Retrospective Study

The Analysis of Percutaneous Balloon Compression on Efficacy and Negative Emotion in the Treatment of Recurrent Trigeminal Neuralgia After Surgical Procedures

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Disclaimer: Drs. Fan and Xu are co-first authors. This study was supported by the National Key R&D Program of China (Grants No. 2020YFC2008400), The Key Science and Technology Project of Henan (International Science and Technology Cooperation Field) (Grants No. 182102410014), The Medical Appropriate Technology Promotion Project of Henan (Grants No. SYJS2020128).

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 manuscript.

Manuscript received: 01-20-2021
Revised manuscript received: 08-06-2021
Accepted for publication: 08-31-2021

Free full manuscript: www.painphysicianjournal.com

Background: Recurrent trigeminal neuralgia (TN) after surgical operations can be quite difficult to treat, and treatment measures have not been standardized. Patients often have long-term, repeated severe pain, which may easily cause anxiety and depression and can exert a negative effect on the quality of life. Despite the known efficacy of percutaneous balloon compression (PBC) for TN, it is unclear whether PBC can be used as the preferred surgical treatment for postoperative recurrent TN and effectively improve patients' negative emotions.

Objectives: This study aimed to evaluate the clinical curative effect of PBC in patients with postoperative recurrent TN and analyze the improvement in conditions such as anxiety, depression, and sleep disorders.

Study Design: Retrospective study.

Setting: Center of Pain Medicine, Department of Anesthesiology, pain, and Perioperative Medicine, the First Affiliated Hospital of Zhengzhou University.

Methods: Clinical data from 121 postoperative recurrent TN patients who underwent PBC between August 2017 and June 2019 were retrospectively reviewed and analyzed. The Barrow Neurological Institute pain intensity (BNI-P) score was used to measure the severity of pain. The Hospital Anxiety and Depression Scale (HADS) and Pittsburgh Sleep Quality Index (PSQI) were used to evaluate anxiety, depression, and sleep status.

Results: On postoperative day 1, 104 patients (86.0%) reported no pain, 9 patients (7.4%) had occasional pain that did not require medication, and 8 patients (6.6%) experienced no significant pain relief. The total efficacy was 93.4%. Moreover, 3 patients (2.5%) reported significant pain relief 2 weeks postoperatively. Within a follow-up time of 12 months, 101 (83.5%) patients remained pain-free, while 5 patients (4.1%) experienced recurrence. Taking into account economic factors, the patients were tolerant to pain after taking medication and did not undergo repeated PBC. Forty-six patients (38.0%) suffered from anxiety, 70 patients (57.9%) had depression, and 62 patients (51.2%) had poor sleep quality preoperatively. There were significant improvements in anxiety, depression, and sleep status postoperatively compared with preoperatively. Postoperative side effects included facial numbness in 115 patients (95.0%), masticatory muscle weakness in 86 patients (71.1%), herpes simplex in 18 patients (14.9%), and diplopia secondary to abducens nerve palsy in 2 patients (1.7%). None of the patients had corneal anesthesia, anesthesia dolorosa, aseptic meningitis, cerebrospinal fluid leakage, subarachnoid hemorrhage, carotid cavernous fistula, or death in this study.

Limitations: This study was a single-center retrospective study, the sample size was small, and the follow-up time was relatively short. Therefore, the long-term efficacy of PBC for postoperative recurrent TN needs further evaluation from multiple centers with a large sample size and long-term follow-up.

Conclusions: PBC is a minimally invasive, safe, and effective procedure. Moreover, it significantly improves the symptoms of anxiety, depression, and sleep quality caused by TN, so it appears to be regarded as an optimized choice for patients with recurrent TN after surgical procedures.

