Predictors of response for percutaneous balloon compression for the treatment of recurrent trigeminal neuralgia following surgical procedures: a retrospective study

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Abstract
Recurrent trigeminal neuralgia (TN) after surgical procedures can be rather difficult to treat, and standardized treatment measures are not available yet. It is unclear whether percutaneous balloon compression (PBC) can be used as the preferred surgical treatment for postoperative recurrent TN. To determine the efficacy of PBC and identify the predictors of response of PBC for the treatment of recurrent TN following TN-related surgeries, we retrospectively collected and analyzed the data of patients with recurrent TN following surgical treatments who underwent PBC under three-dimensional computed tomography (3D-CT) guidance at the Department of Pain Management of Beijing Tiantan Hospital, Capital Medical University from January 2018 to January 2022. We found, within 1 month after PBC, that the total efficacy of PBC on recurrent TN following TN-related surgeries was 86.7%. Based on the effectiveness of PBC 1 month postoperatively, patients were divided into the effective group (130, 86.7%) and the ineffective group (20, 13.3%). Fourteen (10.8%) patients in the effective group had undergone RFT before, which was significantly lower than that in the ineffective group (6, 30%, \(p=0.02\)). Multivariate logistic regression analysis showed that previous RFT alone (OR = 0.20, 95%CI 0.06–0.66, \(P=0.01\)) was an independent predictor of the negative response of PBC. Thus, PBC was found to be a moderately effective and safe treatment for recurrent TN after TN-related surgery. However, previous RFT procedures may predict a slightly worse outcome after PBC.

Keywords Percutaneous balloon compression · Recurrent trigeminal neuralgia · Efficacy · Prediction

Background
It is well known that there is a wide range of medical and surgical treatment options available for trigeminal neuralgia (TN) [1, 2]. Pharmacotherapy, such as carbamazepine is generally the mainstay of treatment of TN. However, for those patients refractory to drug therapy, surgical strategies, including microvascular decompression (MVD), partial sensory rhizotomy (PSR), radiofrequency thermocoagulation (RFT), percutaneous balloon compression (PBC), gamma knife radiosurgery (GKRS), and glycerol rhizotomy (GR), are effective alternatives [3].

Unfortunately, each surgery results in a certain number of recurrences. A meta-analysis based on 8172 surgery patients proved that the pooled recurrence rate was 9.6% for MVD, 12.4% for PSR, 11.9% for RFT, 12.3% for PBC, and 20.9% for GKRS [4]. Another study described that acute pain relief (APR) after GR was 73%, and the pain recurrence rate of GR was 21% within 5 years [5]. Recurrent TN after surgeries often have long-term, repeated severe pain, which may easily cause anxiety and depression and can even exert a negative impact on the quality of life [6]. However, the management of recurrent TN remains difficult and has not been standardized. Furthermore, it is essential to differentiate between true recurrent trigeminal neuralgia and postoperative dysesthiasias observed after the previous lesionectomy since postoperative dysesthiasias could be exacerbated by ablative procedures such as PBC.

PBC has been acknowledged as alternative extensively used to treat TN patients with a relatively high pain relief

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rate [7, 8]. Some centers also reserve PBC for patients who suffer recurrence following previous surgical procedures [9–11]. Inversely, some scholars consider PBC to be less effective in recurrent patients who have previously been treated with other surgical procedures [12, 13]. However, the sample from the above-mentioned studies was relatively small, and the pieces of evidence were inconclusive. It is not clear whether the analgesic effect of PBC on recurrent TN is worse than that of initial PBC. Additionally, there is a rare specific study to confirm the potential prognostic factors which can be used before PBC to preoperatively predict the pain-free outcomes of recurrent patients. Therefore, the objective of this study was to determine the efficacy of PBC and identify the predictors of response of PBC for the treatment of recurrent TN following surgical treatments through a clinical study with a relatively large number of cases.

