Retrospective Study

Meckel's Cave Size Measured by Magnetic Resonance Imaging in the Prognosis of Percutaneous Balloon Compression for Trigeminal Neuralgia

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Background: Percutaneous balloon compression (PBC) is a safe and effective method to treat trigeminal neuralgia. Despite it is known that intraoperative balloon volume is crucial in the prognosis of PBC patients and correlates with Meckel's cave (MC) size, it is a lack of objective and valid criteria for intraoperative balloon volume of PBC.

Objectives: The aim of this study was to evaluate the relationship between the size of MC and the volume of a pear-shaped balloon in improving the prognosis of patients receiving PBC.

Study Design: Retrospective study.

Methods: Patients were divided into 3 groups according to their prognosis, and simple linear regression equations were established separately. Group A was defined as having recurrence. Group B was defined as having no recurrence and a Barrow Neurological Institute facial numbness (BNI-N) score of ≤ 2. Group C was defined as having BNI-N > 2 with no recurrence. Correlation analysis was carried out to determine the association of the intraoperative balloon volume with MC size. We attempted to construct simple linear regression models after verifying that both parameters were in compliance with the requirements of this model.

Results: Until the end of the 6-months follow-up, 60 patients (93.8%) reported no pain, and 4 patients (6.3%) experienced no significant pain relief. Sixteen (25.0%) patients had severe facial numbness, 48 (75.0%) patients had no facial numbness or had only mild numbness. All 3 groups had a significant correlation between balloon volume and MC size. Group A: Balloon volume (cm^3) = -0.371 + 1.883*MC size (R^2 = 0.882); Group B: Balloon volume (cm^3) = 0.110 + 1.274*MC size (R^2 = 0.861); and Group C: Balloon volume (cm^3) = 0.011 + 1.835*MC size (R^2 = 0.857).

Limitations: The main limitation of our study is its observational retrospective nature, and we were unable to further analyze the intraoperative balloon pressure and volume, as well as validate the accuracy of the model. In additional this was a single-center study with a small sample size and a short follow-up period. These may have contributed to the bias in the final results. A multicenter, prospective study with a large sample size should be performed to further investigate the long-term effects of individualized balloon volumes and the correlation between pressures.

Conclusions: The equation [balloon volume (cm^3) = 0.110 cm^3 + 1.274*MC size] yields an appropriate value at which the patient has a low recurrence rate and a low degree of facial numbness. Preoperative measurement of MC size can be used to guide the intraoperative balloon volume and to predict the patient's prognosis.

Key words: Trigeminal neuralgia, percutaneous balloon compression, Meckel's cave, magnetic resonance imaging

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Trigeminal neuralgia is a unilateral disorder characterized by recurrent, brief, shock-like, or stabbing pain. It can be triggered by innocuous stimuli on the face or intraoral trigeminal territory. Trigeminal neuralgia seriously affects the quality of life and can even lead to suicide (1,2). According to epidemiological surveys (3,4), the prevalence of trigeminal neuralgia ranges from 0.012% to 0.3%. Carbamazepine is often suggested in therapeutic guidelines and has been considered the first-choice treatment for the relief of trigeminal neuralgia. However, surgical procedures may be considered when carbamazepine is not effective in pain relief or the drug therapy is discontinued because of side effects (5). Percutaneous balloon compression (PBC) has been widely used in the treatment of trigeminal neuralgia as a safe and effective surgical procedure. It is particularly suitable for patients with recurrent microvascular decompression (MVD) surgery or elderly patients with extensive underlying disease (6-8). Unfortunately, numbness is very common in patients after the PBC procedure (9). This may be due to excessive compression. To achieve pain relief with minimal sensory deficit, individualized intraoperative balloon volumes are necessary.

Anatomically, Meckel's cave (MC) is a diverticulum formed by 2 dural fissures that are located in the middle cranial fossa (10). MC resembles a 3-fingered cavern that contains the trigeminal root, the Gasserian ganglion, and its branches (11). Therefore, MC, an important structure for the PBC procedure, is worth studying. In any case, a pear-like balloon is a parameter that plays an excellent role in outcome (12). However, a pear-shaped balloon alone does not seem to be enough, and balloon volume also has a marked impact on patient outcomes. The intraoperative balloon volume required varies depending on the volume of MC. However, the relationship between the size of MC and the appropriate balloon volume remains unclear.