Key words: Percutaneous balloon compression, recurrent trigeminal neuralgia, anxiety, depression, sleep disorders

Clinical trial registration number and Registry URL: ChiCTR2000038205, www.chictr.org.cn

Pain Physician 2021: 24:E1255-E1262

Trigeminal neuralgia (TN) is a common type of facial neuropathic pain in the clinic that is confined to the distribution of the trigeminal nerve supply. The rate of TN is 3-5/100000. Mostly, it occurs in middle-aged and elderly individuals (1). Due to accelerated population aging in China, the prevalence of TN is increasing. When conservative treatments such as medication are not effective, patients often choose interventional or surgical treatment. Nevertheless, surgical methods, regardless of type, cannot achieve a 100% cure rate (2,3). Moreover, sleep disorders and psychiatric disorders such as anxiety and depression are highly prevalent in patients suffering from TN, seriously affecting patient quality of life and resulting in a heavy burden for families and society (4-6). However, the psychological consequences of TN have not received enough attention.

As a minimally invasive interventional procedure for the treatment of TN, percutaneous balloon compression (PBC) of the trigeminal ganglion was invented and first described by Mullan and Lichtor on the basis of the craniotomy nerve compression technique in 1983 (7,8). PBC is regarded by an increasing number of researchers as the first choice of treatment for primary TN because of its low cost, simple operation, minimal invasiveness, high pain relief rate, low recurrence rate, and repeatability (9). Despite the known efficacy of PBC for TN, limited analyses of the clinical outcomes of PBC for postoperative recurrent TN have been reported. Moreover, few studies have been performed to date that have exclusively evaluated the influence of PBC on related depression and anxiety in patients with postoperative recurrent TN. Whether PBC can be used as the preferred surgical treatment for postoperative recurrent TN and improve patients' negative emotions is still unclear (2,10). To address these questions, we performed a retrospective study, the aim of which was mainly to evaluate the clinical curative effect of PBC in patients with postoperative recurrent TN and secondly to analyze the improvement in conditions such as anxiety, depression, and sleep disorders. This may allow clinicians to make better decisions regarding the choice of treatment for postoperative recurrent TN.

Methods

Patient Population

This study was approved by the Medical Ethics Committee of the First Affiliated Hospital, Zhengzhou University (Institutional Review Board #2020-KY-195). Since this study was retrospective, a waiver of written informed consent was obtained from the Institutional Review Board. The trial was registered prior to patient enrollment at clinicaltrials.gov (ChiCTR2000038205, Principal Investigator: Xiaochong Fan, date of registration: September 13, 2020). All primary data were collected according to procedures outlined in epidemiology guidelines that strengthen the reporting of observational studies. Patients' information was anonymized and de-identified prior to analysis.

The retrospective study included patients clinically diagnosed with primary TN who received PBC treatment in the pain department at the First Affiliated Hospital of Zhengzhou University from August 2017 to June 2019. The detailed inclusion and exclusion criteria are as follows.

The inclusion criteria were as follows: 1) all TN patients who met the ICHD-3 diagnostic criteria for primary TN (11); 2) patients 18-90 years old; 3) TN patients who had unilateral symptoms and Barrow Neurological Institute pain intensity (BNI-P) ≥ grade IV; 4) TN patients who were intolerant or refractory to medical treatment; and 5) TN patients who had a history of TN-related surgery, such as microvascular decompression (MVD), percutaneous radiofrequency thermocoagulation (PRT), gamma knife radiosurgery (GKRS) and PBC. The exclusion criteria were as follows: 1) TN patients who had bilateral symptoms or were diagnosed with secondary TN caused by diseases such as intracranial space-occupying lesions or multiple sclerosis; 2) TN patients complicated with puncture site infections, severe cardiopulmonary insufficiency, blood coagulation

dysfunction; and 3) TN patients who were unable to understand or answer the questionnaires.

A total of 132 patients met the inclusion and exclusion criteria. However, 7 patients were excluded due to incomplete follow-up or clinical data, and 4 patients were lost to follow-up; finally, 121 patients were included. The course of disease ranged from 4 months to 33 years. The demographic and clinical characteristics of the 121 patients are summarized in Table 1. Preoperative magnetic resonance (MR) imaging was routinely performed.