Methods and analysis

The study protocol was approved by the Medical Ethics Committee of Beijing Tiantan Hospital, Capital Medical University before the retrospective collection of patients data. Written informed consent from patients was exempted. The authors vouch for the accuracy of the data. This retrospective study analyzed the data of patients with recurrent TN following surgical treatments who underwent PBC at the Department of Pain Management at Beijing Tiantan Hospital, Capital Medical University, from January 2018 to January 2022. Demographic and perioperative data were retrieved from hospital information systems (HIS) medical records and follow-up data were collected from electronic records. Patients who met the following criteria were eligible for the study: (1) age > 18 years; (2) diagnosed with TN in accordance with the third version of the International Classification of Headache Disorders (ICHD-3) [14]; (3) undergoing PBC operations; (4) history of previous surgeries for TN such as MVD, PSR, RFT, PBC, GKRS, GR, etc. The exclusion criteria were as follows: (1) bilateral TN; (2) diagnosis of secondary trigeminal neuralgia; (3) failure of puncture during PBC procedure; (4) atypical pear balloon shape; (5) patients with incomplete baseline data or follow-up data.

Surgical technique

All procedures were conducted by experienced physicians. Under general anesthesia, surgery by laryngeal mask airway (LMA) was performed on the computed tomography (CT) scanning table with the patient in a supine position. Blood pressure (BP), heart rate (HR), electrocardiogram (ECG), oxygen saturation, and respiratory rate (RR) were continuously monitored. Atropine was used to treat bradycardia and unstable BP. The procedure was guided by 3D-CT. The point of entry into the skin was located approximately 2.5 cm lateral to the angle of the mouth. First, a 14-gauge tipped cannula was advanced parallel to the sagittal plane to avoid penetration of the oral mucosa. Based on the surgeon’s clinical experience, the cannula was advanced less than 7 cm, where the tip reached near the basal part of the mid-cranial fossa. Then, a CT scan was performed. And on a dedicated workstation (GE AW VolumeShare 2, version aw4.4, Wisconsin, USA), automatic 3D reconstruction of the skull was completed in seconds to determine the exact location of the cannula and the foramen ovale (FO). According to its spatial relationship with the FO, the position of the cannula was adjusted until the needle had entered the FO. When the cannula was properly positioned, the stylet was withdrawn, and a disposable balloon catheter (QKS-1850567, Shenzhen Shineyard Medical Device Co.Ltd.) with a guiding wire was inserted into the cannula and then into the Meckel’s cave. When the end of the balloon catheter passed the end of the cannula by approximately 1 cm, the guide wire was removed and 0.3–0.5 ml of non-ionic contrast agent (Omnipaque) was slowly injected into the balloon catheter to inflate the balloon. The balloon appeared to form the shape of a pear when positioned correctly beyond the FO. If satisfactory position or shape was not obtained, the balloon was deflated, the catheter was withdrawn, and the cannula was set back and readjusted according to the CT images. After visual confirmation, the balloon was correctly positioned, and a total volume of 0.3–0.8 ml of contrast agent was injected to compress the nerve. The balloon compression lasted between 1.5 and 3 min, based on the doctor’s surgical experience [15]. After compression, the balloon was deflated and withdrawn. Then, anesthesia was stopped. After emergence from anesthesia and removal of LMA, patients were sent for post-anesthesia care (Fig. 1).

