or claustrophobia); cognitive dysfunction; and history of invasive treatments, such as RFT, balloon compression, destructive chemical injection, gamma knife surgery, peripheral neurotomy, or MVD.

2.2. Instruments
The following instruments were used in this study: an ET-20s multifunction RF heat wave treatment system, consisting of a 20-gauge, 100-mm-long insulated radiofrequency needle with a 5-mm active noncurved tip and RF electrodes (Smith & Nephew Inc., Andover, Massachusetts, USA); a neuronavigation system (Medtronic, Inc., Minneapolis, Minnesota, USA); and a CT scanner (128-slice, Siemens, Erlangen, Germany).

2.3. Procedure and techniques
The 108 enrolled cases were divided into Group G (n = 54) and Group H (n = 54) using a random number table method. Each patient underwent a preoperative CT scan of the head performed at 1-mm interval, and the acquired images were transferred to a planning and neuronavigation system, after which sagittal, coronal, and 3D reconstructions were created. All procedures were performed on hospitalized patients by a single surgeon (Weihua Ding, MD). An ENT reference array (Medtronic, Inc.) was strapped firmly to each patient’s forehead, and an instrument adaptor (Medtronic, Inc.) was attached to the hub of the insulated radiofrequency cannula so that it could be recognized by the navigation system. Next, a trajectory for the surgery was planned. CT images were generated by placing a Passive Planar Blunt Probe (Medtronic, Inc.) on the ENT reference array and using specific facial features, such as the nasal tip, nasion, and superciliars, as indicated by Synergy Cranial software version 2.2. Using the navigation system, the needle was tracked via its attached adaptor. After calibrating and verifying the placement of the needle tip with the instrument calibration matrix, a tip deviation of <0.2 mm was considered acceptable. The entry point was adjusted as defined by the landmarks of Hartel technique in Group H, and the entry point was defined at an ipsilateral
mandibular angle in Group G (Fig. 1). Each trajectory was made to accommodate individual geometric variability in the FO with the purpose of creating an unobstructed linear pathway toward the Gasserian ganglion. In both groups, cannulation was performed under the guidance of continuous navigation mode using the following 4 views in the same window: coronal, axial, guidance, and 3D models (Fig. 2). During cannulation, intravenous fentanyl (25–50 µg, Humanwell Healthcare Co., Ltd, Wuhan, Hubei, China) was administered for pain management. When the needle tip was advanced into the FO, the instrument adaptor was removed from the needle hub, and needle-tip placement was confirmed by lateral fluoroscopy. In Group H the needle tip did not exceed the clival region (Fig. 3); in Group G, the needle tip did not exceed the bottom of the sella (Fig. 4). After the penetration depth into the FO was verified, test stimulations at 50 and 2 Hz were initiated to provoke throbbing paresthesia of the trigeminal nerve and to assess masticatory response. If required, further adjustment to the needle was made, in accordance with the electrophysiological response; paresthesia or masticatory responses were elicited at an average of 0.2 V (range, 0.08–0.35 V) in most cases. Each subject was monitored throughout the procedure by pulse oximetry, continuous electrocardiography, and blood pressure readings. After the administration of intravenous fentanyl (25–50 µg, Humanwell Healthcare Co., Ltd) and disoprofol (1–2 mg/kg, Astrazeneca, London, United Kingdom) for analgesia, radiofrequency lesioning was performed at 75°C for 120 seconds. When branches V2 and V3 of the trigeminal nerve were both targeted, lesioning was started from branch V2 followed by branch V3 by repositioning the needle tip. All patients were hospitalized for 24 hours after RFT to monitor the initial results of the procedure. The patients
Sixty-four patients (59.26%) had pTN affecting the right side, and 44 patients (40.74%) had pTN affecting the left side. The divisions affected were V2 (57/108, 52.78%), V2 and V3 (9/108, 8.33%), and V3 (42/108, 38.89%). The mean duration of TN was 90.48 ± 52.74 months (range, 6 months to 22 years), and the mean duration of follow-up was 36.24 ± 7.36 months. One patient died of stroke approximately 19 months after RFT. Table 2 summarizes the demographics in our series; there were no significant differences in the indices between the 2 groups.

### 3.2. Success rate of cannulation

There were 2 procedural failures in Group H and 5 in Group G, resulting in a success rate of 96.30% (52/54) and 90.74% (49/54), respectively. There was no significant difference in the success rate between the 2 groups (P = 0.24). In the 2 procedural failures in Group H, post-RFT CT imaging reconstruction showed an anomalous FO oriented caudally. We were able to successfully cannulate the FO using an ipsilateral submandibular approach 1 week after the failed procedure. In the 5 procedural failures in Group G, CT imaging reconstruction indicated that FO openings in these cases were horizontal, and we successfully repunctured the FO using Hartel anterior approach 1 week after the failed procedure. Therefore, these 2 approaches have similar procedural success rate, and they can supplement each other to overcome technical difficulties due to FO anatomical variations. For patients that have failed original attempts with Hartel or submandibular approach, they were excluded for the subsequent comparison of efficacy and complications.