Table 1. *The demographic and clinical characteristics of the 121 patients (n, %).*

General information	
Number of patients	121
Gender (male/female)	49 (40.5)/72 (59.5)
Age (years, range)	62.93 ± 10.26 (36-88)
Pain area	
Side (left/right)	52 (43.0)/69 (57.0)
I	12 (9.9)
II	27 (22.3)
III	16 (13.2)
I + II	11 (9.1)
II + III	42 (34.7)
I + III	1 (0.8)
I + II + III	12 (9.9)
Number of prior procedures	
1	90 (74.4)
2	27 (22.3)
≥ 3	4 (3.3)
Type of prior procedure	
MVD	24
PRT	89
PBC	16
GKRS	13
Others	14

Some patients had undergone one operation multiple times or different operations multiple times before the operation. Abbreviations: MVD, microvascular decompression; PRT, percutaneous radiofrequency thermocoagulation; PBC, percutaneous balloon compression; GKRS, gamma knife radiosurgery.

Surgical Technique

All PBC procedures were performed on the patients under tracheal intubation general anesthesia; the patients were placed in the supine position with a thin pillow under their shoulders on the operating table. For all patients, a C-arm x-ray machine was used to determine the location, shape, and size of the foramen ovale through the anteroposterior image. Complete overlap of the bilateral bony external auditory canals and skull base was used to determine the median position of the skull through the lateral image. To prevent trigeminal depressor responses, patients whose heart rate was less than 60 beats per minute were given an appropriate amount of atropine before the operation. Changes in vital signs were closely monitored during the perioperative period, especially changes in heart rate and blood pressure.

The Hartel anterior approach was used to puncture the foramen ovale, and the entry point was selected at the intersection of the vertical line of the lateral canthus and the extended line of the oral angle. The anteroposterior projection of the puncture path was a line connecting the puncture point with the pupil of the affected side, and the lateral projection was a line connecting the puncture point with the anterior external auditory meatus on the affected side (the midpoint of the zygomatic arch). Under the guidance of the C-arm x-ray machine, a 14-gauge needle containing a blunt obturator was used to puncture the foramen ovale. The needle core was withdrawn after the needle tip penetrated the foramen ovale under the lateral image; then the disposable balloon catheter used in brain surgery was advanced into Meckel's cave through the puncture cannula.

After observing the proper position and depth of the balloon catheter in the anteroposterior and lateral positions, the surgical operator withdrew the guidewire and slowly injected 0.5-0.8 mL of iohexol contrast agent to fill the balloon (average 0.6 mL; during the operation, the dosage of iohexol contrast agent should be adjusted appropriately according to the volume of Meckel's cave). Then the filling shape of the balloon was again inspected under the lateral image, and the position of the catheter was adjusted repeatedly in reference to the shape of the balloon until the filling balloon appeared to have an ideal "inverted pear shape." The filled balloon protruded into the posterior fossa near the posterior clinoid process and pituitary fossa (Fig. 1).

After the balloon had an ideal shape, the ganglion was compressed for 4-6 minutes (12) (the time should be adjusted according to factors such as balloon pressure, pain degree, and patient age). After compression, contrast was drained to empty the balloon. Then, the balloon catheter was withdrawn, the needle core was inserted, and the puncture needle was withdrawn. The

