Pilot Study

Short-Term Trigeminal Ganglion Stimulation in Patients with Multi-Branch Trigeminal Herpetic Neuralgia: A Pilot Study

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Disclaimer: Dr. Fan Yang and Yi Yan contributed equally to this work. There was no external funding in the preparation of this article.

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

Article received: 12-09-2023
Revised article received: 04-01-2024
Accepted for publication: 05-22-2024

Free full article: www.painphysicianjournal.com

Background: Trigeminal herpetic neuralgia (THN) presents with severe pain hyperalgesia and is a high-risk factor for postherpetic neuralgia (PHN). The current clinical treatments for THN are unsatisfactory, and new treatments are desperately required.

Objectives: This pilot study aimed to evaluate the efficacy of short-term trigeminal ganglion stimulation in treating patients with multi-branch THN.

Study Design: A prospective pilot study.

Setting: Multi-center study in 3 academic hospitals.

Methods: From July 2021 to October 2022, we enrolled 20 patients with multi-branch THN who received short-term trigeminal ganglion stimulation under general anesthesia from 3 hospitals. All patients completed a 12-month follow-up. The visual analog scale (VAS) and Pittsburgh Sleep Quality Index (PSQI) were used to assess patients' pain and quality of sleep. The Barrow Neurological Institute (BNI) score was used to determine the global outcome of pain relief, and complications were recorded.

Results: Significant and sustained pain relief and sleep improvement were achieved by all the patients who underwent trigeminal ganglion electrode stimulation in the present study. Respective BNI scores of 80% and 85% at 3 and 12 months after surgery were considered good. There were no other serious complications except for 2 patients' experiences of transient trigeminal cardiac reflex during the surgery and transient numbness deterioration in one patient's V3 sensory area.

Limitations: The present study is a pilot study. We expect prospective multi-center, large-sample studies in the future.

Conclusion: Short-term trigeminal ganglion stimulation can be used safely and effectively to treat patients with multi-branch THN and significantly reduce the occurrence of PHN.

Key words: Stimulation, trigeminal herpetic neuralgia, trigeminal ganglion

Pain Physician 2024: 27:E775-E784

The global annual incidence of herpes zoster (HZ) is about 3-5 out of 1000, with 20% of cases invading the trigeminal nerve (1-3). Postherpetic neuralgia (PHN) is a common complication of HZ and seriously affects the patient's quality of life (4). Current clinical treatments for PHN, such as drugs,

nerve blocks, and pulsed radiofrequency, may relieve the pain adequately, but some patients, especially those whose cases of PHN involve the trigeminal nerve, remain unsatisfied (5-7). It is reported that cases involving the trigeminal nerve are more likely to progress into PHN (8,9). Adequate pain control during the acute stage of HZ may reduce the occurrence of PHN (10,11).

For patients with single-branch (V1 or V2) trigeminal herpetic neuralgia (THN) who have been failed by conservative treatment, short-term peripheral nerve stimulation is considered a safe, effective, and minimally invasive alternative and can significantly reduce the occurrence of PHN (12). However, stimulation around the mandibular nerve is rarely used for THN in the V3 innervated area, due to the extremely high risk of electrode displacement (13,14). Moreover, for patients with multi-branch THN, concurrent peripheral stimulation of different nerve branches will undoubtedly increase the difficulty of the surgery and the national economic burden (14,15).

The trigeminal ganglion is the largest cranial ganglion, responsible for transmitting sensation to the whole face, and is an important target in the treatment of intractable facial neuralgia (15,16). Long-term stimulation of the trigeminal nerve has been used successfully in treating patients with various types of intractable facial neuralgia (14,17). However, to our knowledge, short-term trigeminal ganglion stimulation is rarely used to treat multi-branch THN. Therefore, we performed a pilot study to evaluate the clinical efficacy of short-term trigeminal ganglion stimulation in treating patients with multi-branch THN.

Methods

Study Design and Patients

The present study is a prospective multi-center study involving patients diagnosed with THN and admitted to the Pain Department of the First Affiliated Hospital of Nanchang University, the Second Affiliated Hospital of Nanchang University, or Ganzhou People's Hospital between July 2021 and October 2022. The inclusion criteria were as follows:

1. The patients were diagnosed with THN based on the staging criteria of HZ-associated neuralgia established by Dworkin et al (18).
2. The duration of the disease was less than 90 days, and the facial herpes was scabbed and healed.
3. Two or more trigeminal nerve branches were involved.
4. Anti-epileptic, analgesic, and other drugs were ineffective or had intolerable side effects.
5. Each patient's visual analog scale (VAS) score was ≥ 5.

