Retrospective Study

# The Application of the Balloon Pre-Inflating Technique in Percutaneous Balloon Compression for Primary Trigeminal Neuralgia: A Retrospective Study

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**Background:** Percutaneous balloon compression (PBC) is a safe and effective surgical technique for treating trigeminal neuralgia. The filling balloon can compress the trigeminal ganglion in Meckel's cave to achieve the interruption of pain signals. The core of the operation is the successful placement of a balloon catheter into Meckel's cave so that effective compression of the trigeminal ganglion can be achieved after the balloon is inflated.

**Objective:** In this article, we try to determine the application value of the balloon pre-inflating technique (using contrast agents as guides during positioning) by studying its effect on the ideal balloon formation rate in PBC.

**Study Design:** A retrospective study.

**Setting:** A single center.

**Methods:** To compare the small-dose balloon pre-inflating technique with traditional techniques during PBC surgery, we conducted a retrospective study on the clinical data of patients who had primary trigeminal neuralgia and underwent PBC surgery at the Department of Pain Management of the Second Xiangyi Hospital at Central South University in Changsha from January 2018 to January 2024. In total, 170 patients underwent the pre-inflating technique (pre-inflating group), and 199 patients underwent the traditional non-pre-inflating technique (control group).

**Results:** A total of 369 patients were included in the study, with a follow-up period of 12 months. When the initial balloon morphology was suboptimal, the success rate of re-catheterization to obtain the ideal balloon shape in the pre-inflating group and the non-pre-inflating group was 84.3% and 58.9%, respectively. The success rate in the pre-inflating group was significantly higher than in the non-pre-inflated group ($P < 0.001$). The numbers of re-punctures and re-catheterizations were significantly lower than in the non-pre-inflating group, as was the radiation dose. The instances of re-punctures in the pre-inflating group and the non-pre-inflating group were 0.41(ranging from 0.23 to 0.59 instances) and 0.71 (0.55-0.87 instances), respectively; and the re-catheterizations in the pre-inflating group and the non-pre-inflating group took place a respective 1.08 (0.77-1.40 instances) and 1.59 (1.28-1.90) instances. The radiation dose was 5.59 mGy (4.88-6.38 mGy) in the pre-inflating group and 7.69 mGy (6.86-8.52 mGy) in the non-pre-inflating group.

**Limitations:** This single-center investigation may be subject to institution-specific protocols and potential physician biases, with the generalizability of findings further constrained by the limited sample size.

**Conclusion:** We found that using the low-dose balloon pre-inflating technique in PBC surgery significantly improved the success rate of subsequent balloon deployment when the initial balloon morphology was suboptimal. This pre-inflating technique may decrease radiation exposure as well as the occurrences of multiple balloon catheter placements and repeated punctures.

**Key words:** Percutaneous balloon compression, balloon pre-inflating technique, trigeminal neuralgia

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Trigeminal neuralgia (TN) is a type of neuropathic pain that occurs in the head and face, often characterized by recurrent episodes of severe pain in the areas innervated by the trigeminal nerve (1). TN is also characterized by specific trigger points that can be activated by minor facial movements, leading to pain that feels like electric shocks or stabbing sensations. The crude incidence rate of trigeminal neuralgia ranges from 12.6 to 28.9 cases per 10 million people, with a higher incidence in women than in men (2,3). The prevalence of TN escalates with advancing age, exhibiting a notable increase in individuals past the age of 50. Cases of TN typically involve the maxillary and mandibular branches (second and third branches), whereas the ophthalmic branches are affected less frequently (less than 5% of cases) (4).

The first-line medication regimen for primary TN continues to be anticonvulsants, specifically carbamazepine and oxcarbazepine (5). When patients exhibit inadequate response to these medications or experience intolerable side effects, surgical intervention is typically necessary (6). The common surgical methods for treating TN include microvascular decompression (MVD) and other percutaneous techniques (7-9). In recent years, percutaneous techniques, including percutaneous balloon compression (PBC), radiofrequency rhizotomy, and glycerol rhizotomy, have gained increasing popularity and been progressively adopted in clinical practice due to their minimally invasive characteristics, repeatability, and efficacy (10,11).

Among the various percutaneous techniques, PBC has demonstrated considerable significance in the management of TN, having been recognized as a safe and effective interventional approach. Studies have shown that the immediate pain relief rate following PBC was 98.6%, and the effectiveness rate may exceed 90% within 3 years after the procedure (12). PBC was first proposed for the treatment of TN by Mullan and Lichtor in 1983 (13). The procedure of PBC entails the utilization of puncture techniques, guided by X-ray fluoroscopy or computed tomography (CT), to insert a balloon catheter into the Meckel's cave via the oval foramen. Subsequently, the balloon is inflated, exerting physical pressure on the trigeminal ganglion to facilitate pain relief. It is widely recognized that the inflated balloon ideally takes a pear-like shape, which is formed by the compression of the balloon against the trigeminal ganglion and the anterior wall of the Meckel's cave (14). The mechanism by which PBC alleviates pain is not yet clear, but most opinions suggest that effective compression can block the transmission of pain signals by damaging large myelinated nerve fibers (15).

The key to the treatment effect of PBC lies in the effective compression of the trigeminal ganglia after the balloon is inflated. Additionally, the critical factor in achieving optimal balloon inflation is the successful positioning of the balloon catheter within the Meckel's cave (16). Based on our experience, the localization and puncture of the oval foramen generally do not pose significant technical difficulties. Neurosurgeons and pain specialists can typically master the puncture technique with some training.

