Observational Study

Balloon Pressure and Clinical Effectiveness of Percutaneous Microballoon Compression in the Treatment of Primary Trigeminal Neuralgia

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Background: Primary trigeminal neuralgia (PTN) is a type of chronic neuropathic pain disorder caused by neurovascular compression. Percutaneous balloon compression (PBC) is a widely used method for the treatment of PTN.

Objectives: To examine the correlation of balloon pressure (BP) during percutaneous microballoon compression (PBC) with postoperative pain relief and complications in the treatment of primary trigeminal neuralgia (PTN).

Study Design: Forty-five patients diagnosed with PTN and treated with PBC were recruited. The BP was recorded at 2 time points: when the balloon achieved the ideal pear shape (initial BP [IBP]) and when the pressure was maintained for 2 min (final BP [FBP]).

Setting: This study was conducted at the Department of Pain and Rehabilitation of the Second Affiliated Hospital at the University of South China in Hunan, China.

Methods: The patients' Barrow Neurological Institute (BNI) pain intensity score, BNI facial numbness score, masticatory muscle weakness score, and recurrence were recorded before and after surgery. The receiver operating characteristic (ROC) curves were generated for the IBP to predict treatment effectiveness, severe facial numbness, and severe masticatory muscle weakness.

Results: The BNI pain intensity score, BNI facial numbness score, and masticatory muscle weakness score were significantly decreased after surgery (all $P < 0.001$). IBP was positively correlated with the difference between IBP and FBP ($P < 0.01$). Both IBP and the difference between IBP and FBP were negatively correlated with the BNI pain intensity score and positively correlated with the BNI facial numbness score and masticatory muscle weakness score ($P < 0.01$). The IBP and the difference between the IBP and FBP were significantly lower in patients experiencing recurrence than in the nonrecurrent group ($P < 0.05$). The areas under the ROC curves of the IBP for predicting effective pain relief, severe facial numbness, and severe masticatory muscle weakness were 0.875, 0.980, and 0.988, respectively.

Limitations: The sample size was relatively small, and the follow-up time was short. The correlations between the BP and other factors, such as filling amount, Meckel's cavity, and the size of the foramen ovale, were not investigated. The impact of the BP on long-term postoperative outcomes was not explored.

Conclusions: An intraoperative BP of 138.65–153.90 KPa can be maintained for effective PBC treatment without causing serious complications.

Key words: Balloon pressure, clinical effectiveness, complications, facial numbness, microballoon compression, muscle weakness, receiver operating characteristic curves, trigeminal neuralgia

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Trigeminal neuralgia (TN) is a common chronic neuropathic pain disorder that affects the face. The condition is often unilateral, involving one or more branches of the trigeminal nerve. The pain is usually described as knife-cutting, electric-shock-like, and needle-stabbing, with a duration ranging from a few seconds to several minutes (1). The major characteristics of TN are recurrent, transient, severe, and paroxysmal (2). TN pain can be triggered by daily activities such as talking, brushing teeth, chewing, and touching the face (3). There are two types of TN: primary TN (PTN) and secondary TN (4). PTN is caused by neurovascular compression, which refers to the compression of arteries or veins on the trigeminal sensory root near the brain stem (5,6). The closer the compression is to the brain stem, the more likely symptoms are to appear (5,6).

The preferred treatment for TN is anticonvulsants, with carbamazepine and oxcarbazepine being the first-line drugs (7). However, these medications do not provide lasting pain relief, and most patients experience serious side effects with prolonged use (8,9). Percutaneous balloon compression (PBC), first proposed by Mullan and Lichtor in 1983 (10), has been used widely as a TN treatment. PBC can be used not only to alleviate pain in patients who cannot tolerate craniotomy, have failed microvascular decompression, or present atypical symptoms, but also to treat patients with recurrence (11).

There are currently no established standards for the duration of PBC or the range of intraoperative balloon pressure (BP), both of which can be adjusted during the surgery. Few studies have reported on BP during PBC. In this study, we recruited 45 patients who underwent PBC for PTN so we could explore the correlations of BP during PBC with postoperative pain relief, facial numbness, and masticatory muscle weakness. We also determined the safe and effective range of BP during PBC for treating patients with PTN.

Methods

Patients

A total of 45 patients who were diagnosed with PTN and treated with PBC between June 2020 and October 2021 were recruited. All patients were followed for 3 months after surgery. This study was reviewed and approved by the local ethics committee. All patients or their family members provided written informed consent.