Data collection and analysis

Preoperative, intraoperative, and postoperative data from HIS and department follow-up database were collected. Preoperative data included the following: age, gender, body mass index (BMI, weight in kilograms divided by the square of height in meters), comorbidities such as hypertension, diabetes mellitus (DM), heart disease, stroke, duration of disease (length of history before PBC), time to recurrence, baseline numerical rating scale (NRS) scores (0: no pain; 10: the most imaginable severe pain); carbamazepine dose pre-PBC, pain laterality (right/left), distribution of pain, history of previous surgeries for TN (such as MVD, PSR, RFT, PBC, GKRS, GR, etc.), the number of previous surgeries, Barrow Neurological Institute (BNI) facial hypesthesia scale after the last surgery (class I: no facial numbness; class II: mild facial numbness and not bothersome; class III: facial numbness and somewhat bothersome; class IV: facial numbness and
numbness and very bothersome). Intraoperative details of the PBC procedure, such as vital signs fluctuation, including trigeminal cardiac reflex, operation duration, balloon shapes, compression time, balloon volume, intraoperative complications, and side effects were all collected. The postoperative data included the NRS score immediately after PBC and postoperative complications or side effects. The effective rate was defined as cases with a reduction in pain intensity (NRS) > 50%/total number of cases*100% within 1 month. According to whether it is effective within 1 month after PBC, the patients were divided into the effective group and the ineffective group. To improve clinical efficacy and safety, routine follow-ups were done on day 1, week 1, week 2, month 1, month 3, month 6, and 1 year postoperatively. Information on pain recurrence after PBC was collected from outpatient visits, WeChat, or telephone calls. Postoperative complications such as herpes simplex, maseter weakness, facial numbness, facial swelling, diplopia, corneal anesthesia, infection or hematoma at puncture sites, intracranial hemorrhage, or intracranial infection were collected. Once another surgical procedure was performed for recurrent or refractory TN after PBC, patient follow-up was stopped.

Statistical analyses

IBM SPSS Statistics version 24 was used for statistical analyses. The patient data were assessed for normality using the Kolmogorov–Smirnov test. Continuous data following normal distributions were presented as means ± standard deviations (SDs) and were analyzed using a t-test. Non-normally distributed continuous data were shown as medians and ranges and analyzed by Mann–Whitney U test or Kruskal–Wallis H test for intergroup comparisons. For categorical data, numbers (percentages) were calculated, and the chi-squared test or Fisher’s exact was used to compare groups. To identify the independent risk factors associated with the efficacy of PBC following TN-related surgeries, potentially significant variables with P-values < 0.20 in the univariate comparison analysis were further analyzed by multivariate logistic regression. A two-sided p-value < 0.05 was considered statistically significant. A two-sided p-value < 0.05 was considered statistically significant.

Results

Preoperative data of the patients enrolled

Between January 2018 to January 2022, 151 patients with recurrent TN underwent CT-Guided PBC at the department of pain management. One patient who had the characteristic atypical pear-shaped balloon was excluded. Five patients (3.3%) had a history of allergy to carbamazepine. The other 145 patients were either refractory or intolerant to carbamazepine. Detailed characteristics of the 150 enrolled patients are shown in Table 1. The median age (range) was 66 (from 36 to 87) years, with a median disease duration (length of history before PBC) of 7 years. A total of 58.7% patients underwent right-lateralized pain.

Comparison of the data between the effective group and the ineffective group

According to the response 1 month after PBC treatment, the 150 patients were divided into 2 groups. A total of 130 (86.7%) patients were in the effective group, and 20 (13.3%) patients were in the ineffective group. The univariate comparison of exposure factors between the effective group and the ineffective group is shown in Table 2.
were no significant differences in aspects of age, gender, BMI, comorbidities, duration of disease, time to recurrence, baseline NRS score, carbamazepine dose pre-PBC, right laterality, distribution of pain, and BNI facial hypesthesia scale after the last surgery between the two groups. Fourteen (10.8%) patients in the effective group only experienced pain relief within one month after PBC (Table 3). The total efficacy of PBC on recurrent TN following TN-related surgeries was 86.7%. The efficacy of PBC after MVD alone, PBC alone, RFT alone, GKRS alone and GR alone was 90.9%, 77.8%, 70.0%, 92.9% and 83.3%, respectively. Besides, 88.9% patients underwent no less than 2 surgeries before achieving pain relief within one month after PBC (Table 3).