After the puncture needle enters the oval foramen, the wall of the Meckel's cave must be pierced for the balloon catheter to be advanced. During the advancement process, the operator typically relies on a subtle "loss of resistance" sensation as an indicator to ascertain whether the catheter has been positioned correctly within the Meckel's cave. Therefore, whether the balloon catheter has entered the Meckel's cave often depends on the operator's experience, which is not always very reliable. The success rate is related to the operator's technical accumulation and the anatomical situation of the Meckel's cave. If the balloon catheter is inflated when it is not correctly positioned within the Meckel's cave (e.g., located outside the cave, between dural layers, or adjacent to its walls), the catheter can externally compress the cave. This compression leads to the outflow of cerebrospinal fluid, a reduction in the volume of the Meckel's cave, and, consequently, significant difficulty in subsequent catheter placement into the cavity. Such occurrences may adversely affect the success rate of subsequent balloon catheter placements and may also elevate the risk of nerve-related complications.

In our study, we propose a pre-inflating PBC technique that involves using contrast agents as a positioning guide during the operation. This technique can increase the success rate of re-catheterization, improve surgical efficiency, and reduce the occurrence of related complications. Specifically, after the balloon catheter is placed, a small dose of contrast agent (0.1 mL) is first injected to pre-fill the balloon. If the initial shape of the balloon is satisfactory, indicating that the balloon catheter is likely positioned within the Meckel's cave, the remaining contrast agent is then injected into the balloon.

## Methods

### Patients and Group

This study had a retrospective design and was ap-

proved by the Ethics Committee of the Second Xiangya Hospital (retrospectively registered: ethics approval no. LYF20240249), Central South University. Written informed consent was obtained from all individual patients (and/or their legal guardians) included in the study. A total of 400 patients who were diagnosed with primary TN and underwent PBC surgery in the Pain Management Department of the Second Xiangya Hospital between January 2018 and January 2024 were included in this study. Following strict adherence to the inclusion and exclusion criteria, a final sample size of 369 patients was determined (Fig. 1).

The patient inclusion criteria were as follows: 1) diagnosis of primary TN according to the International Classification of Headache Disorders; 2) Pain Visual Analog Scale (VAS) score ≥ 4; 3) duration of TN ≥ 6 months; 4) poor response to medication treatment or inability to tolerate side effects; 5) clear understanding of the experimental process and voluntary participation in this study, signing the informed consent form.

Exclusion criteria: 1) severe systemic diseases and inability to tolerate surgery and anesthesia; 2) preoperative coagulation disorders or local infections at the puncture site; 3) mental illnesses that prohibit the clear expression of subjective feelings; 4) having previously undergone trigeminal-related surgeries, including microvascular decompression and nerve injury; 5) superficial facial sensory loss or abnormalities.

Due to the different habits of surgical procedures among surgeons in our department, 170 patients received a small dose of pre-inflation during the surgery, while the remaining 199 patients underwent adequate balloon inflation during the first inflation. Based on the different methods of balloon inflation, the cases were divided into the pre-inflating group and the non-pre-inflating (control) group.

## Surgical Procedure

In the surgical procedure, depicted in Fig. 2, the patients were placed in a supine position with hyperextension of 15-20° of the neck. Following the administration of general anesthesia, a C-arm x-ray device was utilized to identify the foramen ovale. Specifically, the C-arm x-ray was tilted 30° toward the foot end and 15° toward the operation side. The puncture point was located 2.5 cm outside the corner of the mouth. Under the guidance of a C-arm x-ray, the 14-gauge needle with a blunt obturator was gradually punctured and placed at the opening of the oval foramen. When the needle approached the oval foramen, the mandibular nerve was released, using a probe. The planum sphenoidale and the posterior clinoid in the side view were aligned to obtain the best view of the sella turcica. Then, the #4 Fogarty balloon catheter was inserted carefully, followed by the injection of 0.1 milliliters of