The following were the exclusion criteria:

1. Patients had surgery contraindications such as severe cardiovascular disease, metabolic disease, uncontrolled infections, or dental issues.
2. Communication barriers were present.
3. Patients had vascular lesions or intracranial space-occupying lesions or other causes of facial pain.
4. Patients were unwilling to participate in this clinical trial.

All patients had a one-mm-thick head MRI before surgery. Multi-planar reconstruction technology was used to measure the distance from the foramen ovale to the trigeminal porus (Fig. 1A), and the electrode insertion depth was estimated.

Surgery

All surgical operations in this study were performed in an interventional operating room equipped with digital subtraction angiography (DSA) technology capable of computed tomography (CT)-like functions. The surgery procedure was performed under general anesthesia with endotracheal intubation. Each patient was placed in a supine position, and a wide forehead band was used to secure the head in place and prevent it from moving. The skin entry point was one cm below the intersection of the sagittal line of the lateral orbital wall and the lower edge of the maxilla (inside the mandible's coronoid process). After the DSA angle was adjusted to find the foramen ovale, the skin was punctured with a 14 G syringe needle (Fig. 1B, C). A Cone needle with a blunt No. 14 stylet (Shenzhen Qingyuan Medical Instrument Co., Ltd.) (Fig. 1D) was used to puncture the foramen ovale slowly under DSA (Fig 2A,B). The needle core was removed, and the electrode (Model 3873, Medtronic) was placed according to the depth estimated before the surgery (Fig. 2C). The lateral view indicated that the first electrode passed the trigeminal porus, and that observation was confirmed by CT (Fig. 2D). The final electrode position is shown in the figure (Fig. 3). The puncture needle was pulled out after the stimulating electrode was placed. The patient's mandible was moved under DSA to determine whether the movement would displace the electrode significantly. Then, the electrode was sutured and anchored to the skin before being connected with a multi-electrode test cable (Fig. 2E,F).

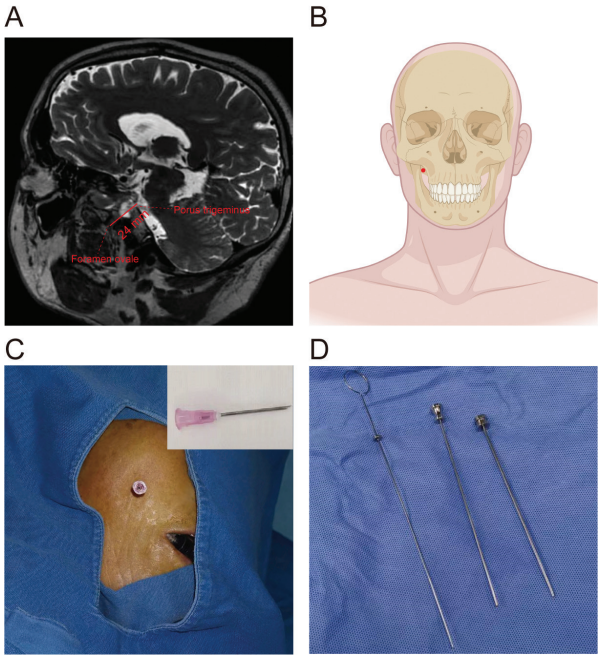

Fig. 1. *Preoperative measurement of puncture depth and location of puncture points on the skin. A: MRI to estimate the depth of electrode placement. B: location of puncture points on the skin. C: the 14 G syringe used to break the skin. D: the Cone needle with the blunt stylet.*