### Multivariate regression analysis for recurrent TN outcome after PBC

Multivariate logistic regression analysis was carried out to identify the predictor of PBC therapeutic effect on recurrent TN following surgical procedures (Table 4). Risk factors with P-values < 0.2 (right laterality, previous MVD alone, previous RFT alone) in univariable comparison analysis were selected for multivariate regression analysis. The multivariate analysis revealed that previous RFT alone was a significant predictor of poor outcome for recurrent TN following PBC (OR = 0.20, 95%CI 0.06–0.66, P = 0.01) (Table 4).

### Complications

Among the 20 patients who failed to respond to PBC, two underwent GKRS at 4, 5 weeks after PBC at other hospitals. The remaining 18 patients underwent RFT at our hospital. All of the 20 patients got satisfactory pain relief after GKRS or RFT.

There were no significant differences in the incidence of trigeminal cardiac reflex, operation duration, balloon volume, compression time, herpes simplex, and diplopia between the two groups. Patients developed herpes simplex
on postoperative days 2–3, and the symptom lasted for 1 week. None of the patients in this study had facial swelling, corneal anesthesia, infection, hematoma at the puncture site, intracranial hemorrhage, intracranial infection, or death. Forty-five patients (34.6%) suffered masseter weakness in the effective group, and 2 (10.0%) suffered that in the ineffective group ($P = 0.04$, Table 3). In addition, 119 (91.5%) patients developed facial numbness in the effective group compared to 4 (20.0%) in the ineffective group ($P = 0.00$, Table 3).

### Discussion

The main finding of the present study is that the total pain relief rate within 1 month after PBC under 3D-CT guidance for recurrent TN following surgical procedures was 86.7%,
which was significantly lower than that of PBC for refractory TN in our previous study (95.7%) [16]. This result showed that previous surgical treatments may reduce the chance of pain relief and increase the failure rate. There were several small case series studies reporting the pain relief rate of PBC guided by C-arm for the treatment of recurrent TN. To be specific, in Fan et al.’s study, a total effective rate of 91.7% was observed after PBC in 121 recurrent TN patients following MVD, RFT, PBC, or GKRS [11]. Montano et al. reported that only 81.81% of patients obtained an APR after PBC in 22 patients suffering from one or more procedures before [17], which was much lower than those not following other surgical procedures. Similarly, Omeis et al. reported that PBC had an 83% pain relief in a series of 29 relapsing patients after other surgical procedures [18]. One of the reasons why the effective rate varied in these reports was that the proportion of previous surgical procedures for participators varies. Different types of previous surgical procedures may have had different effects on the treatment of PBC for recurrent TN. Xu et al. reported that the efficacy of PBC for patients with recurrent TN after MVD was 92.9% [9]. Our results demonstrate that, after MVD alone, the effective rate of patients receiving PBC was 90.9%, which was consistent with Xu et al.’s study [9]. Unlike Chen et al.’s report, in which the effective rate of PBC after MVD was only 81% [4]. We also found that, after repeated PBC alone, only 7 patients (77.8%) who had undergone previous PBC experienced pain relief within 1 month. Chen et al. reported that of the 32 patients with recurrent TN after PBC, 30 (93.8%) were immediately relieved of their neuralgia after repeated PBC [10]. The efficacy of the present study was inferior to Chen et al.’s report [10]. Of course, the number of patients who underwent repeated PBC in this study was only 9, so our results need to be further confirmed.

In the present study, failure of a puncture during PBC procedure or procedures with atypical pear balloon shape were excluded. Hence, we suspect a higher failure rate of PBC in patients whose therapeutic target is the semilunar ganglion for recurrent TN after TN-related surgeries, which may also be related to the once-damaged local structure of semilunar ganglion during previous surgical procedures. Unfortunately, the specific mechanism of lower analgesic efficacy of PBC for recurrent TN following surgical procedures was uncertain to date, which needs to be further confirmed by conducting animal experiments.