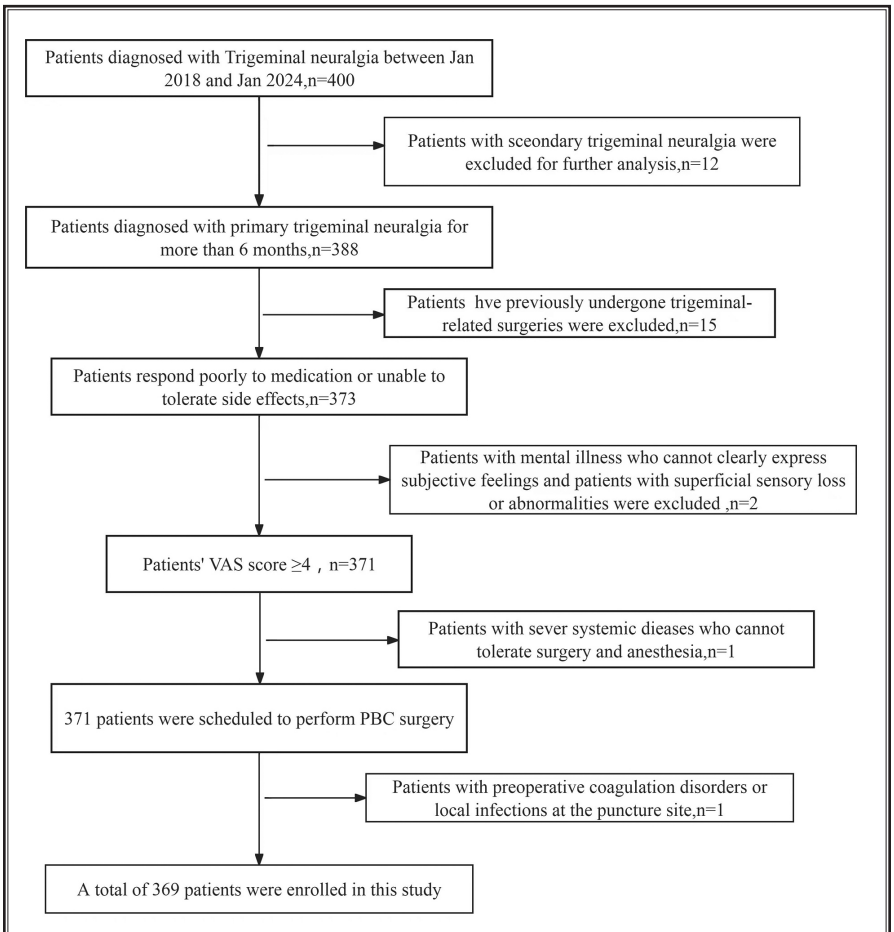



Fig. 1. *Flowchart of the process of selecting and excluding patients.*

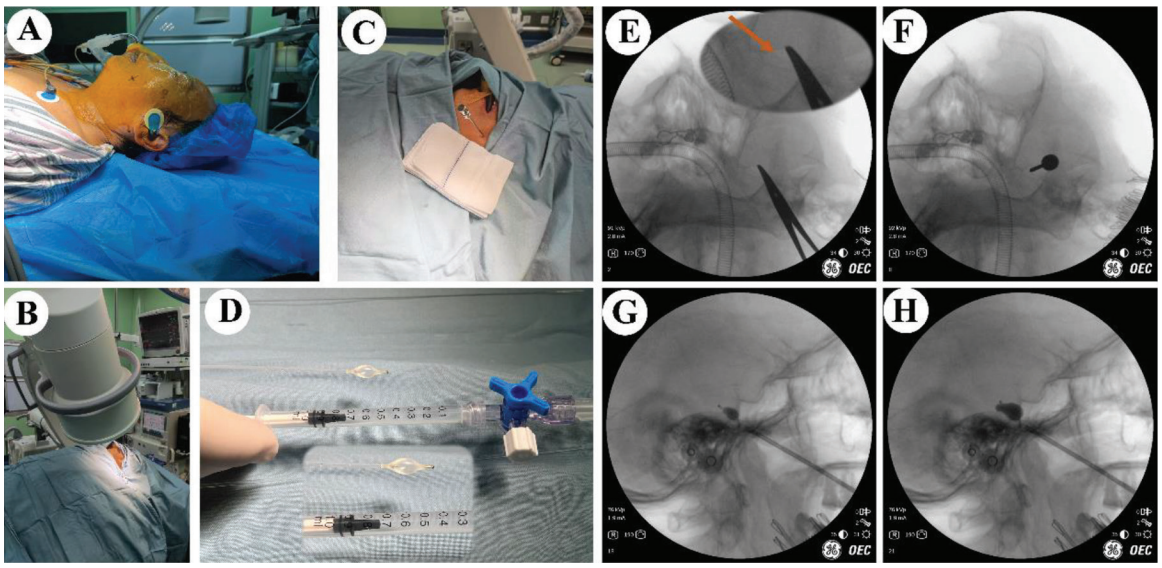



Fig. 2. *Pre-inflating technique in PBC procedure.*
*(A) Patient positioning. (B) Positioning of the C-arm X-ray. (C) Surface localization of the puncture site. (D) Shape of the balloon after 0.1 mL of contrast agent was injected. (E) Radioscopic location of the foramen ovale. (F) The needle with a blunt obturator was punctured and placed at the opening of the oval foramen. (G) Shape of the pre-inflating balloon. (H) Pear-like shape of the balloon after complete inflation.*

iohexol contrast agent for the purpose of pre-inflation. The location of the balloon catheter was estimated by the shape of the pre-inflating balloon. (The cases of the pre-inflating balloon are presented below.) If the balloon's pre-inflation shape was unsatisfactory, the balloon catheter would be adjusted and the balloon would be inflated again. If the pre-inflation results showed a satisfactory balloon shape, the remaining 0.4 mL of the contrast agent was injected. Once the balloon exhibited a pear shape under the C-arm x-ray, pressure was meant to be maintained for a duration of 180 seconds, after which the contrast agent should have been withdrawn and the balloon catheter removed. Scenarios requiring re-puncture and re-catheterization were as follows: If the pre-inflating balloon shape (in the pre-inflating group) or the initial fully inflated balloon shape (in the control group) was deemed unsatisfactory (e.g., irregular, spherical, or dumbbell-shaped), it indicated that the catheter tip was likely not in an optimal position within the Meckel's cave. In such cases, the balloon catheter was first withdrawn and slightly readvanced with adjusted trajectory. If repeated adjustments failed to yield an ideal shape, the puncture needle was then completely withdrawn, and a re-puncture was performed from a different angle or entry point to re-access the foramen ovale.

## Data Collection and Outcome Follow-Up

Each patient's age, gender, side of pain, duration of pain, pain area distribution, and prior surgical interventions (if any) for TN were extracted from the Hospital Information System (HIS). During the surgery, detailed records were kept of the number of percutaneous punctures, the number of balloon catheter insertions, total surgery duration, total radiation dose, intraoperative compression time, and balloon volume. Postoperative data included pain relief status and the occurrence of complications, such as facial numbness, masticatory muscle weakness, tinnitus, diplopia, keratitis, lip herpes, and cerebral hemorrhage.

After the PBC surgery, patients underwent routine outpatient follow-ups or telephone interviews at one day, one week, one month, 6 months, and 12 months post-operation. The effectiveness of the surgery was assessed according to the Barrow Neurological Institute (BNI) criteria, on which BNI grade I indicated no pain and no medication; grade II indicated occasional pain not requiring medication; grade III indicated some pain that was adequately controlled with medication; grade IV indicated some pain not adequately controlled with medication; and grade V indicated severe pain or no relief. For this study, BNI grades I-III were considered effective relief, while grades IV and V were classified

as insufficient pain relief. Once a patient experienced a recurrence of pain after the PBC surgery, the follow-up was terminated. The follow-up work was managed by an independent supervising nurse, and all patients were followed up via phone, WeChat, or outpatient visits. A total of 369 patients were successfully followed up.