Therefore, the aim of this study was to collect 3.0T magnetic resonance imaging (MRI) data of patients with trigeminal neuralgia to accurately model MC with Siemens syngo.via (Siemens Healthcare, Erlangen, Germany) and then analyze the relationship between MC size and intraoperative balloon volume in a PBC procedure.

Methods

Study Design

This was a retrospective study to examine the relationship between balloon volume and MC size. In addition to the baseline assessment, the Barrow Neurological Institute pain severity (BNI-P) and Barrow Neurological Institute facial numbness (BNI-N) scores were routinely measured at one day and at one, 3, and 6 months postoperatively. This study has been reported in line with the STROCSS criteria (13). The follow-up period ended in January 2021. The requirement for informed consent was waived because of the retrospective case-control nature of the study.

Setting and Patients

The inclusion criteria were as the follows: a clear diagnosis of trigeminal neuralgia; complete clinical data retention; age of patient ≥ 18 years; no other comorbid chronic headache disorder, such as migraine or tension-type headache; a pear-shaped balloon; and compression lasting 180 seconds. The exclusion criteria were as follows: secondary trigeminal neuralgia; mental disability or psychiatric disorder; having undergone other surgical intervention, such as MVD or radiofrequency; and refusal to participate in the study. Researchers regularly checked surgical records and identified eligible patients. The flow chart of patient selection is shown in Fig. 1.

Grouping Design

Six-four patients were included in this study, and these patients were divided into 3 groups according to BNI-P and BNI-N scores at month 6 (T4) time. Patients with BNI-P > 2 were included in Group A, those with both BNI-P and BNI-N scores of ≤ 2 were included in Group B, and those with BNI-P ≤ 2 but BNI-N > 2 were included in Group C.

Assessment of Pain Intensity

With reference to 'the Chinese expert consensus on the diagnosis and treatment of trigeminal neuralgia' (14), the pain intensity was assessed using the BNI-P scale. In addition to its baseline measurement, the pain intensity was recorded preoperatively (T0), at postoperative day 1 (T1), month 1 (T2), month 3 (T3), and T4. Details are shown in Table 1.

Assessment of Facial Numbness

Facial numbness was assessed using the BNI-N scale. The BNI-N score was tested at day 1and at T1, T2, T3, and T4. Details are shown in Table 2.

Meckel's Cave Measurement

Cranial 3.0T MRI was performed on Siemens equipment (equipment models: Prisma, GE750, GE75W). The data were transferred to Siemens syngo.via for the reconstruction of MC to obtain MC size. After the MRI images were processed using slap maximum intensity projection, the MC was manually plotted and modeled in the transverse section planes after confirmation of the MC edge, and finally there was software to calculate the volume and the specific morphology. The reconstruction was carried out by 2 independent practitioners, and the final result was the mean of the 2 calculations. Measurement of MC is shown in Fig. 2.

Surgical Technique

After successful general anesthesia, the patient was placed in the supine position with the head slightly tilted back. The needles were punctured into the foramen ovale at the intersection of the vertical line of the outer orbital margin and the labial line, according to the Hartel anterior approach (15). The anterior-posterior projection of the puncture path was the line between a puncture point and the pupil of affected side, and the lateral projection was the line between a puncture point and the affected anterior external auditory canal. After evacuation of air from the balloon, the balloon was placed into MC under C arm or digital subtraction angiography guidance. Subsequently, the balloon was slowly filled with an iohexol contrast agent (16). On a lateral view of the skull, the surgeons determined the position and shape of the balloon and adjusted the balloon position according to the lateral view until a standard pear shape appeared for optimal results. When the pear-shaped balloon appeared, continuous compression was applied for 180 seconds (Fig. 3). After compression, the contrast was drained to remove the