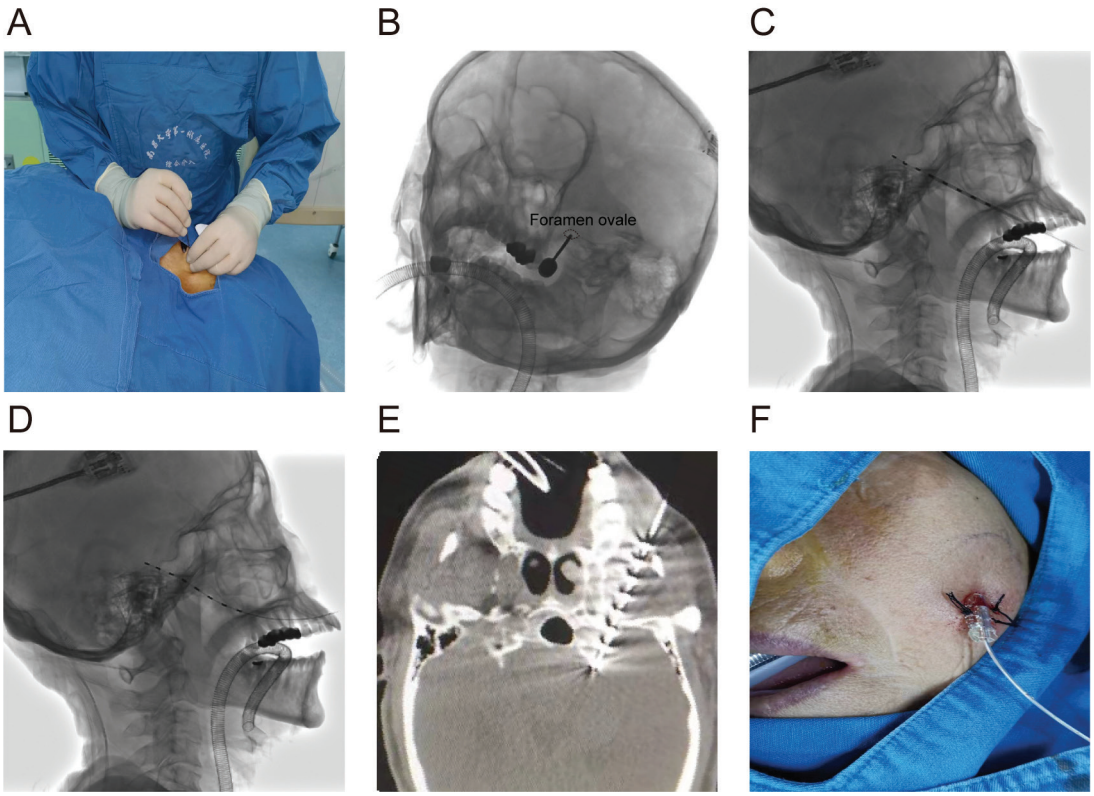

Fig. 2. *Representative images of the electrode implantation procedure. A - D) puncture and placement of the electrode. E) CT-confirmed electrode location. F) fixed electrode.*