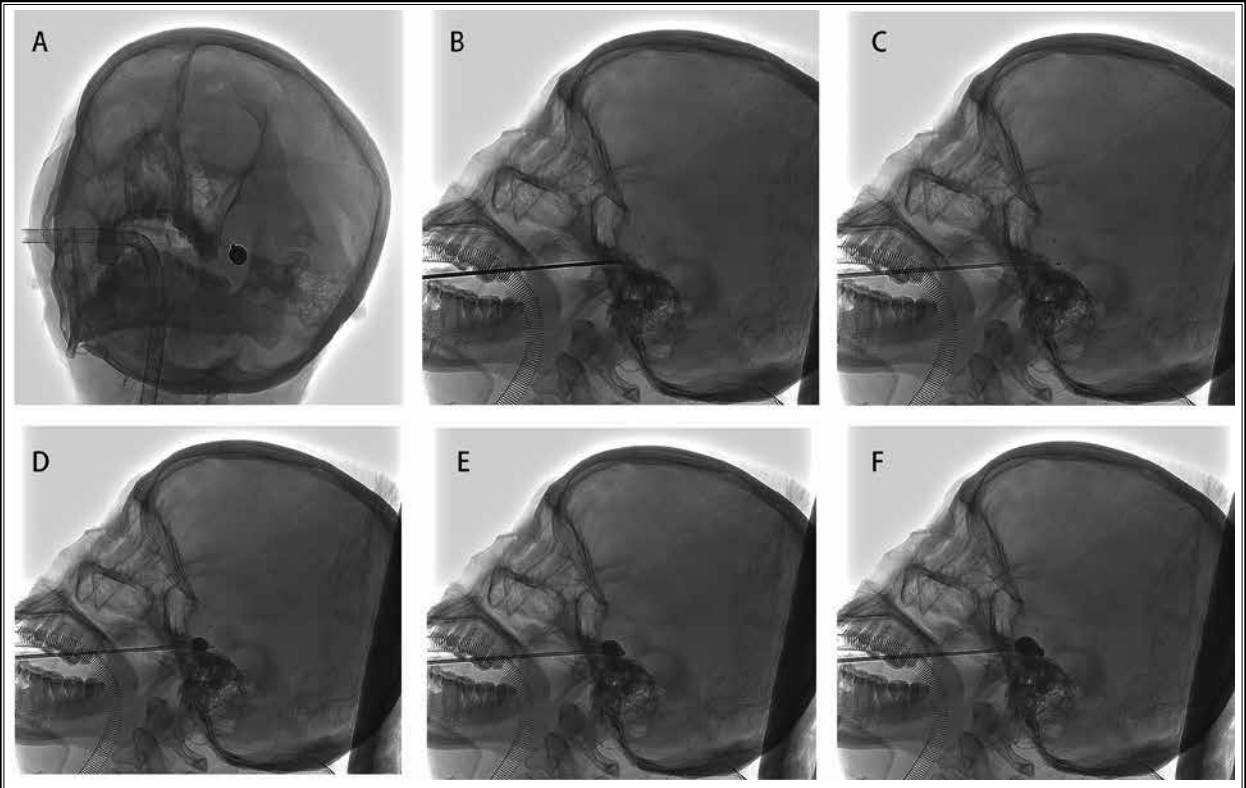

Fig. 1. *The filled balloon appears gradually to have an ideal "inverted pear shape" on lateral images.*

puncture wound was compressed for approximately 3 minutes, and then a sterile dressing and ice pack were applied to the cheek. The patient was discharged on the third day after the operation.

All patients were routinely treated with antibiotics and antiviral drugs and received supplemental drugs such as gabapentin and pregabalin after the operation; the patients were instructed to carry out masticatory muscle function exercise after the operation. If the postoperative pain was not well relieved, the patients were observed closely for 2 weeks. During this period, the patients were given carbamazepine or oxcarbazepine only when the pain was intolerable. If the pain was not relieved after 2 weeks, further treatment was administered, such as medication or minimally invasive interventional therapy.

Follow-Up and Effect Evaluation

With reference to 'the Chinese expert consensus on the diagnosis and treatment of trigeminal neuralgia' (1), the assessment of the degree of postoperative pain relief was based on the BNI-P score (13) (Table 2).