The inclusion criteria were: 1) clinical manifestations consistent with the diagnostic criteria of PTN; 2) the performance of magnetic resonance imaging of the skull and neurofunctional imaging to exclude secondary TN; 3) no significant pain relief after conventional treatment or an inability to tolerate the side effects of drug treatment; 4) a Barrow Neurological Institute (BNI) pain intensity score of ≥ 3; 5) an American Society of Anesthesiologists classification of $\leq$ III; and 6) complete clinical and follow-up data.

Exclusion criteria were: 1) intolerance of general anesthesia due to severe cardiopulmonary insufficiency or other organ dysfunction; 2) hematological disorders or abnormal coagulation function; 3) sensory and motor disorders in the area controlled by the trigeminal nerve; 4) coexistence of other cranial nerve diseases; 5) mental illness or speech communication difficulties; 6) refusal to cooperate with the follow-up; and 7) infection at and around the puncture site.

Surgery Procedure

The patient was placed in a supine position and administered general anesthesia through endotracheal incubation. After the satisfactory induction of general anesthesia, the foramen ovale on the affected side was fully exposed, and its outer edge was aligned with the mandibular edge. The target point was located at the junction of one-third of the foramen. The skin projection point was used as the puncture point. The Hartel method was used for the puncture and conducted under double C-arm digital subtraction angiography guidance with a brain surgery balloon catheter kit (Model: QKS-0050005; Shenzhen Qingyuan Medical Equipment Co., Ltd.). After the puncture needle was removed, the soft tissues around the trigeminal ganglion were separated by a guide rod. The contrast agent (5 mL; iodohydrin:normal saline = 1:1) was prepared during the operation, and the gas in the balloon was discharged. Then, the balloon catheter was placed in the Meckel's cavity, and 0.3-one mL of the contrast agent was slowly injected through a 1 mL syringe. The balloon was inflated to a "pear-shaped" appearance and placed in the Meckel's cavity. Subsequently, the "3-way" valve of the balloon was closed. The trigeminal ganglion was continuously compressed for 2 min. The procedure was performed by the same physician. A patient's preoperative magnetic resonance imaging scan is shown in Fig. 1. The double C-arm digital subtraction angiography-guided procedure is shown in Fig. 2.

Pressure Monitoring

Before puncture, the tail end of the balloon catheter was connected to a pressure gauge (Model: HT-1895; Dongguan Xintai Instrument Co., Ltd.) on one side and to a one mL syringe on the other side to inject the contrast agent. The BP at which the ideal

