Retrospective Study

Analysis of the Therapeutic Efficacy of Percutaneous Balloon Double Compression for the Treatment of Recurrent Trigeminal Neuralgia

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Background: A more secure and efficacious therapy than has been developed so far is imperative for patients suffering from recurrent trigeminal neuralgia (TN). Despite numerous reports on the use of enhanced percutaneous balloon compression (PBC) techniques, such as altering compression duration and balloon pressure, none have yielded satisfactory outcomes. With these issues in mind, we have employed the PBC double-compression technique for the first time. This technique involves initially inflating a balloon to expand the adhesive tissue in Meckel's lumen, followed by emptying of the contrast medium and subsequent slight catheter adjustment for further compression. The total duration of compression remains unchanged and may even be shortened.

Objectives: The objective of this study was to assess the clinical effectiveness of the PBC double-compression technique in patients with recurrent TN and to analyze the technique's efficacy, subsequent duration of patients' facial numbness, and other complications.

Study Design: Retrospective study.

Setting: A single-center study.

Methods: Retrospective analysis was conducted on clinical data from 125 patients with postoperative recurrent TN who underwent double compression of the PBC and 65 patients who underwent single compression of the PBC between August 2017 and April 2022. The Barrow Neurological Institute Pain Intensity (BNI-P) score was utilized to quantify the severity of pain, while the Barrow Neurological Institute Facial Numbness (BNI-N) score was employed to separately evaluate the extent of postoperative pain relief and facial numbness.

Results: The BNI-P and BNI-N scores before and after PBC treatment are presented herein. At T0, there was no significant difference in the BNI-P scores between the single-compression group and the double-compression group; however, at T1-T4, the BNI-P scores of the double-compression group were lower than those of the single-compression group ($P < 0.05$). There was no significant difference in BNI-P scores between the 2 groups at T5. At T1-T4, the BNI-N score of the double-compression group was significantly lower than that of the single-compression group ($P < 0.05$). However, there was no significant difference in BNI-N score between the double and single compression groups at T5. In the single-compression group, one patient (1.5%) experienced insignificant pain relief on postoperative day one, while 2 patients (3.1%) suffered from pain recurrence during the 1-4-year follow-up period. Similarly, in the double-compression group, one patient (0.8%) had inadequate pain relief on postoperative day one, and 3 patients (2.4%) experienced pain recurrence during the same follow-up period. The remaining patients did not require further surgical intervention but continued to rely on regular oral analgesia. In the single-compression group, masticatory muscle weakness was observed in 50 cases (76.9%), while in the double-compression group, it was observed in 92 cases (73.6%). Perioral herpes affected 4 patients (7.1%) and 6 patients (4.8%) in the single- and double-compression groups, respectively. Facial hematoma occurred in 7 cases (10.8%) and 13 cases (10.4%) of the single- and double-compression groups, respectively; each group included one patient suffered who from diplopia. Notably, none of the patients in this study reported any instances of corneal anesthesia, anesthesia pain, aseptic meningitis, cerebrospinal fluid leakage, subarachnoid hemorrhage, carotid-cavernous fistula, or mortality.

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

Conclusions: The double PBC method boasts a high cure rate, a low recurrence rate, and minimal complications, rendering the option appropriate for patients with recurrent TN and thus deserving of clinical promotion.

Key words: Percutaneous balloon compression, recurrent trigeminal neuralgia, double-compression method

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Trigeminal neuralgia (TN) is a severe facial disorder characterized by paroxysmal stabbing pain that is provoked by stimuli (1). Carbamazepine is the first-line drug for TN treatment, but its effective dose often correlates with the severity of adverse effects (2). Surgical intervention may be considered when medication fails to control pain or causes serious side effects. The current "gold standard" for TN treatment is microvascular decompression (MVD), which can provide initial pain relief of up to 100% (3,4). However, MVD may not always be a viable option due to surgical contraindications or patient preference. Other clinical treatments include injection therapy, radiofrequency therapy, peritrigeminal branch avulsion, glycerol neurolysis, and gamma-knife radiosurgery; however, these treatments have a general recurrence rate, with one study reporting postoperative recurrence in at least 19% of surgically treated patients (5). Patients experiencing recurrence of TN often suffer from comorbid anxiety, depression, and other psychiatric symptoms that significantly impair their quality of life. Therefore, there is a pressing necessity for safer, more efficacious treatments that address the needs of these patients.