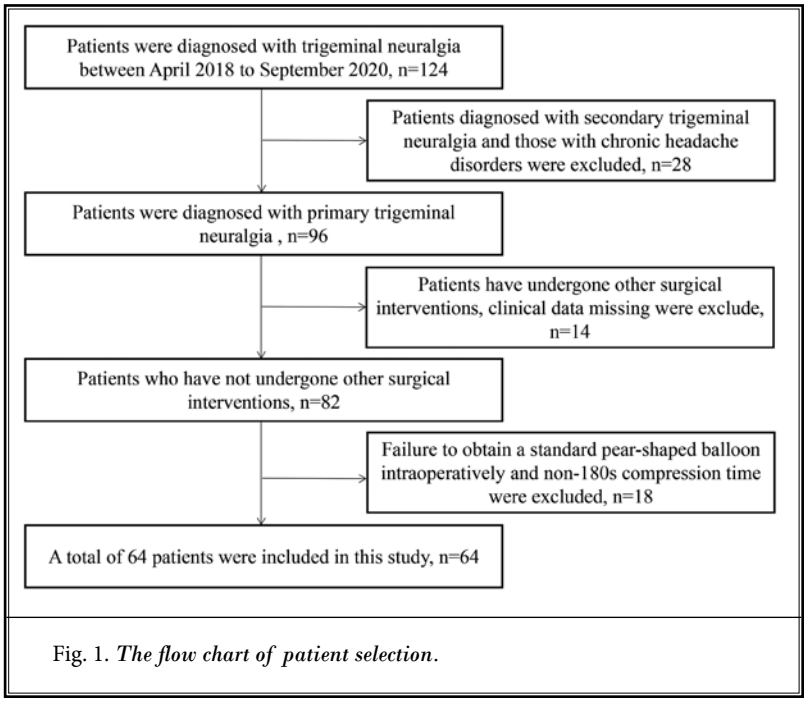

Fig. 1. *The flow chart of patient selection.*

Table 1. *BNI-P scoring system.*

Pain Intensity Grade	Definition
I	No pain, no medication
II	Occasional pain, no medication required
III	Some pain, adequately controlled with medication
IV	Some pain, not adequately controlled with medication
V	Severe pain/no pain relief

BNI-P, Barrow Neurological Institute pain severity.

Table 2. *BNI-N scoring system.*

Numbness Intensity Grade	Definition
I	No facial numbness
II	Mild facial numbness, not bothersome
III	Facial numbness, somewhat bothersome
IV	Facial numbness, very bothersome