Although a sizable body of studies demonstrated the importance of objective clinical predictors of curative effect, the selection of recurrent TN patients undergoing previous surgeries for PBC was still subjective. To our knowledge, there was fewer objective scale established for the prediction of recurrent TN patients following PBC. Therefore, this is the first study of its kind with a relatively large number of cases to propose predictive factors of PBC therapeutic efficacy for recurrent TN. In our study, among preoperative data such as age, gender, BMI, comorbidities, duration of disease, time to recurrence, baseline NRS score, carbamazepine dose pre-PBC, affected side of TN, distribution of pain, history of previous surgeries, and BNI facial hypesthesia scale after the last surgery, we found that only previous RFT was an independent variable to predict PBC therapeutic efficacy for recurrent TN.

### Table 3 Operation variables, efficacy, and complications

| Variable                              | Effective group | Ineffective group | P  |
|---------------------------------------|----------------|------------------|----|
| Number, no. (%)                       | 130 (86.7%)    | 20 (13.3%)       |    |
| Trigeminal cardiac reflex during operation, no. (%) | 48 (36.9%) | 9 (45.0%)       | 0.49 |
| Operation duration, mean ± SD (min)   | 24±6           | 25±4             |    |
| Balloon volume, mean ± SD (ml)        | 0.61±0.12      | 0.58±0.09        | 0.29 |
| Compression time, mean ± SD (s)       | 101±14         | 97±15            | 0.24 |
| The NRS score immediate after PBC, median (range) | 2 (0, 4) | 7 (6, 8)       | 0.00 |
| Complications, no. (%)                |                |                  |    |
| Herpes simplex, no. (%)               | 17 (13.1%)     | 1 (5.0%)         | 0.51 |
| Masseter weakness, no. (%)            | 45 (34.6%)     | 2 (10.0%)        | 0.04 |
| Facial numbness, no. (%)              | 119 (91.5%)    | 4 (20.0%)        | 0.00 |
| Diplopia, no. (%)                     | 6 (4.6%)       | 1 (5.0%)         | 0.62 |

Data are expressed as mean ± standard deviation, median (range), or number (%). NRS, numeric rating scale.

### Table 4 Multivariate logistic analysis for recurrent TN outcome after PBC

| Variable                  | OR    | 95% CI           | P   |
|---------------------------|-------|------------------|-----|
| Right laterality          | 1.90  | 0.71–5.07        | 0.20|
| Previous MVD alone        | 0.68  | 0.22–2.11        | 0.51|
| Previous RFT alone        | 0.20  | 0.06–0.66        | 0.01|

OR, odds ratio; CI, confidence interval.
predictor of lower analgesic efficacy. Other previous surgeries such as MVD, PBC, GKRS, and GR did not affect the analgesic efficacy of PBC. It is generally known that the rationale of RFT on TN is to destroy Aα and Aβ fibers, thus interrupting the peripheral stimuli and reaching the central nervous system [19]. It is not clear why the curative effect of PBC after RFT would be limited. We speculate that RFT may form scar tissue in the semilunar ganglion, which may be the reason for the lower analgesic efficacy of PBC. In the ineffective group of our study, six out of 20 patients with recurrent TN following previous RFT underwent repeated RFT for further nerve destruction, and all of them achieved good pain relief. Consequently, we can speculate that repeated RFT may be suitable for patients with recurrent TN after RFT. Several previous studies showed that, in addition to the shape of the balloon, the volume, as well as the duration of compression, may be related to PBC outcome [20]. It can be speculated that regular compression time and balloon volume may not be suitable for recurrent TN patients with a previous history of RFT. Perhaps, increasing the volume of the balloon and prolonging compression time may improve the pain relief rate. As a result, optimal PBC compression time and balloon volume for patients who had a history of previous RFT need to be investigated in future studies. Similarly, Liu et al. reported that patients who underwent repeated RFT and achieved an “excellent” or “good” pain relief condition (VAS score ≤ 1) were 96.8% at 6 months and 83.9% at 1 year [21]. Therefore, we speculate that in patients with recurrent TN after RFT, repeated RFT might be a useful treatment option. Certainly, prospective, randomized, and controlled clinical trials need to be conducted, for optimization of treatment modules in recurrent TN patients following previous failed surgical interventions.