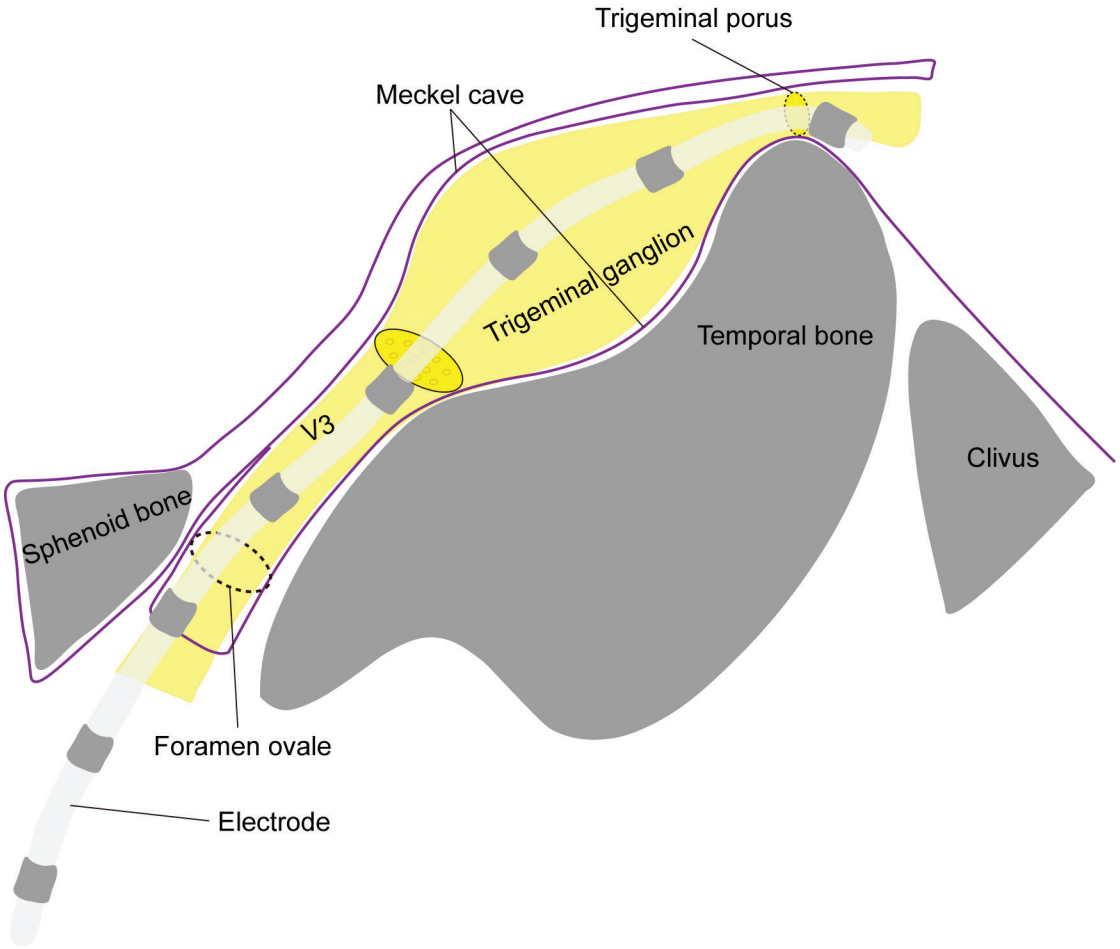

Fig. 3. *Electrode placed in the trigeminal ganglion. The trigeminal ganglion electrode enters Meckel's cave through the foramen ovale and crosses the trigeminal porus.*

After patients woke up and returned to the ward, the program-controlled instrument was connected. The test parameters were set as a pulse width of 360-450 μs, a frequency of 40-60 Hz, and a stimulation intensity of 0.1-1.0 V to cover the painful area. After the surgery, the stimulation parameters were adjusted according to the patient's feelings. The electrode was removed one week after the surgery. The relevant analgesics were gradually discontinued one month postoperatively.

Outcome Measures

The VAS was used to assess each patient's pain intensity before the surgery and one, 3, and 7 days as well as one, 3, 6, and 12 months after the surgery. In addition, the Pittsburgh Sleep Quality Index (PSQI) (19) was used to assess each patient's quality of sleep before and one, 3, 6, and 12 months after the operation. The extent of postoperative pain relief was also evaluated on the Barrow Neurological Institute (BNI) pain intensity scale (20) at 3 and 12 months after the surgery. Each score on the BNI scale was classified as good (BNI grade I–II) or bad (BNI grade III–V), as shown in Table 1. Complications were also recorded.

Statistical Analyses

All data were expressed as mean ± standard deviation. The repeated measures data analysis of variance was used, and the t-test was used to compare VAS and PSQI scores. *P*-values < 0.05 were considered statistically significant. IBM® SPSS® Statistics 22.0 (IBM Corporation) was used for statistical analysis.

Results

General Information

Finally, 20 patients were included in the present study (11 patients from the Pain Department of the First Affiliated Hospital of Nanchang University, 3 patients from the Pain Department of the Second Affiliated Hospital of Nanchang University, and 6 patients from the Pain Department of Ganzhou People's Hospital) (Fig. 4). All 20 patients were followed up for 12 months. The estimated preoperative depth of implanted stimulating electrodes was 25.95 ± 1.70 (23-29) mm. The general information is shown in Table 2.

Follow-up

The intensity of all patients' pain was significantly relieved at one day after surgery, and the VAS score was reduced from 6.15 ± 0.67 before surgery to 2.65 ± 0.67 at one day after surgery. The VAS score decreased significantly with stimulation, reaching 1.85 ± 0.74 at 3 days after surgery and 1.40 ± 1.10 at 7 days ($P < 0.001$). Additionally, the VAS score remained stable across the 3-month (1.00 ± 1.12), 6-month (0.95 ± 1.15), and

Table 1. *Barrow Neurological Institute pain score.*

Score	Pain Description
I	No pain, no medications
II	Occasional pain, no medications required
III	Some pain, adequately controlled with medications
IV	Some pain, not adequately controlled with medications
V	Severe pain or no pain relief