BNI-N, Barrow Neurological Institute facial numbness

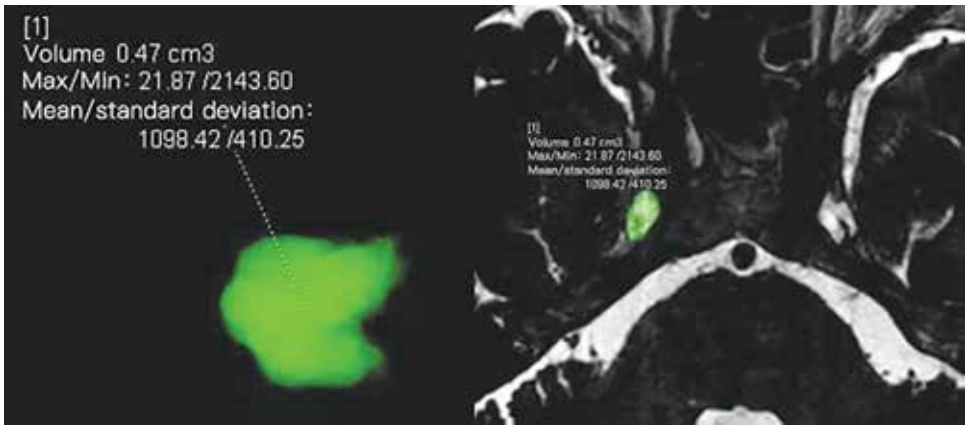

Fig. 2. *MC measurement process.*

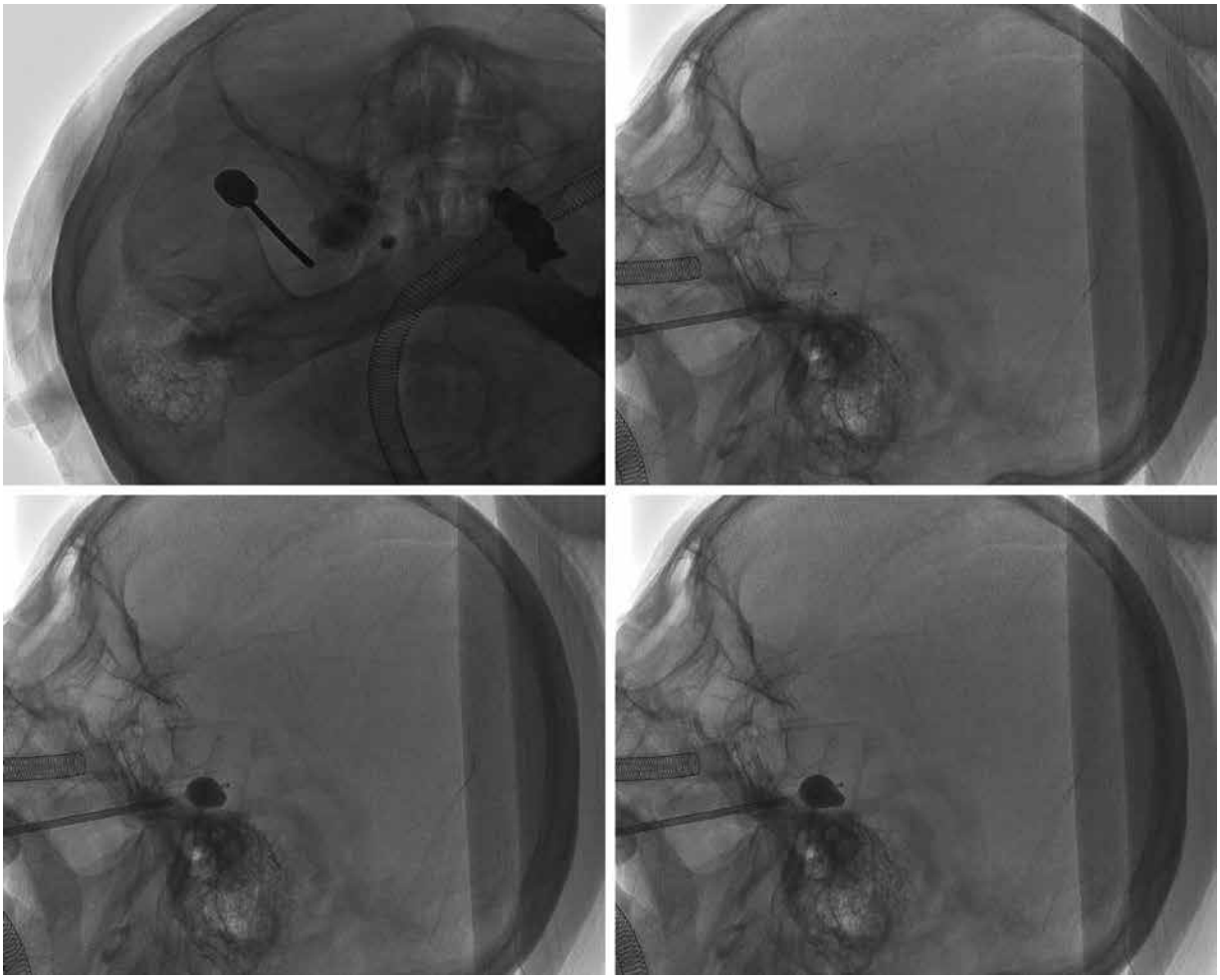

Fig. 3. *Presentation of the pear-shaped balloon on the lateral view.*

compression on the ganglion. Then, the catheter and puncture needle were withdrawn, and the puncture site was compressed for approximately 5 minutes. The volume of the injected contrast agent was recorded as the intraoperative balloon volume. Patients were also closely monitored for changes in vital signs during the perioperative period to prevent dramatic hemodynamic fluctuations. After the procedure, the patients were monitored for 6 hours and discharged after being determined to be free of risk. Postoperatively, patients were instructed to perform functional exercises for the masticatory muscles. Postoperative pain scores and side effects were recorded. In the case of "delayed remission," appropriate glucocorticoids were used.

Follow-up

Patients were routinely followed-up until 6 months postoperatively. The BNI-P score was used to assess the degree of pain, and the BNI-N score was used to assess facial numbness. The scores were measured at T0, T1, T2, T3, and T4. Preoperative and postoperative information was obtained from a review of medical records and questionnaires. Postoperative follow-ups were carried out in the outpatient department or by telephone with an independent doctor. All patients were followed-up for 6 months without consideration of recurrence. In this study, the surgery, follow-ups, and data analyses were carried out independently, with no communication between personnel.