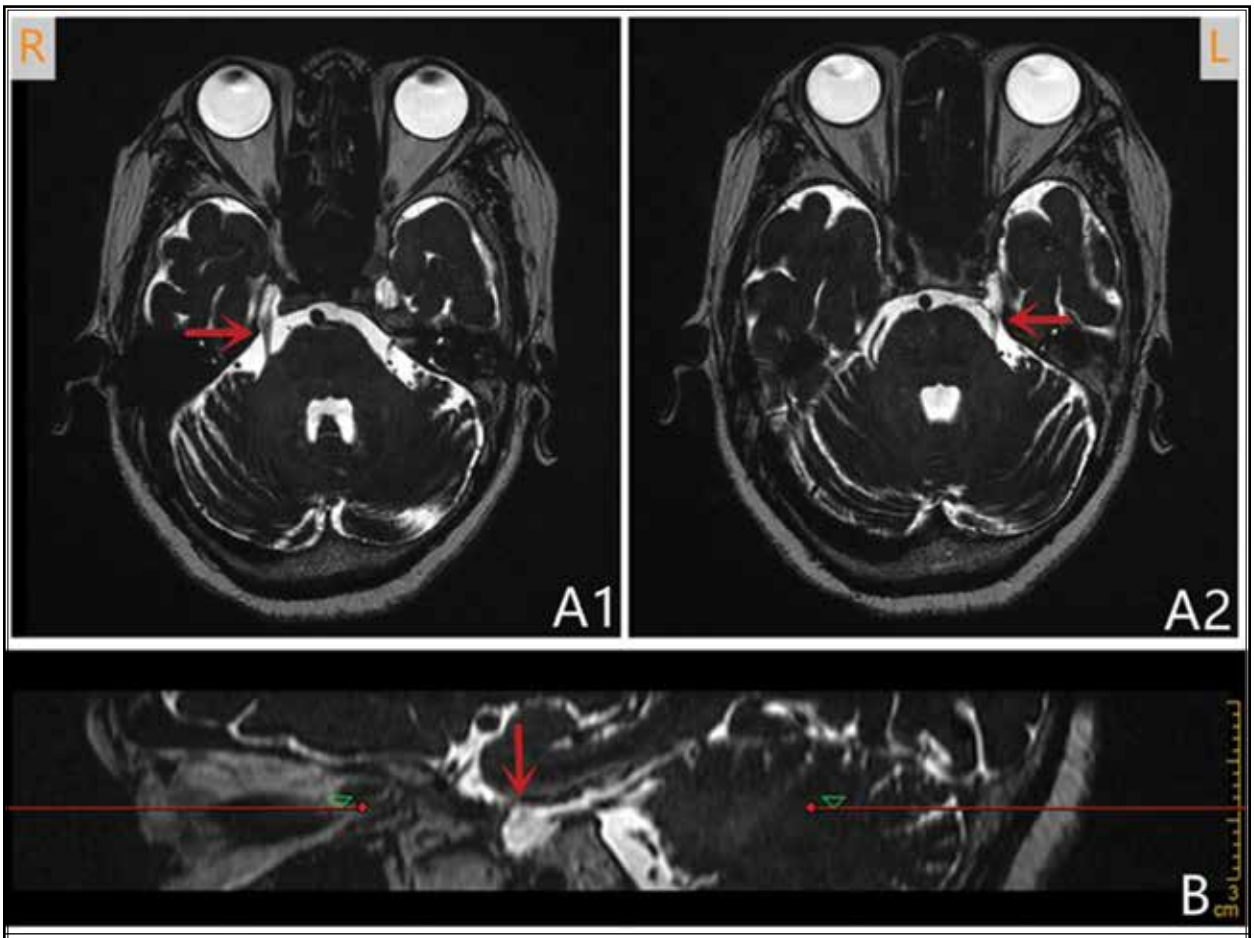

Fig. 1. *Functional magnetic resonance imaging of the trigeminal nerve. A1. The contralateral trigeminal nerve; A2. The affected trigeminal nerve compressed by blood vessels; B. The Meckel's cavity (sagittal plane).*

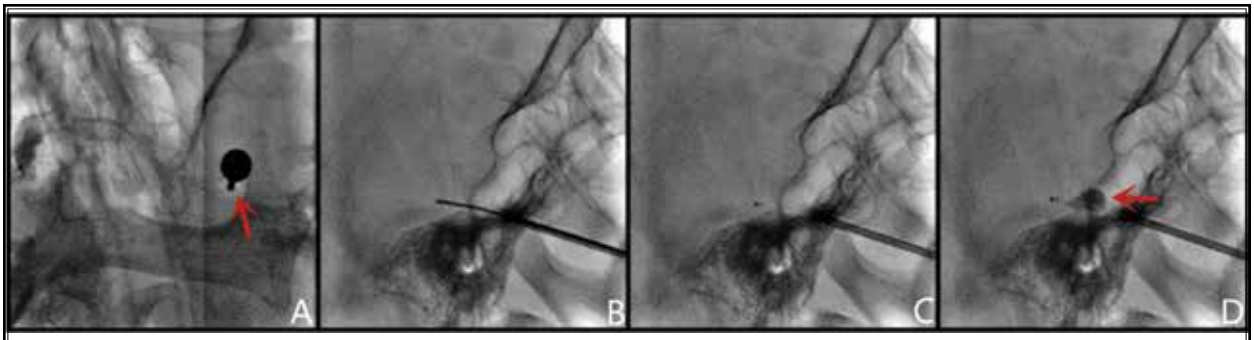

Fig. 2. *Illustration of the operation process. A. Puncture positioning; B. Guide rod placement; C. Balloon catheter placement; D. Contrast agent filling to form a pear shape.*

pear shape was achieved was recorded as the initial BP (IBP) (Fig. 3A). Meanwhile, the syringe was closed. The BP achieved by continuous pressing for 2 min was recorded as the final BP (FBP) (Fig. 3B). The difference between the IBP and FBP was also recorded.