### Statistical Analysis

IBM SPSS Statistics 23.0 was used for the statistical analysis of all data, with a *P*-value of less than 0.05 considered statistically significant. For the demographic characteristics of patients and the related features of TN, normally distributed continuous data were reported as the mean and SD, while non-normally distributed data were presented as the median (25th quartile to 75th quartile). Descriptive data were displayed in terms of frequency and percentage. The analysis of categorical variables was conducted using the chi-square test, while numerical variables were compared using the independent samples u-test.

## Results

According to the inclusion criteria, this study included a total of 369 patients who were diagnosed with primary TN and subsequently underwent PBC surgery at the pain management department of the Second Xiangya Hospital, Central South University. Among the patients participating in the study, there were 148 men and 221 women, with an age range of 58 to 82 years and an average age of 65 ± 2 years. In the pre-inflating group, the respective proportions of patients affected on their left sides and those affected on their right sides were 42.4% and 57.6%; while in the control group, those proportions were 44.2% and 55.8%. Neither group included any patients who had bilateral involvement. In patients diagnosed with TN, the involvement rates were found to be highest in the second (maxillary) and third (mandibular) branches. Specifically, within the pre-inflating group, the involvement rates for the second and third branches were observed to be 32.9% and 61.8%, respectively; whereas in the control group, these rates were 40.2% and 55.8%. All patients had received medication treatment prior to the PBC surgery and had not undergone other surgical interventions, including microvascular decompression (MVD), gamma knife, radiofrequency thermocoagulation, etc. Moreover, the patients were all plagued by intolerable side effects of drugs or a decline in the efficacy of pain management. The details of the demographic characteristics of the patients included in the study are presented in Table 1. No significant differences were observed between the 2 groups of patients (pre-inflating group and control group) in age, height, weight, side of TN, or gender.

In both groups, we considered the ideal outcome to be a satisfactory pre-inflating balloon shape or standard pear shape obtained during the initial puncture and catheter insertion. The evaluation of the pre-inflating balloon morphology depended primarily on the surgeon's subjective judgment. The various morphologies of pre-inflating balloons observed during the procedure are illustrated in Fig. 3. Among them, the ideal balloon morphologies are depicted in Fig. 3(B1- B5), which is characterized by an overall small pear-shaped appearance, especially in the sharp and flat anterior segment of the balloon, which is caused by the pressure within the Meckel's cave. In contrast, the nonideal balloon shape cases—irregular shapes such as balls, dumbbell shapes, and ovals—are shown in Fig. 3(A1-A5). These shapes usually mean that the balloon catheter is not successfully placed into the Meckel's cave. To reiterate, at present, the satisfactoriness of the balloon shape depends mainly on the surgeon's subjective judgment.

Table 1. *The demographic characteristics of the 369 patients treated with percutaneous balloon compression (PBC).*

| | Pre-Inflating Group (n = 170) | Control Group (n = 199) | $X^2$/Z | *P* value |
|---|---|---|---|---|
| Gender | | | 0.002 | 0.969 |
| Men | 68 (40%) | 80 (40.2%) | | |
| Women | 102 (60%) | 119 (59.8%) | | |
| Age | 66 (59.00, 73.25) | 65 (58, 73) | -0.673 | 0.501 |
| Disease duration (months) | 36 (12,96) | 36 (12,90) | -0.043 | 0.966 |
| Affected side | | | 0.130 | 0.718 |
| Left | 72 (42.4%) | 88 (44.2%) | | |
| Right | 98 (57.6%) | 111 (55.8%) | | |
| Affected branch | | | 2.195 | 0.334 |
| V1 | 9 (5.3%) | 8 (4.0%) | | |
| V2 | 56 (32.9%) | 80 (40.2%) | | |
| V3 | 105 (61.8%) | 111 (55.8%) | | |
| Medication | | | 1.641 | 0.440 |
| Carbamazepine | 138 (81.2%) | 155 (77.9%) | | |
| Oxcarbazepine | 23 (13.5%) | 36 (18.1%) | | |
| Gabapentin | 9 (5.3%) | 8 (4.0%) | | |