A pain score of 0 indicated complete painlessness; a score of 3 indicated uncontrollable pain or ineffectiveness of the drug; and a score ≤ 1 indicated that the operation was effective. Recurrence was defined as an increasing BNI-P score from 0 or 1 to 2 or 3 during the follow-up period after the operation. Facial numbness was evaluated by the BNI facial numbness (BNI-N) score (13).

In addition, the HADS was used to evaluate the anxiety and depression degree of the patients, and the Pittsburgh Sleep Quality Index (PSQI) was used to evaluate the sleep status of the patients (14,15). According to ethnic characteristics, a score < 9 in the HADS for anxiety or depression was negative, a score ≤ 7 in the PSQI was negative; otherwise, it was positive.

Preoperative and postoperative data were obtained from a review of the medical charts and postoperative questionnaires. The follow-up was completed by an independent supervisor nurse, and all patients were followed at the outpatient department or by telephone. Regardless of recurrence, the follow-up time of all patients was 12 months postoperatively.

The BNI-P, HADS, and PSQI scores were recorded preoperatively (T0) and 1 day (T1), 1 month (T2), 3 months (T3), 6 months (T4), and 12 months (T5) postoperatively.

In addition, operative side effects were also recorded immediately after the operation and at follow-up.

Statistical Analyses

Data analysis was performed using SPSS Version 21.0 (IBM Corporation, Armonk, NY); all variables were examined for normal distribution. The measurement data are expressed as the mean ± standard deviation (SD); repeated measures analysis of variance was used to analyze the BNI-P score at different time points. The enumeration data are expressed as percentages; nonparametric Cochran's Q test was used to analyze the HADS and PSQI scores at different time points. A statistical significance level was set at $P < 0.05$.

Results

The outcomes of the 121 patients are shown in Table 3. The efficacies at the different time points were 93.4%, 95.9%, 95.9%, 94.2%, and 91.7% (BNI-P score ≤ 1). In this study, 8 patients (6.6%) had no significant pain relief 1 day postoperatively, of whom 3 patients (2.5%) had significant pain relief 2 weeks postoperatively. The other patients could be tolerant to residual pain by means of medication postoperatively. Within a follow-up time of 12 months after PBC, 101 (83.5%) patients remained pain-free, and 5 patients (4.1%) had recurrence. In 4 of the recurrent patients, pain was adequately controlled with medication; the pain was not adequately controlled in one patient, but the patient was tolerant to pain after taking medication. Taking into account economic factors and efficacy, the patients were tolerant to pain after taking medication and did not undergo repeated PBC. As shown in Table 4 and Fig. 2, the BNI-P, HADS, and PSQI scores significantly decreased at T1- T5 compared with T0 ($P < 0.05$).

The postoperative side effects and recovery times are listed in Table 5. Facial numbness was the most common side effect; 6 patients (5.0%) had no facial numbness (BNI-N I), and 110 patients (90.9%) had mild and moderate facial numbness (BNI-N II-III), but almost all of them could tolerate it well. Eighty-six patients (71.1%) had masticatory muscle weakness with variable severity; all of them recovered within 4 months after PBC by means of functional exercise. Herpes simplex occurred in 18 patients (14.9%), and the symptoms dis-

Table 2. *Barrow Neurological Institute pain intensity (BNI-P) score.*

Pain intensity grade	Pain score	Definition
I	0	No pain, no medication
II	1	Occasional pain, no medication required
III	2	Some pain, adequately controlled with medication
IV	3	Some pain, not adequately controlled with medication
V	3	Severe pain / no pain relief

Table 3. *The postoperative outcomes of the 121 patients (n, %).*

Pain score	1 day postoperatively, no. of patients	During the postoperative period, no. of patients
0	104 (86.0)	101 (83.5)
1	9 (7.4)	10 (8.3)
2	7 (5.8)	8 (6.6)
3	1 (0.8)	2 (1.7)

Abbreviations: no., number.