Pain Relief Assessment

The same medical staff performed follow-up evaluations. Each patient's BNI pain intensity score was used to assess pain before surgery and at one day, one month, and 3 months after surgery. The grading system was as follows: 1, no pain and no need for medication; 2, occasional pain without medication; 3, pain can be controlled with medication; 4, pain is slightly relieved but not fully controlled with medication; and 5, no pain relief after medication. The surgery was considered effective when the BNI pain intensity score was one or 2 after surgery. Recurrence was defined as a postoperative change in the BNI pain intensity score from one or 2 to 3-5. Immediate pain relief rate equaled the number of patients showing a decrease in BNI intensity score one day after surgery divided by the total number of patients and multiplied by 100%.

Evaluation of Complications

Patients' BNI facial numbness scores were used to assess the degree of facial numbness on the first day and one and 3 months after surgery. The grading system was as follows: 1, no numbness; 2, mild numbness without affecting daily life activities or mood; 3, moderate numbness that occasionally affected daily life activities, mood, and sleep; and 4, severe numbness that seriously affected daily life activities. The rating standard for masticatory muscle weakness was developed based on the BNI facial numbness score: 1, normal muscle strength; 2, mild weakness that did not affect daily life activities or mood; 3, moderate weakness that occasionally affected daily life activities, mood, and sleep; and 4, severe weakness that seriously affected daily life activities. The masticatory muscle weakness score was recorded on the first day and one and 3 months after surgery.

Fig. 3. *BP monitoring. A. Injection of contrast agent to fill the balloon; B. Continuous compression of the balloon for 2 min.*
BP: balloon pressure.

Statistical Analyses

SPSS 26.0 software was used for the data analyses. Continuous variables are presented as the mean ± standard deviation, while categorical data are shown as frequencies and percentages. The paired sample t-test was used to compare the difference between the IBPs and FBPs. The 2-sample independent t-test was used to compare the difference in the BPs between the recurrent and nonrecurrent groups. The repeated measures analysis of variance was performed to compare patients' differences in pain, sleep quality, facial numbness, and masticatory muscle weakness before and after surgery. The Spearman's rank correlation analysis was used to analyze correlations. A BNI pain intensity score of ≤ 2 on the first day after surgery indicated that the surgery was effective, whereas a score of > 2 indicated ineffectiveness. A BNI facial numbness score of ≤ 3 on the first day after surgery indicated mild to moderate numbness, whereas a score of > 3 indicated severe numbness. Receiver operating characteristic (ROC) curves were plotted, and then the optimal BP range was determined. All tests were 2-tailed, and $P < 0.05$ was considered statistically significant.

Results

Basic Characteristics

A total of 45 patients who underwent PBC for PTN were recruited. The demographic and clinical characteristics of all patients are shown in Table 1.

Intraoperative BP

The mean IBP was significantly higher than the mean FBP (137.63 ± 29.35 KPa vs. 110.3 7± 26.23 KPa; $P < 0.001$). The difference between IBP and FBP was 27.25 ± 5.49 KPa, which was positively correlated with the mean IBP ($r = 0.650$, $P < 0.01$).

BNI Pain Intensity Score

Of the total 45 patients, 42 (93.3%) showed a

Table 1. *Basic characteristics of patients (n = 45).*

Characteristic	Number of Cases	Percentage (%)
Age (years)		
> 60	39	86.7
≤ 60	6	13.3
Gender		
Male	20	44.4
Female	25	55.6
Disease Duration (years)		
≤ 5	28	62.2
> 5	17	37.8
Pain Location		
Left	21	46.7
Right	24	53.3
Distribution Area		
Branch I	8	17.8
Branch II	11	24.4
Branch III	3	6.7
Branch I + Branch II	6	13.3
Branch II + Branch III	12	26.7
Branch I + Branch III	5	11.1

decrease in their BNI pain intensity scores on the first day after surgery. The remaining 3 patients showed a significant improvement in pain relief at one month after surgery. The pain levels were significantly reduced on the first day and at one and 3 months after surgery compared to the preoperative measurements (P < 0.001). The pain intensity scores at one and 3 months after surgery were significantly lower than those on the first day after surgery. However, there was no significant difference between the pain score at one and 3 months after surgery (Table 2 and Supplemental Table 1).