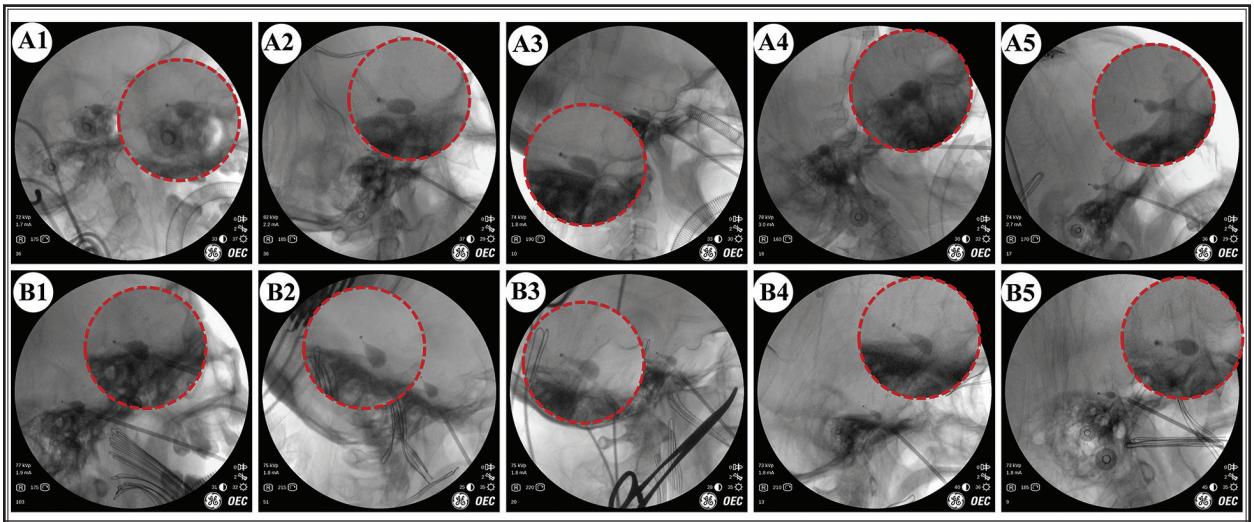



Fig. 3. *The diverse morphologies of pre-inflating balloons during PBC surgery. (A1-A6) unideal pre-inflating balloon shape. (B1-B6) ideal pre-inflating balloon shape.*

We first analyzed the initial catheterization for patients in both groups. Among the 170 patients in the pre-inflation group, 83 patients' balloons did not achieve the ideal pre-inflating shape at the initial catheterization. In the non-pre-inflating group, 90 out of 199 patients' balloons did not achieve the ideal pear shape. The success rates for the initial catheterization in the pre-inflating and non-pre-inflating groups were 51.2% and 54.8%, respectively, with no statistically significant difference observed between the 2 cohorts ($P = 0.558$). Since the success rate of the first puncture catheterization is mainly related to the surgeon's experience and skills, the results indicate that the surgical operations conducted by different operators in our department do not have a significant impact on the catheterization success rate.

After the initial puncture and catheter insertion, the failure to achieve an ideal balloon shape typically indicates that the balloon catheter has not been successfully placed in the Meckel's cave. In this case, the position of the balloon catheter needs to be adjusted, and the re-puncture may even be necessary. The re-puncture and re-catheterization after the initial catheter placement failure in each group were also investigated. As shown in Fig. 4A, the success rate of re-catheterization to obtain the ideal balloon shape was 84.3% in the pre-inflating group and 58.9% in the non-pre-inflating group. The success rate in the pre-inflating group was significantly higher than that in the non-pre-inflating group ($P < 0.001$). The distribution of the respective number of patients who underwent re-puncture and re-catheterization in each group is shown in Figs. 4D and 4E. The average number of re-punctures was 0.41(ranging from 0.23-0.59) in the pre-inflating group and 0.71(ranging from 0.55-0.87) in the non-pre-inflating group; and the average number of re-catheterizations was 1.08 (ranging from 0.77-1.40) in the former group and 1.59 in the latter group (ranging from 1.28-1.90). The results showed that the number of re-punctures and re-catheterizations in the pre-inflating group were significantly lower than in the non-pre-inflating group ($P < 0.001$). The surgery time and radiation dose received by each group are shown in Fig. 4 (B and C). After the first catheter insertion, if the balloon inflation was not satisfactory, the surgery time and radiation dose in the pre-inflating group were 25 minutes (range: 20-36 minutes) and 5.59 mGy (range: 4.88-6.38 mGy), and the surgery time and radiation dose in the non-pre-inflating group were 30.5 minutes (range: 24-43.25 minutes) and 7.69 mGy (range: 6.86-8.52 mGy). The results showed that the pre-inflating technology could significantly shorten the surgery time ($P = 0.01$) and reduce radiation dose ($P < 0.001$) in cases where the first catheter placement was not ideal. Additionally, the surgery time and radiation dose of all patients in the pre-inflating group and the non-pre-inflating group were also studied. As shown in Fig. 5, the overall radiation dose received by the pre-inflating group was also lower than in the non-pre-inflating group ($P < 0.001$). However, no significant difference was observed in the overall surgical time between the 2 groups ($P = 0.127$). This phenomenon may be due to