Statistical Analysis

Date analysis was performed with SPSS software (Version 24.0) (IBM Corporation, Armonk, NY). All variables were examined for normal distribution. The measurement data are expressed as the mean ± standard deviation (SD). The enumeration data are expressed as percentages. The Shapiro-Wilk test was used to analyze the overall distribution of the data. Generalized estimating equations were used to analyze the BNI-P and BNI-N scores at different time points. Analysis of variance was performed on the balloon volume and MC size, and the Durbin-Watson test for independence was also conducted. The Pearson correlation coefficient test was performed for variables with a normal distribution. The statistical significance level was set at $P < 0.05$.

Results

Characterization of the Study Population

The clinical data of 124 patients suffering from trigeminal neuralgia were examined. A total of 60 patients were excluded from the study based on the rules of inclusion and exclusion. Finally, 64 patients were included in our retrospective study. The mean age was 62 years (range, 42-89 years), and most of the patients were women. The demographic and clinical characteristics of the patients are shown in Table 3.

Clinical Outcomes

In our study, the efficacies at the different time points were 92.2%, 96.9%, 95.3%, and 93.8% (BNI-P score of ≤ 2), respectively. Five patients (7.8%) had no significant pain relief one day after surgery, and 4 of them reported the disappearance of pain one week postoperatively. Facial numbness was the most common side effect, and on the first postoperative day, only 2 patients did not develop facial numbness, and one of them had recurrence. The prevalence of facial numbness at all time points was 96.9%, 96.9%, 93.8%, and 92.2%, respectively. At the end of the 6-month follow-up, 16 patients still reported BNI-N ≥ III. The recurrence rate was significantly lower than that reported

Table 3. *General demographic information and clinical profile of the patients*

General Information				
	Group A	**Group B**	**Group C**	***P* value**
Age (mean ± SD, y)	54 ± 7	63 ± 11	60 ± 11	0.236
Gender (men/women)	2/2 (50/50)	18/26 (40.9/59.1)	6/10 (37.5/62.5)	1.000
Pain Area				
Side (left/right)	1/3 (25/75)	18/26 (40.9/59.1)	2/14 (12.5/87.5)	0.085
I	0 (0)	2 (4.5)	0	/
II	2 (50)	15 (34.1)	4 (25)	
III	0	6 (13.6)	2 (12.5)	
I + II	0	7 (15.9)	2 (12.5)	
II + III	2 (50)	13 (29.5)	6 (37.5)	
I + III	0 (0)	0 (0)	1 (6.25)	
I + II + III	0 (0)	1 (2.2)	1 (6.25)	
Preoperative Pain Severity				
BNI-P Grades I-II	0	0	0	1.000
BNI-P Grades III-V	4 (100)	44 (100)	16 (100)	

BNI-P, Barrow Neurological Institute pain severity

in previous studies (17). In contrast, the prevalence of facial numbness was 92.2%, and the proportion of severe facial numbness was 25%, higher than previous studies (18). The patients' postoperative pain relief and facial numbness are shown in Table 4.

The Relationship Between MC Size and Balloon Volume

In Fig. 4, we show the relationship between balloon volume and MC size for each of the 3 groups. Our findings suggest that the relationship between balloon volume and MC size is an important indicator of the prognosis of patients undergoing PBC. The ratio of balloon volume/MC size for each group was defined as the compression coefficient. In Table 5, we show the balloon volume, MC size, and compression coefficient for each group. There was no statistical difference between the balloon volumes of the groups ($P > 0.05$) and they were 0.61 cm^3 in Group A, 0.67 cm^3 in Group B, and 0.61 cm^3 in Group C. There was a statistical difference between the MC sizes of the groups ($P < 0.05$) and they were 0.52 cm^3 in Group A, 0.44 cm^3 in Group B, and 0.32 cm^3 in Group C. There was a statistical difference between the balloon volume compression coefficients of the groups ($P < 0.05$) and they were 1.16 in Group A, 1.54 in Group B, and 1.87 in Group C. In all 3 groups, the balloon volume and MC size were normally distributed; and therefore, the Pearson correlation test was used to analyze the correlation between the 2. The results showed a significant positive correlation between balloon volume and MC size in Group A ($r = 0.960$, $P < 0.05$), Group B ($r = 0.930$, $P < 0.05$), and Group C ($r = 0.931$, $P < 0.05$). At the same time, we verified the independence, homogeneity of variance, and linearity characteristics, and after confirming that they were consistent with the characteristics of the simple linear regression model, we attempted to construct simple linear regression models for the 3 groups and finally concluded the following: Group A: Balloon volume (cm^3) = -0.371 + 1.883*MC size ($R^2 = 0.882$); Group B: Balloon volume (cm^3) = 0.110 + 1.274*MC size ($R^2 = 0.861$); and Group C: Balloon volume (cm^3) = 0.011 + 1.835*MC size ($R^2 = 0.857$).