### 3.3. Efficiency of initial pain relief and durability of the pain response

One day after the procedure, 50/52 (96.15%) patients in Group H experienced initial pain relief, with BNI pain scale scores of I in 44 patients (84.62%), II in 1 patient (1.92%), and III in 5 patients (9.62%). In Group G, 48/49 (97.96%) patients experienced initial pain relief, with BNI pain scale scores of I in 42 patients (85.71%), II in 3 patients (6.12%), and III in 3 patients (6.12%) (Table 3). Long-term outcomes were assessed using log-rank test. Successful response to RFT was maintained in 89.80% of patients at 1 year, 85.71% at 2 years and 81.63% at 3 years in Group G. Successful response to RFT at 1, 2, and 3 years was 82.69%, 76.47%, and 60.78% (P = 0.03, Group G vs Group H) in Group H, respectively (Fig. 5). Recurrence was defined as an initial improvement followed by deterioration in BNI pain scale score. In Group H, the 24- and 36-month recurrence rates were 12/51 (23.53%) and 20/51 (39.22%), respectively; in Group G, these recurrence rates were 7/49 (14.24%) and 9/49 (18.33%), (P = 0.03), respectively. The mean QOL score at 36 months for Group G (74.60 ± 22.25) was significantly higher than that for Group H (62.21 ± 28.46) (P = 0.04) (Table 4).
3.4. Complications

Complications of RFT include hematoma formation associated with needle entry, extraterritorial numbness due to unintentional thermal damage to neighboring trigeminal nerve branches, diminished corneal reflex, and masseter weakness. There was 1 case of facial hematoma in Group H, presumably due to repeated needle entries during the procedure. No case of hematoma was noticed in Group G. At post-RFT day 1, complications including extraterritorial numbness, diminished corneal reflex, and masseter weakness occurred in 51.92% (27/52) of patients in Group H. These complications occurred in 14.29% (7/49) patients in Group G. The complication rate was significantly lower in Group G than in Group H (P < 0.01). These complications typically resolved within 12 months in both groups. At 12 months post-RFT, there was no significant difference in the complication rates between the 2 groups (9/52 vs 4/49, P > 0.05). At 36 months post-RFT, persistent facial numbness were present in 22.45% (11/49) of patients in Group G, a significantly higher rate than that in Group H (3.92%, 2/51, P < 0.01), as shown in Table 5. Vast majority cases of masticatory muscle weakness resolved within 6 months except in 2 cases, which resolved in 9 to 14 months. Corneal hyporeflexia was treated with eye drops containing recombinant bovine basic fibroblast growth factor (Essex Bio-Technology Co., Ltd, China) and resolved within 12 months in all cases. The facial numbness was described as "not disturbing and not troublesome" by 6/13 (46.15%) patients, as "rare and a mild disturbance" by 3/13 (23.08%) patients (3/11 in Group G), as "an occasional and moderate disturbance" by 3/13 (23.08%) patients (1/2 in Group H; 2/11 in Group G), and as "a frequent and severe disturbance" by 1/13 (7.69%) patients (1/11 in Group G). No mortality or permanent cranial nerve deficits, with the exception of facial dysesthesia, occurred.

Table 3

<table>
<thead>
<tr>
<th>Barrow Neurological Institute (BNI) pain score (Group H: n = 52; Group G: n = 49).</th>
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<tr>
<td>Group</td>
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<td></td>
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<tr>
<td>H</td>
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<td>G</td>
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Note: a (P < 0.01) compared with preoperation, b (P = 0.04) compared with Group H.

QOL score (point, x±s) (Group H: n = 52; Group G: n = 49; * n = 51 in Group H).

<table>
<thead>
<tr>
<th>Group</th>
<th>Preoperation (n = 54)</th>
<th>Postoperation</th>
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<tr>
<td></td>
<td>1 d</td>
<td>7 d</td>
</tr>
<tr>
<td>H</td>
<td>51/52</td>
<td>52/52</td>
</tr>
<tr>
<td>G</td>
<td>47/49</td>
<td>48/49</td>
</tr>
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Note: Compared with Group H, a (P = 0.02), b (P < 0.01).

Facial numbness in the 2 groups (Group H: n = 52; Group G: n = 49).

<table>
<thead>
<tr>
<th>Group</th>
<th>Preoperation</th>
<th>Postoperation</th>
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<tr>
<td></td>
<td>1 d</td>
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<td>H</td>
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<td>G</td>
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Note: Compared with Group H, a (P = 0.02), b (P < 0.01).
4. Discussion

The present study examined the safety and effectiveness of using a submandibular trajectory for FO cannulation. Our results showed that a submandibular approach is associated with a less TN recurrence rate at 36 months post-RFT when compared with conventional Hartel approach. In addition, the long-term complication rates were comparable between submandibular approach and Hartel approach. Moreover, submandibular approach and Hartel approach can supplement each other to overcome technical difficulties associated with FO anatomical variations.