Regarding complications, facial numbness is the most common side effect after PBC, but it is relatively mild and closely related to the treatment mechanism and PBC operation. According to previous reports, the incidence rates of postoperative facial numbness ranged from 89 to 100% [9, 13]. In our study, 91.5% presented with facial numbness in the effective group, which was much higher than those in the ineffective group (P = 0.00). This shows that the patients who had facial numbness had a greater likelihood of being pain-free. Participants who had complete pain relief had worse or new trigeminal numbness [10]. Masseter weakness was also reported to be a common complication after PBC. In our study, 34.6% of patients developed masseter weakness in the effective group, which was higher than that in the ineffective group (10%, P = 0.04). The complications were similar to those reported by Xu et al. [9], which were higher than in previous studies [10, 22]. Diplopia after PBC was reported previously by Bergenheim and Linderoth [23]. Although in our study, 4.6% of patients developed diplopia in the effective group compared to 5.0% in the ineffective group, it was most often transient and had resolved within 3 months. Furthermore, no serious side effects were observed in our study, which is in line with the current opinion that these procedures are generally safer with image guidance.

Limitation

This study has several limitations. First, this is a retrospective study, and the retrospective nature of this study creates inherent bias. So, prospective validation of the prognostic tool is still needed. Second, in the case of RFT, previous intraoperative parameters such as temperature and duration of the first definitive lesion may have affected the effectiveness of PBC. However, we were unable to obtain these parameters. A stratified study on previous parameters of radiofrequency thermocoagulation needs further exploration. Third, due to the lack of specific detailed intraoperative records, our study did not differentiate MVD from PSR. Fourth, the pressure of the balloon was not measured during the PBC procedure, which might have affected the effectiveness of PBC. Therefore, our research findings should be acknowledged with caution. Fifth, the follow-up period was relatively short. Long-term effects of PBC on recurrent TN need a longer patient follow-up period. The good news is that all of these patients will be continuously monitored, and further reports could give a clearer picture of PBC on recurring TN.

Conclusion

In this study, PBC was found to be a moderately effective and safe treatment for recurrent TN after TN-related surgery. However, previous RFT procedures may predict a slightly worse outcome after PBC and should be considered in clinical decision-making.

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Author contribution FL was responsible for the study design. FL conceived the idea for this study. Study conduction and data collection were led by LL, ZS, YZ, and GF M. Study analysis and figure generation were done by LL, supervised by FL. LL and ZS wrote the main manuscript text and YZ and GF M prepared Fig. 1. LL and ZS contributed equally to this work and should be considered co-first authors. All authors reviewed the manuscript.

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access to all the data in the study; all the co-authors were responsible for making the final decision to submit for publication.

**Data availability** Patient data will not be available because this was not a concern when the study was conducted, and the patients were not informed.

**Declarations**

**Ethics approval and consent to participate** All procedures performed were in accordance with the ethical standards. Our study was approved by the Medical Ethics Committee of Beijing Tiantan Hospital, Capital Medical University. All experiments were performed in accordance with relevant named guidelines and regulations. The study is exempt from the requirement for informed consent.

**Human and animal ethics** This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Beijing Tiantan Hospital, Capital Medical University. The research involved human participants, their data, and vital signs.

**Consent for publication** All authors consent to the submission of the manuscript in Neurosurgical Review. All authors guarantee that the research findings have not been previously published.

**Competing interests** The authors declare no competing interests.

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