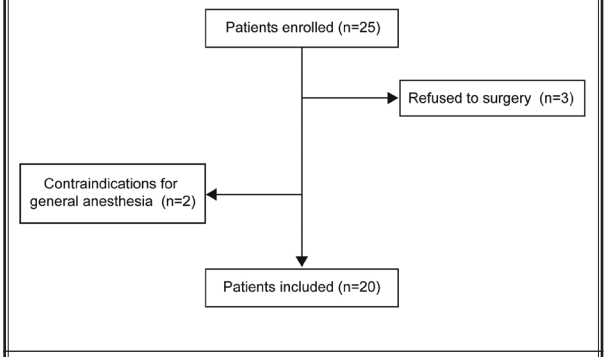

Fig. 4. *Study design and procedure.*

Table 2. *General information of included patients with THN.*

Cases	Age	Gender	Area	Duration (D)	Drug of presurgery (mg)	Trigeminal porus depth (mm)
1	85	F	V1+2 (R)	38	PGB (150) +DLX (30)	24
2	73	M	V1+2 (R)	33	PGB (150) +DLX (30)	23
3	77	M	V1+2 (L)	36	PGB (150) +DLX (30)	27
4	59	F	V1+2 (L)	52	PGB (75) +DLX (60)	28
5	59	F	V1+2 (R)	31	PGB (150) +TRA (100)	26
6	76	F	V1-3 (R)	82	PGB (150) +TRA (50)	29
7	55	M	V1-3 (L)	36	PGB (75) +TRA (100)	26
8	67	M	V1+2 (R)	37	PGB (75) +TRA (50)	23
9	70	M	V1+2 (L)	32	PGB (150) +TRA (100)	26
10	67	M	V1+2 (R)	49	PGB (75) +TRA (100)	27
11	75	F	V1+2 (L)	39	PGB (75) +TRA (50)	26
12	77	F	V1+2 (L)	82	PGB (75) +TRA (100)	26
13	74	F	V1+2 (L)	67	PGB (75) +TRA (50)	24
14	63	M	V1+2 (R)	37	PGB (75) +TRA (100)	27
15	62	M	V1+2 (L)	61	PGB (150) +TRA (100)	25
16	58	F	V1-3 (R)	46	PGB (150) +DLX (30)	28
17	56	M	V2+3 (R)	34	PGB (75) +TRA (100)	26
18	68	F	V1+2 (L)	45	PGB (150) +TRA (50)	24
19	55	M	V1-3 (R)	36	PGB (150)	26
20	67	M	V1+2 (R)	30	PGB (75) +TRA (100)	28

M: male; F: female; PGB: pregabalin, DLX: duloxetine, TRA: tramadol

12-month (0.75 ± 0.97) follow-ups. The VAS score at 12 months after the surgery was statistically different from the 7-day postoperative score ($P < 0.05$) (Fig. 5A). All VAS scores are shown in Table 3. The PSQI score rose from 16.50 ± 1.28 before the surgery to 7.95 ± 1.50.99 at one month after the surgery ($P < 0.001$). During the 12-month follow-up period, the PSQI score remained steady at 7.50 ± 1.40, 7.30 ± 1.40, and 7.00 ± 1.21 at 3, 6 and 12 months after surgery, respectively. The PSQI score at 12 months after the surgery was further improved compared to the PSQI at one month after the surgery ($P < 0.05$) (Fig. 5B). All PSQI scores are shown in Table 4. As for the BNI score, there were 10 cases of grade I, 6 cases of grade II, and 4 cases of grade III at 3 months after the surgery and 14 cases of grade I, 3 cases of grade II, and 3 cases of grade III at 12 months after the surgery. Respective BNI pain scores were 80.00% and 85.00% at 3 and 12 months postoperatively, amounting to a good rate (Fig. 5C). Case 2 and 3 required sustained oral administration of 150 mg of pregabalin; Case 9 required sustained oral administration of 100 mg sustained-release tramadol tablets; and Case 19 required sustained oral administration of 150 mg of pregabalin and 200 mg sustained-release tramadol tablets. Other patients completely stopped using the drugs at one month after the surgery.

Complications

No patient suffered serious adverse events such as intracranial infection, cerebrospinal fluid leakage, or electrode displacement. Two of the patients experienced bradycardia, a vital manifestation of a trigeminal-cardiac reflex that usually occurs when the trigeminal nerve is operated on, during the puncture process. Such cardiac arrhythmia was managed by withdrawing the puncture needle slightly and injecting atropine. In addition, the numbness in one patient's V3 sensory area was worse postoperatively. No special treatment was given, and the numbness was relieved spontaneously 4 weeks after surgery.