Discussion

PBC has been a safe and effective option for the treatment of trigeminal neuralgia for over 30 years since it was first used by Mullan et al (16) and Lichtor et al (19). For the most part, PBC is usually applied as

Table 4. *Outcomes of the BNI-P and BNI-N scores at the various postoperative time points.*

	General Population		Group A		Group B		Group C	
Time	BNI-P (mean ± SD)	BNI-N (mean ± SD)	BNI-P (mean ± SD)	BNI-N (mean ± SD)	BNI-P (mean ± SD)	BNI-N (mean ± SD)	BNI-P (mean ± SD)	BNI-N (mean ± SD)
T0	4.44 ± 0.07	1.00 ± 0.00	4.50 ± 0.58	1.00 ± 0.00	4.37 ± 0.62	1.00 ± 0.00	4.63 ± 0.50	1.00 ± 0.00
T1	1.28 ± 0.11	3.47 ± 0.07	4.75 ± 1.50	2.50 ± 0.58	1.33 ± 0.97	3.40 ± 0.49	1.06 ± 0.25	3.94 ± 0.25
T2	1.13 ± 0.07	3.23 ± 0.08	2.50 ± 1.73	2.00 ± 0.00	1.05 ± 0.21	3.11 ± 0.58	1.00 + 0.00	3.88 ± 0.34
T3	1.20 ± 0.08	2.73 ± 0.10	3.00 ± 1.41	1.75 ± 0.50	1.09 ± 0.29	2.50 + 0.70	1.06 ± 0.25	3.63 ± 0.50
T4	1.33 ± 0.11	2.14 ± 0.11	4.50 ± 0.58	1.50 ± 0.58	1.14 + 0.35	1.73 ± 0.45	1.06 + 0.25	3.44 ± 0.51
Statistics	1434.462	1329.597	36.000	44.000	1307.819	1280.296	954.667	2434.268
P value	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

BNI-P, Barrow Neurological Institute pain severity; BNI-N, Barrow Neurological Institute facial numbness; SD, standard deviation

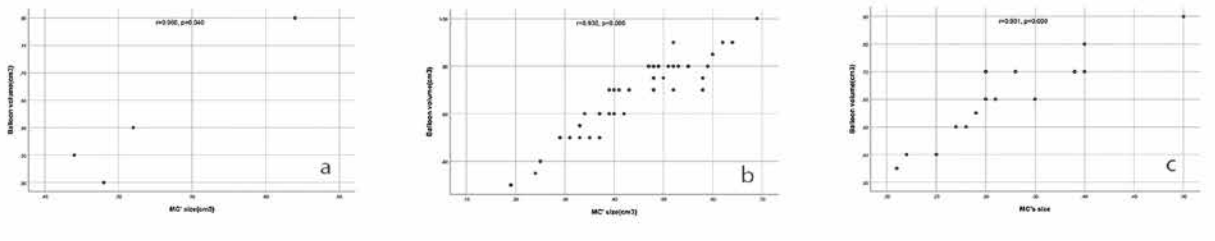

Fig. 4. *Relationship between MC size and balloon volume in group A (a), group B (b), and group C (c).*

an option for recurrence after other procedures, such as MVD or gamma knife radiosurgery (20,21). In fact, it is not the total efficacy rate of PBC that confuses painologists, but rather, its serious side effects. Severe facial numbness, in particular, is not recovered by local functional exercises, as in the case of side effects, such as masticatory muscle weakness, and is likely to stay with the patient for a long time, seriously affecting their quality of life (15). In our study, the effective relief rate for PBC was 93.8%, and the incidence of severe facial numbness was 25%. The recurrence rate was much lower than that in the previous literature, probably because of the longer duration of compression and the inclusion of only patients with pear-shaped balloons in our investigation (22,23). Additionally, this explains the higher rate of severe facial numbness in this study (24).