Postoperative BNI Facial Numbness Score

There were 41 cases (91.0%) with facial numbness on the first day after surgery, 32 (71.1%) at one month after surgery, and 17 (37.8%) at 3 months after surgery. Compared to the first day after surgery, the patients' degrees of facial numbness significantly improved at both one and 3 months after surgery (P < 0.001). The numbness scores measured at 3 months after surgery were also significantly lower than those measured at one month after surgery (P < 0.001) (Table 3 and Supplemental Table 2).

Postoperative Masticatory Muscle Weakness Score

There were 32 patients (71.1%) with masticatory muscle weakness on the first day after surgery, 22 (48.9%) at one month after surgery, and 9 (20.0%) at 3 months after surgery. The weakness of masticatory muscles was significantly improved at one and 3 months after surgery compared to the first day after surgery (P < 0.001). The degree of masticatory muscle weakness at 3 months after surgery was significantly lower than that at one month after surgery (P < 0.001) (Table 4 and Supplemental Table 3).

Table 2. *Multiple comparisons of BNI pain intensity scores (n = 45).*

Time Point 1	Time Point 2	Mean Difference (Before-After)	*P*
Before surgery	One day after surgery	2.222	< 0.001
	One month after surgery	3.289	< 0.001
	3 months after surgery	3.178	< 0.001
One day after surgery	One month after surgery	1.067	< 0.001
	3 months after surgery	0.956	< 0.001
One month after surgery	3 months after surgery	-0.111	0.799

Table 3. *Multiple comparisons of BNI facial numbness score (n = 45).*

Time Point 1	Time Point 2	Mean Difference (Before-After)	*P*
One day after surgery	One month after surgery	0.689	< 0.001
	3 months after surgery	1.200	< 0.001
One month after surgery	3 months after surgery	0.511	< 0.001

Correlation Between BP and Each Observed Index

The IBP and the difference between the IBP and FBP were negatively correlated with the BNI pain intensity score on the first day after surgery (r = -0.681, -0.449, P < 0.01), positively correlated with the BNI facial numbness score (r = 0.790, 0.623, P < 0.01), and positively correlated with the masticatory muscle weakness score (r = 0.873, 0.567, P < 0.01).

BP and Recurrence

Recurrence was observed in four (8.9%) patients. The IBP (98.23 ± 1.30 vs. 141.47 ± 27.87, P < 0.001) and

the difference between IBP and FBP (20.83 ± 1.70 vs. 27.88 ± 5.33; P = 0.012) in the recurrence group were significantly lower than those in the nonrecurrence group.

ROC Curves

A BNI pain intensity score of ≤ 2 on the first day after surgery indicated effective treatment, whereas a score of > 2 suggested ineffective treatment. The area under the ROC curve (AUC) was 0.875 (P < 0.001), with a maximum Youden index of 0.686 and an optimal threshold value of 138.65 KPa. These data indicate that the likelihood of effective treatment is greater when the IBP is higher than 138.65 KPa (Fig. 4A).

A BNI facial numbness score of ≤ 3 on the first day after surgery was considered mild-to-moderate numbness, whereas a score of > 3 indicated severe numbness. The AUC was 0.980 (P < 0.001), with a maximum Youden index of 0.914 and an optimal threshold value of 153.90 KPa. These results suggest that the risk of developing severe facial numbness is higher when the IBP is greater than 153.90 KPa (Fig. 4B).

A masticatory muscle weakness score of ≤ 3 on the first day after surgery was considered mild-to-moderate weakness, whereas a score of > 3 indicated severe weakness. The AUC was 0.988 (P < 0.001), with a maximum Youden index of 0.944 and an optimal threshold value of 161.40 KPa. These findings demonstrate that the risk of developing severe masticatory muscle weakness is higher when the IBP is greater than 161.40 KPa (Fig. 4C).

Based on the above results, the PBC treatment is likely to be effective, and the facial numbness and masticatory muscle weakness are likely to be mild to moderate when the IBP is greater than 138.65 KPa and less than 153.90 KPa. Therefore, the optimal range of the IBP is 138.65 to 153.90 KPa.

Table 4. *Multiple comparisons of masticatory muscle weakness score (n = 45).*

Time Point 1	Time Point 2	Mean Difference (Before-After)	*P*
One day after surgery	One month after surgery	0.644	< 0.001
	3 months after surgery	0.978	< 0.001
One month after surgery	3 months after surgery	0.333	< 0.001

Other Complications

Of all recruited patients, 12 (26.7%) experienced herpes labialis, and one (2.2%) had diplopia.