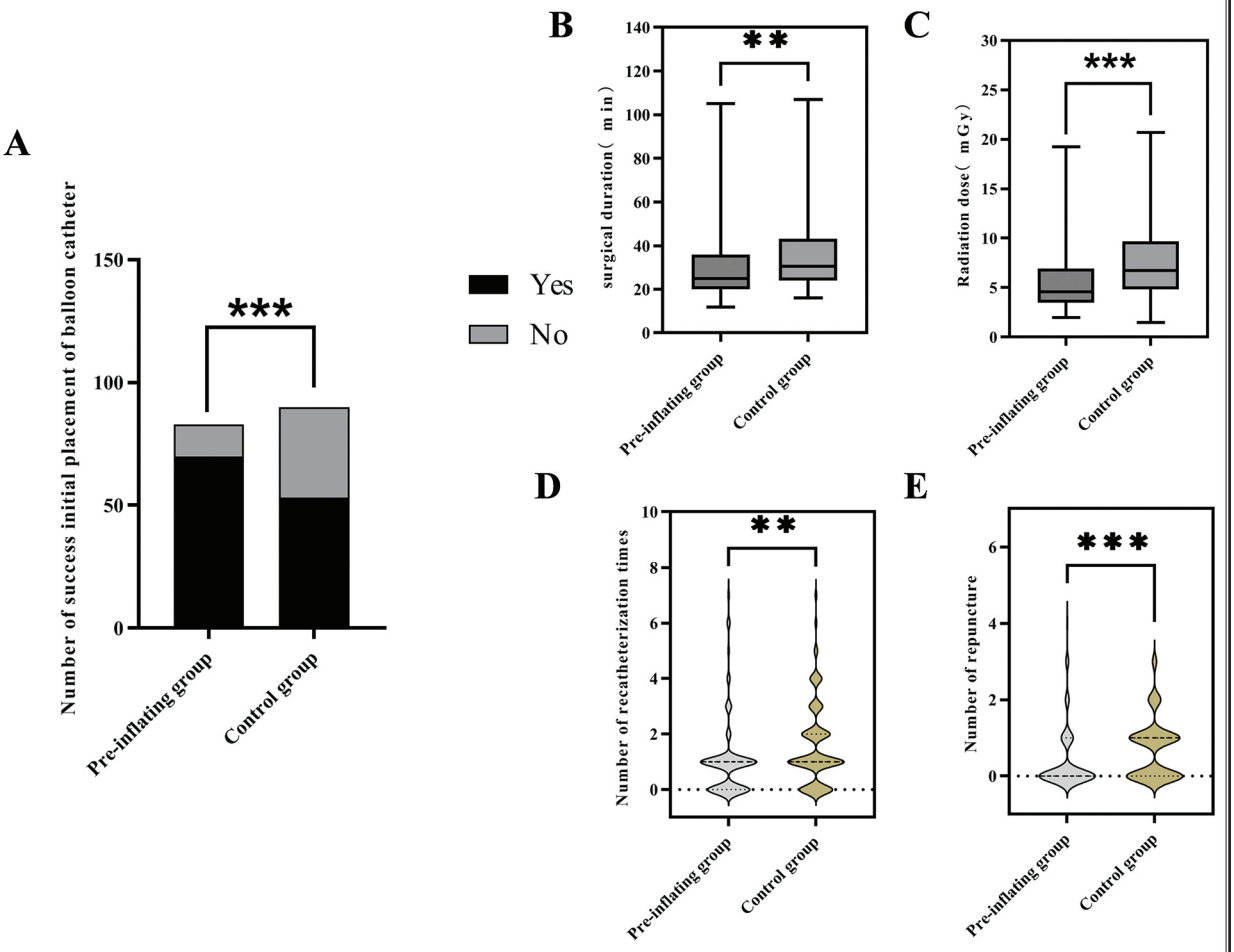



Fig. 4. *(A) The respective proportions of the pre-inflating group and the non-pre-inflating group that achieved the ideal balloon shape on the first puncture and catheter insertion. In the context of failed initial catheter placement, the (B) surgical duration, (C) total radiation dose, (D) number of re-catheterization instances, and (E) number of repeat punctures were compared between the 2 groups.*

the presence of cases with successful initial catheter placement.

The follow-up assessments were conducted immediately postoperatively and subsequently at one-month and 6-month intervals. The treatment outcomes of 369 patients with TN are presented in Table 2. In the pre-inflating group, 169 patients experienced immediate effective pain relief after the PBC procedure, and one patient's pain relief was poor; in the non-pre-inflating group, pain relief was immediate and effective for 197 patients and poor for 2 patients. There was no significant difference in immediate pain relief rate between the 2 groups. There was no recurrence in 369 patients within 6 months after surgery.

The incidence of postoperative complications is shown in Table 3. Facial numbness was the most common complication, occurring in 152 cases (89.4% of the total cases) in the pre-inflating group and 170 cases (85.4% of the total cases) in the non-pre-inflating group ($P = 0.252$). The incidences of facial hematoma, lip herpes, trismus, decreased corneal reflex, and diplopia in the 2 groups were 0% versus 1.5% ($P = 0.305$), 20.6% versus 23.6% ($P = 0.485$), 8.2% versus 9.5% ($P = 0.660$), 0.6% versus 0.5% ($P = 1.000$), and 0.6% versus 1.5% ($P = 0.730$), respectively. Furthermore, no serious complications such as subarachnoid hemorrhage, carotid cavernous fistula, or death were observed in either group. The above results indicate that there was no significant difference in complications between the pre-inflating group and the non-pre-inflating group.

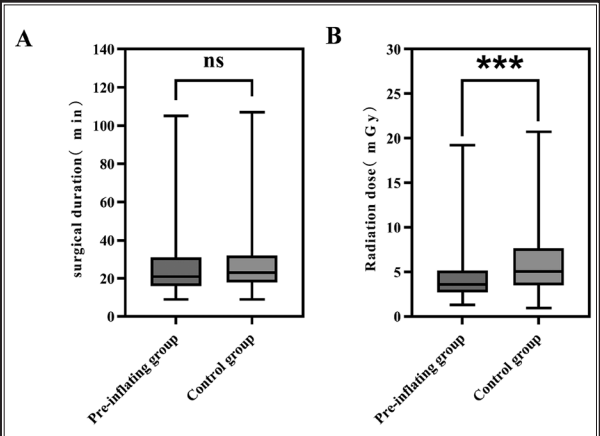



Fig. 5. *(A) The surgical duration experienced and (B) total radiation dose received by all patients in the 2 groups.*

Table 3. *The complications of the 369 patients after PBC.*

| Secondary Outcome | Pre-Inflating Group (n = 170) | Control Group (n = 199) | $X^2$ | *P* value |
|---|---|---|---|---|
| Facial hematoma, n(%) | 0 (0) | 3 (1.5) | 1.053 | 0.305 |
| Herpes labialis, n(%) | 35 (20.6) | 47 (23.6) | 0.4870 | 0.485 |
| Masseter weakness, n(%) | 14 (8.2) | 19 (9.5) | 0.1940 | 0.660 |
| Facial numbness, n(%) | 152 (89.4) | 170 (85.4) | 1.3100 | 0.252 |
| Decreased corneal reflex, n(%) | 1 (0.6) | 1 (0.5) | 0.0000 | 1.000 |
| Diplopia, n(%) | 1 (0.6) | 3 (1.5) | 0.1200 | 0.730 |
| Recrudescence, n(%) | 2 (1.2) | 12 (6.0) | 5.917 | 0.015 |