The key to successful PBC is effective compression of the Gasserian ganglion and nerve root (25). Balloon shape can help to predict whether effective compression is being performed. There is little doubt that the pear-shaped balloon is the most important factor affecting prognosis (26,27). In addition, balloon pressure is also an essential factor. A pressure less than 600 mmHg may be ineffective, and the target intraluminal balloon pressure may vary in the range of 1099 to 1309 mmHg. In some of the relevant literature (28-30), it has been reported that the maximum balloon pressure is almost twice as high as the minimum pressure, both of which achieve a standard pear-shaped balloon during surgery (25,30). However, pressure monitoring is not routinely performed by the surgeons. This can cause inappropriate intraoperative balloon pressures and ultimately lead to recurrence or serious side effects in the patient. At present, the use of balloon volume instead of balloon pressure seems to be a more feasible option. With the development of imaging technology, 3.0T MRI is routinely used in the preoperative management of trigeminal neuralgia to rule out the secondary trigeminal neuralgia due to its noninvasive, multisequence, multiparametric imaging, and high soft tissue resolution; therefore, this approach does not add to the financial burden of the patients. The measurement of MC size also does not require additional equipment and can be carried out with Siemens syngo.via or 3-dimensional slicer software (31). We can even estimate MC size by following simple formula: $y(mm^3)$ = -387.05 + 29.21*length + 26.30*width + 29.58*height + 31.64*gender (men = 0, women = 1). The distance between the front wall and the back wall of MC is defined as the length. The distance between the inner wall and the outer wall of MC is defined as the width. The distance between the upper wall and the lower wall of MC is defined as the height (32). Using this prediction formula, we can estimate MC size and guide intraoperative individualization of the balloon volume by simply measuring Meckel's length, width, and height on a 3.0T MRI trigeminal nerve thin-section scan.

Table 5. *Intraoperative balloon volume and MC size.*

	Balloon Volume	MC Size	Compression Coefficient
Group A	0.61 ± 0.13	0.52 ± 0.07	1.16 ± 0.11
Group B	0.67 ± 0.15	0.44 ± 0.11	1.54 ± 0.13
Group C	0.61 ± 0.15	0.32 ± 0.08	1.87 ± 0.18
Statistics	1.188	9.755	48.230
P value	0.312	0.000	0.000

MC, Meckel's cave

Although there is clearly a relationship between balloon volume and MC size, it has rarely been reported on this topic. Individualized balloon volumes do not seem to have attracted much attention since it was proposed (33). In the present study, we found no statistical difference between groups in balloon volume; whereas, there was a statistical difference between MC size and compression coefficient. The possible reason for this is that during PBC, the clinician's "feel" may not be reliable and most balloon volumes fluctuate within a fixed range; whereas, MC anatomy is more variable and the difference in the final ratio between the 2, i.e., the compression coefficient, may be a factor contributing to the different prognosis of patients. Our study suggests that in clinical practice, MC images can be obtained preoperatively by cranial 3.0T MRI, followed by post-processing or a simple formula to obtain MC size, and finally filling the balloon based on the formula [balloon volume (cm^3) = 0.110 + 1.274*MC size] to alleviate side effects associated with excessive compression (using this model presupposes a pear-shaped balloon and a compression time of 180 seconds).

Limitations

The main limitation of our study is its observational retrospective nature, and we were unable to further analyze the intraoperative balloon pressure and volume, as well as validate the accuracy of the model. Additionally, this was a single-center study with

a small sample size and a short follow-up period. These may have contributed to the bias in the final results. A multicenter, prospective study with a large sample size should be performed to further investigate the long-term effects of individualized balloon volumes and the correlation between pressures.

Conclusions

From the available evidence, PBC is an effective, minimally invasive technique for trigeminal neuralgia with a high rate of pain relief. Preoperative measurement of MC size is a potential indicator of balloon volume in the standard pear-shaped balloon situation.

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