Table 4. *Outcomes of the observation indexes before and after PBC treatment (n, %).*

Time	BNI-P (mean ± SD)	HADS				PSQI	
		HADS (A) < 9	HADS (A) ≥ 9	HADS (D)< 9	HADS (D) ≥ 9	PSQI ≤ 7	PSQI > 7
T0	3.00	75 (62.0)	46 (38.0)	51 (42.1)	70 (57.9)	59 (48.8)	62 (51.2)
T1	0.22 ± 0.58	112 (92.6)	9 (7.4)	114 (94.2)	7 (5.8)	114 (94.2)	7 (5.8)
T2	0.17 ± 0.51	118 (97.5)	3 (2.5)	117 (96.7)	4 (3.3)	119 (98.3)	2 (1.7)
T3	0.18 ± 0.55	120 (99.2)	1 (0.8)	119 (98.3)	1 (0.8)	118 (97.5)	2 (1.7)
T4	0.22 ± 0.59	119 (98.3)	2 (1.7)	120 (99.2)	1 (0.8)	118 (97.5)	3 (2.5)
T5	0.26 ± 0.66	117 (96.7)	4 (3.3)	118 (97.5)	3 (2.5)	117 (96.7)	4 (3.3)
Statistics	F = 1856.81	Q = 180.57		Q = 308.52		Q = 259.94	
P	< 0.001	< 0.001		< 0.001		< 0.001	

Abbreviations: PBC, percutaneous balloon compression; BNI-P, Barrow Neurological Institute pain intensity score; HADS (A), Hospital Anxiety and Depression Scale (Anxiety); HADS (D), Hospital Anxiety and Depression Scale (Depression); PSQI, Pittsburgh Sleep Quality Index; SD, standard deviation.

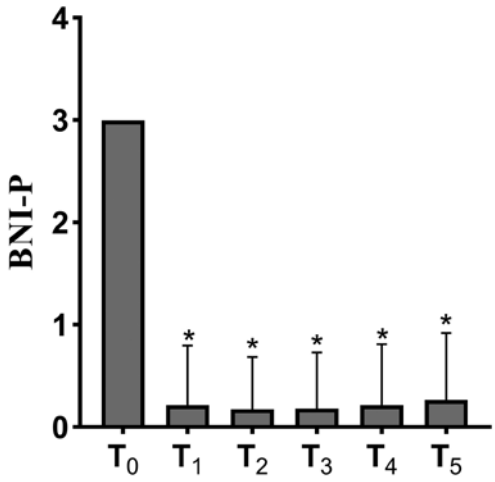

Fig. 2. *Changes in BNI-P scores after percutaneous balloon compression compared with preoperative scores (T0), *P < 0.05. Abbreviations: BNI-P,Barrow Neurological Institute pain intensity score.*

appeared within 2 weeks. In addition, 2 patients (1.7%) had diplopia secondary to abducens nerve palsy; the patient's vision returned to normal within 2 months. No other side effects occurred, such as corneal anesthesia, anesthesia dolorosa, aseptic meningitis, cerebrospinal fluid leakage, subarachnoid hemorrhage, carotid cavernous fistula, or death, in this study.

Discussion

PBC has been applied for more than 3 decades and has been shown to be a simple, safe, and effective treatment for TN (7,16,17). In terms of this minimally invasive treatment for TN, the rate of pain relief after PBC is similar to that reported after PRT and is higher than that associated with GKRS or percutaneous retrogasserian glycerol rhizotomy (18,19). However, the efficacy of PBC is superior to that of PRT regarding long-term outcomes (20). Although PBC is considered to be preferred for the treatment of postoperative recurrent TN (21,22), some researchers showed that patients previously treated with other surgical operations had a lower efficacy (23). Nevertheless, there are only a few reports on this topic (10,12,17,21,24).