Discussion

HZ in the trigeminal area becomes more common with age and primarily affects the ophthalmic branch. The maxillary or mandibular branches are less commonly involved, and involvement of the multi-branch trigeminal nerve is rare (21,22). Treating THN is more challenging than treating herpetic neuralgia in other areas of the body. Short-term spinal cord or peripheral nerve stimulation has been widely used in China to treat HZ-related neuralgia (23,24). However, there are few reports on treating THN with short-term stimulation of the trigeminal ganglion.

Previous studies have reported that electric stimula-

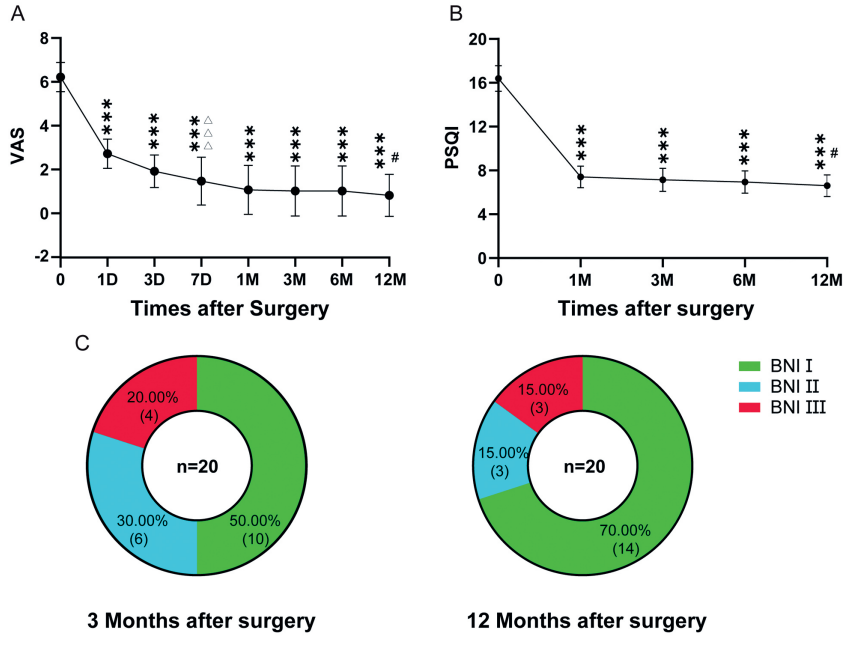

Fig. 5. *Outcomes of 12-month follow-up. A: VAS of 12-month follow-up (*P < 0.001, compared to presurgery; *P < 0.001, compared to one day after surgery; #P < 0.05, compared to 7 days after surgery). B: PSQI score of 12-month follow-up (*P < 0.001, compared to presurgery; #P < 0.05, compared to 7 days after surgery). C: BNI score at 3 and 12 months after surgery.*

Table 3. *VAS (visual analog scale) scores collected at each follow-up visit.*

Cases	VAS							
	Presurgery	1D	3D	7D	1M	3M	6M	12M
1	7	3	1	1	1	1	1	1
2	6	3	2	3	2	2	3	2
3	6	4	3	3	3	3	2	2
4	6	3	2	3	0	0	0	0
5	7	3	3	1	0	1	1	0
6	6	2	1	1	1	0	0	0
7	6	2	2	1	0	0	0	0
8	6	3	1	1	0	0	0	0
9	7	3	3	3	2	3	3	1
10	6	3	2	0	0	0	0	0
11	6	2	2	0	0	0	0	0
12	5	2	1	0	0	0	0	0
13	6	3	2	2	3	2	2	2
14	6	1	1	0	0	0	0	0
15	5	3	2	1	1	1	1	1
16	7	3	2	2	2	2	2	2
17	6	2	1	1	1	1	1	1
18	5	2	1	1	0	0	0	0
19	7	3	3	3	3	3	3	3
20	7	3	2	1	1	0	0	0