Discussion

The effectiveness of PBC is affected by several factors, such as the shape and size of the balloon, the BP, and the compression time (12). Pear-like and pear-shaped balloons are key to achieving positive surgical outcomes, whereas other shapes are associated with poor efficacy and early recurrence (13,14). Excessive compression may increase the risk of postoperative

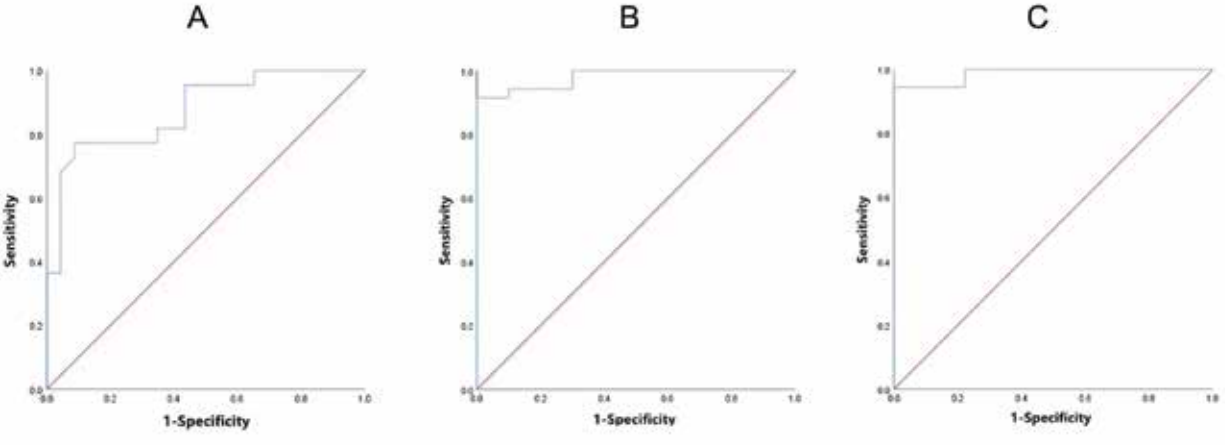

Fig. 4. *ROC curves of IBP. A. ROC curve of IBP for predicting the effectiveness of the surgery; B. ROC curve of IBP for predicting severe facial numbness; C. ROC curve of IBP for predicting severe masticatory muscle weakness.*
ROC: receiver operating characteristic; IBP: initial balloon pressure.

complications, whereas inadequate pressure may result in surgical failure (15). Our results suggest an optimal range of intraoperative BP between 138.65 and 153.90 KPa to perform effective PBC treatment that does not present serious complications.

In this study, 93.3% of the patients achieved pain relief on the first day after surgery, a result consistent with previous studies (16,17). PBC treatment further reduced pain at one month after surgery, with continued improvement observed at 3 months after surgery. Large myelinated nerve fibers were selectively damaged and demyelinated due to BP during PBC. The delayed pain relief may be attributed to the gradual demyelination process caused by sequential histological changes in the ganglia (18).

Because PBC is a traumatic operation on the trigeminal nerve root, complications related to nerve trauma are common. The incidence of complications observed in this study was consistent with the findings of Du et al (19). Although the degree of facial numbness cannot be entirely controlled, monitoring the pressure and position of the balloon, observing the patient's autonomous response during compression, and adjusting the compression duration can reduce the risk of severe facial numbness and improve the prognosis (20). In our study, both the BNI facial numbness score and the masticatory muscle weakness score gradually decreased over time. Most patients experienced gradual improvement or even complete recovery within a 3-month period.

The comparison between patients with recurrence and patients without recurrence showed that the IBP and FBP of the recurrence group were significantly lower than those of nonrecurrent patients, indicating a potential correlation between BP and recurrence. In the rabbit model, PBC treatment selectively damaged and blocked the conduction of pain impulses, and the preganglionic fibers of the trigeminal nerve did not regenerate for 270 days, indicating that delayed regeneration may contribute to a higher recurrence rate (21). Therefore, we presume that if the balloon undergoes too little pressure while filling to a satisfactory pear shape, the balloon may not destroy the myelinated nerve fibers in the semilunar ganglion, leading to a higher risk of preganglionic fiber regeneration and recurrence. In cases of recurrence, after in-depth communication with both the patients and their families, we made a careful decision regarding the most appropriate approach to pain relief, involving either radiofrequency thermocoagulation or repeat PBC (22).