In our study, we observed a total efficacy of 91.7% and a recurrence rate of 4.1 % during follow-up. The recurrence rate was significantly lower than that reported in previous studies, which may be related to the improvements in surgical techniques, the progress of image localization, and the strict requirement of "inverted pear-shaped" balloons or a "pear-like" balloon shape during the operation (12,24-26).

Table 5. *Postoperative side effects and recovery times.*

Side effects	No. of patients (n, %)	Average recovery time (mean ± SD)
Facial numbness	115 (95.0)	5.6 ± 1.9
Masticatory muscle weakness	86 (71.1)	2.3 ± 0.8
Herpes simplex	18 (14.9)	1.2 ± 0.4
Diplopia	2 (1.7)	1.5 ± 0.7

The unit for the recovery time of herpes simplex is weeks, and the unit for recovery time is months. Abbreviations: No., number; SD, standard deviation.

The BNI-P, BNI-N, and HADS scores represent simple and reliable methods with high reliability and validity. The PSQI is also highly correlated with polysomnography and self-rating anxiety and depression scales (13-15), so it is often used to evaluate clinical efficacy. Patients suffering from TN often have a long disease course and experience severe pain. Long-term repeated severe pain can easily cause anxiety and depression, and anxiety and depression will further aggravate pain. In addition, TN frequently leads to poor sleep quality and even sleep disorders. Previous studies have confirmed that patients suffering from TN are at a higher risk of developing depression and anxiety than the general population and those with chronic pain (5,27). However, no studies have been performed to date that have evaluated the influence of PBC on related depression and anxiety in patients with postoperative recurrent TN. In our study, we observed that the HADS and PSQI scores at T1-T5 were significantly lower than those at T0. The results suggest that PBC can not only effectively treat postoperative recurrent TN but also improve the negative emotions of patients.

Facial numbness and masticatory muscle weakness are common side effects after PBC, but they are relatively mild and closely related to the treatment mechanism and PBC operation; most patients can recover or become tolerant within 6 months. The proportion of facial numbness increased slightly compared with that in previous studies (9), which may be related to the increase in intraoperative balloon pressure and compression time in patients with recurrent TN compared with those undergoing surgical procedures for the first time. Among these side effects, the incidence of herpes simplex decreased compared with that in previous studies (24), which is attributed to the routine prophylactic antiviral therapy used after the operation. In this study, 2 patients (1.7%) with diplopia returned

to normal within 2 months after the operation. The deep position of the balloon catheter and cavernous sinus compression may lead to injury to the abducens nerve (28). Although this side effect is not common, it is temporary and reversible.

Moreover, 3 patients (2.5%) had no immediate pain relief postoperatively, but the pain was gradually relieved within 2 weeks after the operation, which some scholars call "delayed remission." This may be related to the sequential changes in nerve tissue in the ganglia, which are compressed by balloons postoperatively, and selective destruction of myelinated nerve fibers and demyelination occur within a certain amount of time (29,30).

This study was a single-center retrospective study, the sample size was small, and the follow-up time was relatively short. Therefore, the long-term efficacy of PBC for postoperative recurrent TN needs further evaluation from multiple centers with a large sample size and long-term follow-up.

Conclusions

PBC has unique advantages, such as a high pain relief rate, minimal invasiveness, mild side effects, and repeatability. Moreover, it significantly improves the symptoms of anxiety, depression, and sleep quality caused by TN, so it appears to be regarded as an optimized choice for patients with recurrent TN after surgical procedures.

Author contributions:

Xiaochong Fan: This author helped to conceive, design, and examine the manuscript.

Fuxing Xu: This author helped to collect, assemble, and analyze the data, and write the manuscript.

Huan Ren: This author helped to collect and assemble the data and write the manuscript.

Zhongyuan Lu: This author helped to collect and assemble the data.

Huilian Bu: This author helped to conceive and design.

Letian Ma: This author helped to analyze and interpret the data.

Cunlong Kong: This author helped to analyze and interpret the data.

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