tion can relieve pain by modulating synaptic plasticity and neuroinflammation (25,26). In this pilot study, short-term stimulation of the trigeminal ganglion was shown to quickly relieve the pain and improve the sleep quality of multi-branch THN patients. Seven days after the surgery, 100% of patients reported more than 50% pain relief, which was superior to the results associated with pulsed radiofrequency of the trigeminal ganglion (27). The good rate of pain relief at 12 months postoperatively was 85.00%, based on the BNI score. This finding is consistent with the findings of Wan et al and Iseki et al on treating herpetic neuralgia with short-term stimulation (28,29). However, Taub et al demonstrated that none of the 4 patients with trigeminal PHN achieved 50% pain relief during the electrical stimulation test (30). One possible explanation for this result is that patients with PHN may experience central sensitization and negative emotions, all of which can impair the effectiveness of stimulation (31,32). Another reason may be electrode displacement (33,34). The Hartel approach is always used for stimulator implantation into the trigeminal ganglion. During this approach, the entry point is one cm below the corner of the mouth. However, this area is hypermobile during speech and eating. Using the Hartel approach may predispose an operation to lead migration, but moving the puncture point away from the aforementioned areas can reduce the risk of electrode displacement (34). In the present study, the puncture point was much higher than the corner of the mouth. During the surgery, each patient's mandible was moved under DSA, and the results revealed that raising the puncture point could reduce electrode displacement by mandibular movement.

In this study, the pain intensity was further improved after the electrodes were removed, indicating that herpetic neuralgia tends to heal itself. This finding is consistent with Watson et al's clinical observation research on the natural history of PHN (35). However, severe pain from HZ affects patients' quality of life, which is a risk factor for PHN (36). Therefore, when drugs are ineffective for treating acute and subacute herpetic neuralgia, further surgery should be implemented to prevent PHN from developing.

Previously, trigeminal ganglion electrode implantation was usually performed under local anesthesia and intraoperative wake-up anesthesia (30,33). During the surgery, the patient can figure out whether the painful area has been covered completely. Nonetheless,

Table 4. *Pittsburgh Sleep Quality Index (PSQI) scores collected at each follow-up visit.*

Cases	PSQI				
	Presurgery	1M	3M	6M	12M
1	16	7	7	6	6
2	17	7	7	7	7
3	15	8	6	6	6
4	17	7	6	6	5
5	17	8	8	7	6
6	16	8	8	8	7
7	15	7	6	8	8
8	15	6	8	8	8
9	17	8	7	7	8
10	16	7	7	7	7
11	16	7	7	7	7
12	17	7	7	5	6
13	18	10	10	9	7
14	15	8	7	7	6
15	19	11	10	10	9
16	15	9	7	7	7
17	16	10	8	9	8
18	16	7	7	6	6
19	18	11	11	10	10
20	19	6	6	6	6

local anesthesia can cause severe pain, while awakening under anesthesia during the surgery will lengthen the surgery time and increase the risk of gastroesophageal regurgitation, intraoperative pain, and fear (37). The trigeminal ganglion is located in Meckel's cave and has a relatively fixed position. Soft electrodes can be inserted into the trigeminal porus via the foramen ovale and Meckel's cave (15). In this study, all patients' painful areas were covered completely. Therefore, trigeminal ganglion stimulation implantation under general anesthesia was feasible.

Taub et al, studying 34 patients who received trigeminal ganglion stimulation implantation, reported that 2 cases resulted in injury to the trochlear nerve or abducens nerve during the puncture and electrode placement process (30). It is likely that placing the electrode too deep may cause nerve injury to the middle cranial fossa. Before each operation in our study, thin-slice cranial MRI and multi-planar reconstruction techniques were used to estimate the depth of the electrode placement. Furthermore, intraoperative CT measurement was applied to ensure that the electrode tip reached the preoperative estimated depth. Using the aforementioned imaging techniques can help minimize the risk of intracranial tissue damage. Moreover, decreasing the puncture angle in the sagittal position may reduce the risk of intracranial tissue damage, cerebrospinal fluid leakage, and damage to the upper wall of Meckel's cave. The reduction of these risks may be an additional advantage of raising the puncture point (Fig. 6).

Infection has been reported as a serious complication of trigeminal ganglion stimulation (30,33). The risk of infection increases with prolonged implantation duration (34). The absence of infection in this study may be due to the short term of the electrode implantation period. Additionally, oral mucosal injury may be another significant cause of infection (33). In our study, a 14 G syringe needle was used to break the skin at the planned puncture point, and a blunt needle was used for a nonviolent puncture, which might have prevented oral mucosal damage.

In the present study, 2 patients exhibited bradycardia during the puncture process, which was related to the trigeminal cardiac reflex. The trigeminal cardiac reflex is common in facial surgery (38,39). Withdrawing the needle slightly and administrating anticholinergics (such as atropine) can relieve bradycardia. Another patient reported transient numbness in the V3 sensory area after the surgery. This effect was thought to be caused by mandibular nerve injury during the puncture process.