Table 2. *The outcomes of the 369 patients after PBC.*

| BNI Grade | Pre-Inflating Group (n = 170) | Control Group (n = 199) | *P* value |
|---|---|---|---|
| Baseline | | | 0.127 |
| BNI grades I-III | 0 (0%) | 0 (0%) | |
| BNI grades IV | 44 (25.9%) | 66 (33.2%) | |
| BNI grades V | 126 (74.1%) | 133 (66.8%) | |
| Initial relief | | | |
| BNI grades I-III | 169 (99.4%) | 197 (99.0%) | 1.000 |
| BNI grades IV-V | 1 (0.6%) | 2 (1.0%) | |
| One month | | | |
| BNI grades I-III | 169 (99.4%) | 197 (99.0%) | 1.000 |
| BNI grades IV-V | 1 (0.6%) | 2 (1.0%) | |
| Last follow-up | | | |
| BNI grades I-III | 170 (100%) | 199 (100%) | 1.000 |
| BNI grades IV-V | 0 (0%) | 0 (0%) | |

## Discussion

Our study has shown that the small-dose pre-inflating technique may significantly improve the success rate of re-catheterization during PBC surgery, demonstrating an increase from 58.9% to 84.3% and a reduction in the number of re-catheterizations from 1.59 to 1.08. In addition, this technique contributes to a decrease in both the duration of the procedure and the radiation exposure. It is worth noting that there were no significant differences between the pre-inflating technique and the traditional technique in terms of postoperative pain relief rates and the degree of pain alleviation. Additionally, none of the patients experienced severe complications, including intracranial infection, intracranial hemorrhage, corneal injury, diplopia, or carotid-cavernous fistula. Importantly, facial numbness is a common and often expected side effect of the PBC procedure, since the mechanism of action involves intentional compression of the trigeminal ganglion. Therefore, while we report the complication here for completeness, its high incidence is consistent with the therapeutic goal of the procedure rather than an unforeseen adverse event.

Over 30 years have passed since the introduction of the PBC technology, and its safety, effectiveness, and minimally invasive characteristics have been validated through long-term clinical practice. A retrospective analysis performed by Skirving et al (17) involving 496 patients indicated that the immediate pain relief rate of PBC was 100%, whereas the recurrence rate after 5 years was recorded at 19.2%. The mechanism of PBC surgery primarily involves the use of a balloon to physically compress the trigeminal ganglion, aiming to selectively damage the myelin present in large myelinated fibers, thereby blocking the transmission of pain signals. The trigeminal ganglion, located within the Meckel's cave, is the therapeutic target of this surgery, and effective compression is the core of the surgical procedure. Numerous studies and clinical experiences have indicated that a fully inflated pear-shaped balloon is generally considered ideal in shape. This shape aligns well with the spatial structure formed by the trigeminal ganglion, trigeminal nerve roots, and dural protrusions within the Meckel's cave (18). A pear-shaped balloon may achieve higher pressure. During the inflation

process, the balloon first fills the space within Meckel's cave, then its anterior part protrudes from the trigeminal foramen, forming the pear-shaped head (19,20).

The traditional focus of the PBC procedure has predominantly been on the identification of the foramen ovale and the associated puncture pathway. Although localization and puncture pathways are important sections in the surgical process, we believe that the successful placement of the balloon catheter into the Meckel's cave is the key factor determining the success of the surgery. From the technical perspective, as our comprehension of the local anatomical structures advances and imaging technologies continue to evolve, the challenges associated with the localization and puncture of the foramen ovale have diminished significantly. After an initial learning phase, most surgeons can master the techniques of localization and puncture. Consequently, the precise placement of the balloon catheter into the Meckel's cave has emerged as the core of the PBC procedure.

The Meckel's cave is an evagination formed by the pressure exerted by the trigeminal nerve root on the lateral aspect of the tentorium cerebelli as it approaches the anterior surface of the petrous part of the temporal bone, located below the trigeminal ganglion. The adjacent anatomical structures of the Meckel's cave was shown in Fig. 6A. The structure of the Meckel's cave can be divided into the superior wall, inferior wall, anterior wall, posterior wall, medial wall, and lateral wall. The cavity's anterior and superior walls are adjacent to the posterior venous space of the posterior cavernous sinus, while the lateral wall connects with the dura mater of the medial fossa. The anterior part of the medial wall is adjacent to the posterior cavernous segment of the internal carotid artery. The Meckel's cave extends from the posterior cranial fossa to the posterior medial part of the middle cranial fossa and contains an arachnoid pocket filled with cerebrospinal fluid, which is the trigeminal nerve subarachnoid cistern, an extension of the basal/prepontine cistern of the SAS. Due to the fragility of its structure, it is difficult to preserve and depict the arachnoid layer in gross anatomy. There is currently no consensus on the relationship between the arachnoid and the trigeminal nerve, with the main controversy focusing on the determination of their interface location. The trigeminal nerve root passes