The approach of accessing the FO anteriorly through the cheek proposed by Härtel[17] has been used for decades to facilitate the application of RFT to the Gasserian ganglion.[7,18] The FO is an oval-shaped opening in the posterior part of the sphenoid bone. Posterior and medial to the FO is the carotid canal.[19–21] The FO varies in its shape and size in population. In addition, the FO differs in shape and size throughout the natural life.[22] These anatomical variations pose technical difficulties in FO cannulation. The use of X-ray to guide puncture of the FO is a common clinical practice.[23] However, Gerber[24] indicated that even with appropriate positioning of the head it is challenging to identify the FO in some patients. Neuronavigation-guided RFT with CT images has gained popularity in recent years. The CT images that are utilized in the navigation system offer a satisfactory resolution of skull base osseous structures. Additionally, the ability to concurrently exhibit diverse views (guidance, 3D modes, axial, and coronal views) is particularly helpful in cases with anatomical variations. In our present study, we used neuronavigation-guided RFT with CT images for all patients. In 2 of the 54 patients in Group H, we were not able to go beyond FO despite guidance from the neuronavigation views. In these 2 patients, subsequent CT reconstruction demonstrated that FO had caudal orientation. One week after the failed attempts with Hartel approach, we were able to successfully puncture the FO using a submandibular trajectory (Fig. 6A and B). In Group G, the FO could not be clearly visualized in 5 of the 54 patients using submandibular trajectory on neuronavigation views. In these 5 cases, the advancement of needles was prevented by osseous structures in the FO. Subsequent CT reconstructions demonstrated the FO openings were horizontal in these cases (Fig. 6C and D). In all 5 cases, Hartel anterior technique was employed to reapproach the FO, allowing successful entry of the needle. Our experience suggest that the conventional Hartel approach and the submandibular approach can supplement each other in overcoming technical difficulties posed by FO anatomical variations.

The Gasserian ganglion is situated in Meckel cave and contains the sensory neurons of the 3 branches of the trigeminal nerve. The trigeminal sensory root and a smaller motor root coming out of the pons at its junction join the Gasserian ganglion in Meckel cave.[25] There are numerous reports of the application of RFT using X-ray- or CT-guided puncture through the FO into the cranial Gasserian ganglion. In such cases, the needle may enter Meckel cave, its ganglion, or its posterior root, but determining whether the tip of the electrode has been positioned correctly in the Gasserian ganglion from the FO is not possible.

In our cadaver studies, using Hartel approach and submandibular approach to access the FO, we showed that with Hartel approach the puncture trajectory was in parallel to the horizontal plane, which pointed toward the sensory root of trigeminal nerve. In contrast, with submandibular approach, the trajectory was
nearly parallel to the coronal plane and pointed cephalad from the V3 to V1 near Gasserian ganglion (Fig. 7 and Supplemental Video, http://links.lww.com/MD/B340). Based on this pattern, previous studies have shown that neuroapoptosis may occur when damaged axons are in close proximity to cell bodies.[26–28] In contrast, reversible axonal injury occurs when RFT targets are not in proximity to cell bodies. Our cadaver studies indicated that RFT targets were in proximity to the Gasserian ganglion in Group G. Lesioning these targets may lead to trigeminal neuroapoptosis and subsequent long-term facial numbness reported in this study at the 3-year follow-up assessments. Despite the higher incidence of long-term facial numbness in Group G than in Group H (Table 5), the QOL scores were considerably higher in Group G than in Group H (Table 4), suggesting that long-term facial numbness is well tolerated in patients with TN.

In Group H, there was 1 case of bleeding and swelling in the cheek during surgery. When examining a cadaveric model, it was evident that the facial, middle meningeal, and maxillary arteries could be injured when using Hartel approach, particularly when repeated punctures were necessary to approach the FO. Such injuries occurred despite the use of CT and neuronavigation and were likely a main cause of hematoma. Using a submandibular trajectory to approach the FO avoids contact with the infratemporal fossa and can therefore decrease the likelihood of causing damage to the maxillary artery (Fig. 8). Though a submandibular trajectory is close to the mandibular angle, the likelihood of damaging the facial artery minimized due to arteriopalms of the facial artery and its incisures is identified easily in anteromedial part of the mandibular angle. Based on CT angiography, puncturing the FO from a mandibular angle can be safely performed without damaging the internal carotid artery (Fig. 9).

The limitation of present study is that all procedures were performed in single institute by the same pain specialist. Although subsequent BNI and QOL scoring were recorded by other members of the team in a blinded fashion, a multicenter trial could potentially address the inherent limitations associated with single center trial.

5. Conclusions

In this study, we utilized CT and neuronavigation to guide the placement of a radiofrequency catheter to access the Gasserian ganglion from a mandibular angle. This approach has higher target selectivity for RFT of the Gasserian ganglion than Hartel anterior approach. In addition, the submandibular approach and Hartel approach can supplement each other to overcome technical difficulties associated with FO anatomical variations. Compared with Hartel approach, the submandibular approach offers similar complication profile but better long-term efficacy. Therefore, the submandibular approach is a viable option to deliver RFT to the Gasserian ganglion to manage TN.

References