Limitiations

There were a few limitations in this study. First, this present study is a pilot study. We expect prospective multi-center, large-sample studies in the future. Secondly, the electrode in the present study was implanted for 7 days. Determining whether the reduction or extension of the implantation time would influence the clinical effect would have required further investigation.

Conclusion

Short-term trigeminal ganglion stimulation can be used safely and effectively to treat patients with multibranch THN and significantly reduce the occurrence of PHN.

Acknowledgments

We appreciate the effort of the individuals in executing this study.

Availability of Data and Materials

The datasets generated and/or analyzed during

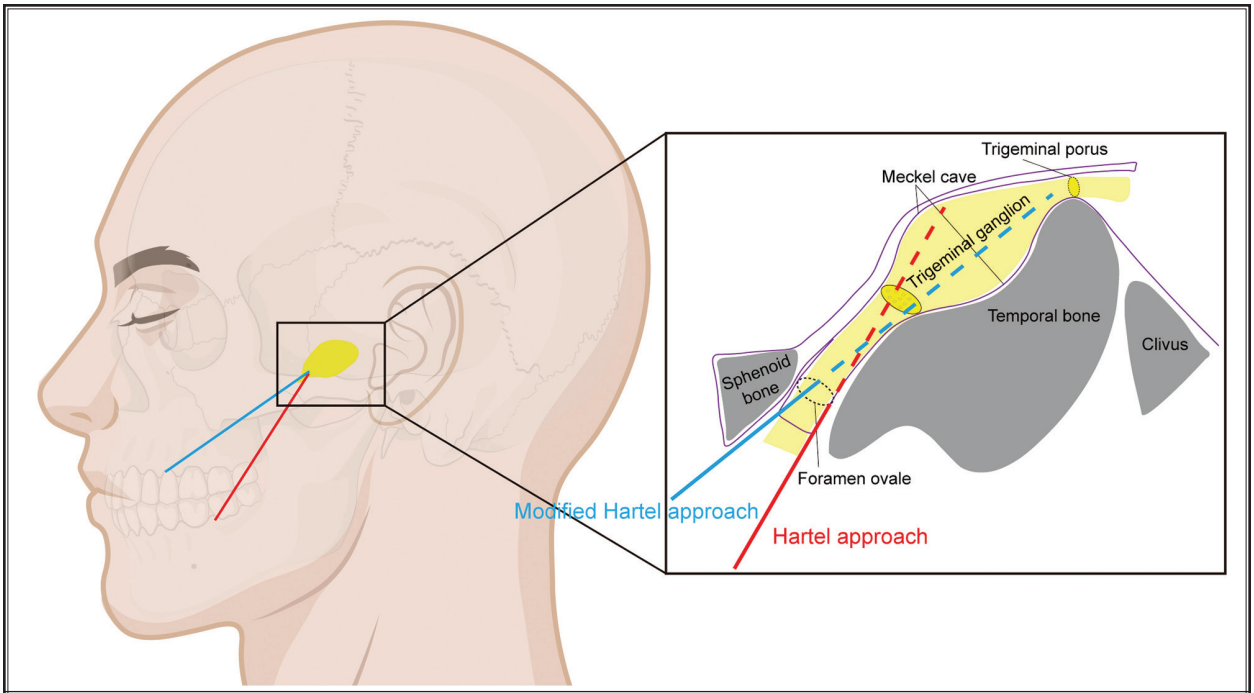

Fig. 6. *Schematic image of puncture of the trigeminal ganglion through the foramen ovale at Hartel approach and modified Hartel approach (reducing the puncture angle in the sagittal position).*

the current study are available from the corresponding author upon reasonable request.

Authors' Contributions

All authors made a significant contribution to this study. ZY and YY designed this study and collected the clinical data. ZY, ZXX, ZDY, JCH and YF performed the surgery. ZY, WYQ and YY drafted the manuscript. YZW performed MRI data analysis. YF, YY supervised this study and revised the article.

Disclaimer

This study was approved by the ethics committee of the First Affiliated Hospital of Nanchang University (2022 No. 36). In accordance with the Declaration of Helsinki, all patients provided written informed consent, and all clinical data were kept confidential. This study was funded by the Natural Science Foundation of Jiangxi Province [20224BAB216046 and GLL210161 to YY; 20232BBG70027 to ZXX] and the National Natural Science Foundation of China [82360975 to ZY; 8240488 to YY]. Consent for publication is not applicable.

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