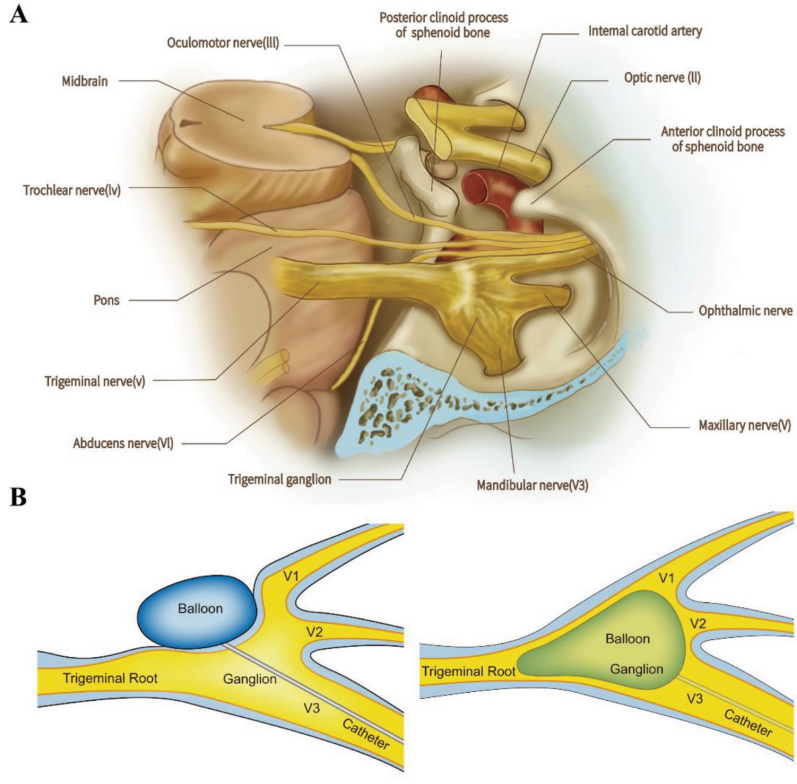



Fig. 6. *(A) The anatomical diagram of the Meckel's cave. (B) A schematic delineating a balloon catheter not placed in the Meckel's cave but fully inflated. When the balloon catheter is fully inflated without being placed in the Meckel's cave, it causes external pressure on the cavity, and at this time, the cerebrospinal fluid is squeezed into the prepontine cistern through the narrow trigeminal porus. This phenomenon will cause the distance between the trigeminal nerve in the Meckel's cave and the surrounding dura to become extremely narrow. The schematic on the right depicts an ideal pear-shaped balloon within the Meckel's cave.*

through the trigeminal porus to reach the posterior cranial fossa (21).

During the inflation of the balloon, effective compression is difficult to achieve while the balloon is located outside the Meckel's cave, between the 2 layers of the dura mater on the lateral wall of the Meckel's cave, and outside the inner/lower wall of the Meckel's cave. As shown in Fig. 6B, when the balloon catheter is not correctly positioned within the Meckel's cave and is subsequently inflated, it exerts pressure on the trigeminal nerve and the adjacent dura mater. This pressure results in the displacement of cerebrospinal fluid from the trigeminal cistern through the trigeminal porous into the prepontine cistern, making it impossible to refill in a short period of time. This phenomenon can be likened to the venturi effect in fluid mechanics (22). Specifically, compared to the internal space of the Meckel's cave, the trigeminal porus and the mouth of the Meckel's cave (MOMS) may be seen as a short and narrow conduit. When external pressure is applied, as the fluid passes through the narrow conduit, the decrease in the cross-sectional area causes an increase in fluid velocity, resulting in a jetting effect that expels a large amount of cerebrospinal fluid. This situation causes the distance between the trigeminal nerve inside the Meckel's cave and the surrounding dura mater to become extremely narrow, making it difficult to achieve the ideal position when reintroducing the balloon catheter.

Regarding the dosage and the morphology assessment of the pre-inflated balloon, we rely mainly on our clinical experience. During the PBC procedure, we observed that in most cases, the position of the balloon in Meckel's cave could be determined based on the shape of the balloon when using 0.1 mL of a contrast agent for pre-inflating. When the dosage of the contrast agent is too low, assessing its position effectively is impossible, while an overly high dosage may lead to the overflow of cerebrospinal fluid. When the balloon is located within the Meckel's cave, its morphology typically presents a more elongated characteristic after pre-inflating, which is due to the structural constraints within the cavity.

### Limitations

This study has several limitations. Firstly, its retrospective and single-center design may introduce selection bias and limit the generalizability of our findings. The assessment of balloon morphology was subjective and reliant on surgeons' experience, which could be a source of variability. We also hope to develop more objective and reasonable assessment tools in the future to improve the efficiency of assessing the balloons' morphology. Secondly, while the sample size is substantial, a larger, prospective, multi-center randomized controlled trial would provide stronger evidence. Finally, the follow-up period of 12 months is sufficient to assess procedural efficiency, but a longer-term follow-up is needed to evaluate any potential impact of the procedure on pain recurrence rates. Furthermore, we acknowledge a potential limitation in the fundamental premise of grouping. Because the control group underwent the "traditional" technique, it is possible that some operators intuitively performed minor, unrecorded adjustments during the initial contrast injection under live fluoroscopy. Such a practice shares similarities with the pre-inflating technique in principle. This potential blurring of techniques between groups might limit the external validity and the measured magnitude of difference between the 2 strategies.

## Conclusion

The low-dose balloon pre-inflating technique significantly improves the success rate of balloon catheter repositioning when the initial balloon morphology is suboptimal during percutaneous balloon compression for primary trigeminal neuralgia. It also reduces the number of repeat punctures and catheterizations, as well as radiation exposure, without compromising immediate pain relief or increasing complication rates. This simple modification enhances surgical efficiency and may be a valuable adjunct to standard PBC procedures.

### Author Contributions

All authors contributed to the conceptualization of the study. Xinghua Jiang designed the study protocol and performed the procedure. Wei Gao acquired and analyzed the data. Wu Di and Wei Zhang created the figures and tables and drafted the manuscript. Yaping Wang and Dingquan Zou revised the manuscript for the intellectual content. All authors approved the final manuscript.

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