A significant difference between the IBP and FBP was observed in this study, in accordance with the report by Lee et al (23). They found that the pressure increased as the contrast agent was injected until the balloon was fully expanded, and a gradual decrease in pressure over time followed. In addition, the pressure of the filled balloon in the posterior cranial fossa was lower than the balloon pressure in the Meckel's cavity. The Meckel's cavity is formed by two layers of dense collagen fibers, which are easy to deform and have little elasticity (24). The dual membranes of the Meckel's cavity may be stretched and deformed under pressure, or the balloon catheter may be slightly displaced to the posterior cranial fossa during compression. The second possibility is caused by the change in pressure that occurs during the injection of the contrast agent.

Correlation analysis showed that the IBP and the difference between the IBP and FBP were negatively correlated with the BNI pain intensity score on the first day after surgery but were positively correlated with the scores in BNI facial numbness and masticatory muscle weakness. PBC requires continuous compression of the trigeminal ganglion with an inflated balloon, leading to mechanical damage to the sensory nerve fibers that transmit pain and the blocking of the transmission of pain pathways. We speculate that a smaller change in pressure attenuation may cause more severe mechanical damage to the trigeminal ganglion, resulting in more effective pain relief. However, our results showed that the smaller the difference between the IBP and FBP, the poorer the pain relief. Additional studies with a larger sample size are needed to verify these findings.

In our cohort, 12 (26.7%) patients experienced mouth and lip herpes despite prophylactic antiviral treatment, which improved within one to 2 weeks of follow-up. In the study by Berra et al (25), 14.7% of the patients (n = 34) treated with PBC developed herpes labialis. The authors proposed that reactivation of the herpes simplex virus in the trigeminal ganglion was a sign of mechanical injury to the ganglion cells. Previous studies have also shown that stress may alter the function of ganglion neurons and suppress the immune system, although the mechanisms remain unclear (25). In our study, one (2.2%) patient had diplopia on the second day after surgery and recovered after one month of follow-up. Urculo et al (26) reported a case of diplopia that returned to normal 2 months after surgery. Diplopia is associated with trochlear nerve paralysis, catheter penetration, and compression time. If the catheter moves forward slightly due to inertia during

the placement of the balloon catheter or the injection of the contrast agent, the balloon becomes overfilled, leading to compression of the cavernous sinus, which may result in temporary damage to the trochlear, abducens, or oculomotor nerve and reversible paralysis. However, this type of damage usually recovers on its own with time (26).

Limitations

This study had several limitations. First, the sample size was relatively small, and the follow-up duration was short. Future studies involving a larger sample size and longer follow-up duration are needed. Second, additional studies are needed to investigate the correlations between BP and factors such as the filling amount, the Meckel's cavity, and the size of the foramen ovale. Lastly, it will be important to determine BP's impact on long-term postoperative outcomes and whether patients with recurrence after PBC treatment or with secondary TN require greater intraoperative pressure.

Conclusion

In conclusion, PBC treatment improved pain, facial numbness, and masticatory muscle weakness in patients with PTN. The ideal pressure range for producing effective pain relief and fewer complications during PBC was determined to be between 138.65 and 153.90 KPa. These findings suggest that reducing postoperative complications is crucial for the treatment of PTN.

Ethics Statements

This study was reviewed and approved by the ethics committee of the Second Affiliated Hospital of the University of South China (approval number: 2022K091301). All patients or their family members provided written informed consent.

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Supplemental Table 1. *BNI pain intensity score (n = 45)*.

	Before Surgery	One Day After Surgery	One Month After Surgery	3 Months After Surgery	F	*P*
BNI pain intensity score	4.53 ± 0.55	2.31 ± 0.95	1.24 ± 0.48	1.36 0.71	272.62	< 0.001

Supplemental Table 2. *BNI facial numbness score (n = 45)*.

	One Day After Surgery	One Month After Surgery	3 Months After Surgery	F	*P*
BNI facial numbness score	2.60 ± 0.94	1.91 ± 0.73	1.40 ± 0.54	74.16	< 0.001

Supplemental Table 3. *Masticatory muscle weakness score (n = 45)*.

	One Day After Surgery	One Month After Surgery	3 Months After Surgery	F	*P*
Masticatory muscle weakness score	2.22 ± 1.08	1.58 ± 0.66	1.24 ± 0.48	43.62	< 0.001