Percutaneous microballoon compression (PBC), a neurointerventional treatment initially proposed by Mullan and Lichtor in 1983 (6), has become a widely accepted therapeutic option for TN due to the procedure's simplicity, minimally invasive nature, high efficacy in pain relief, low recurrence rate, and repeatability (7). The management of recurrent TN considers percutaneous balloon compression (PBC) a top priority (8,9). Some individuals have adapted the PBC protocol for treating recurrent TN by prolonging the duration of compression and increasing the pressure applied to the balloon. Although these techniques can effectively alleviate patients' pain, they carry greater risks during operation, such as severer facial numbness and longer-lasting weakness in masticatory muscles. Conversely, some scholars have attempted to reduce the compression time involved in PBC and yielded promising results over a short period; however, this approach is associated with a higher recurrence rate (10). In clinical practice, balloon rupture frequently occurs during PBC surgery, and achieving the original pear shape after balloon reimplantation is challenging. The most common shape achieved is pear-like, with occasional dumbbell shapes observed. However, we have observed that a total duration of at least 60 seconds for multiple compressions yields comparable positive clinical outcomes. By comparing patients who received a single intraoperative compression to those who received double compressions, we observed that pain relief was more effective in the latter group, even when the total compression time was shorter. Therefore, in this study, PBC "double compression" was employed as a treatment for recurrent TN. A retrospective analysis of efficacy and safety was conducted on 190 cases to provide clinicians with a reference for selecting an appropriate and effective treatment plan for this condition.

Methods

Patient Population

The study was reviewed by the Medical Ethics Committee of the Fifth Affiliated Hospital of Zhengzhou University. A total of 190 patients with recurrent TN were selected from the Department of Neurosurgery at the Fifth Affiliated Hospital of Zhengzhou University from August 2017 to April 2022. The general conditions of these patients are presented in Table 1. Prior to treatment, the patients' families were informed about the treatment plan and potential complications, and informed consent was obtained.

Inclusion criteria: (i) The craniofacial pain met the diagnostic criteria for ITN as defined by the third edition of the International Classification of Headache Disorders (ICHD-3) (11) and was strictly unilateral. (ii) All patients had a history of previous TN-related surgeries,

including injection therapy, radiofrequency therapy, microvascular decompression, peripheral trigeminal nerve avulsion, glycerin nerve ablation, gamma knife radiation therapy, and PBC. The patients were subsequently diagnosed with TN again after discharge. (iii) The BNI-P score was ≥ IV, and complete clinical and follow-up data were available.

Exclusion criteria: (i) secondary TN resulting from neoplastic lesions confirmed by computed tomography or magnetic resonance imaging; (ii) preoperative blood routine, coagulation function, liver and kidney function, electrocardiogram, etc., indicating significant surgical contraindications; (iii) inability to comprehend or respond to the questionnaire.

Instruments and Equipment

Mobile C-arm: OEC 9900 Elite (General Electric, USA). Balloon: disposable balloon catheter kit for brain surgery (Shenzhen DynaSpring).

Procedures for PBC Treatment

Tracheal intubation is performed anteriorly under general anesthesia using the Hartel technique. The site of pain is identified and marked prior to positioning the patient in a supine position for tracheal intubation under fluoroscopic guidance, with adjustment of the C-arm and head position to ensure the bilateral bony external auditory canals are at the same level. A 14-gauge needle is utilized to puncture the skin approximately 2.5 cm lateral to the corner of the mouth and is then, under fluoroscopic guidance, inserted into the foramen ovale. After reaching this point, the needle core is removed before penetrating through to reach the bony structures. The disposable brain surgery balloon catheter is then introduced into Meckel's cavity via a puncture tube sheath. One group employs the single-compression method, wherein a pear or dumbbell shape is formed and compressed for 120-180 seconds; another group employs double-compression techniques, wherein the pear or dumbbell shape is achieved by compressing the balloon for 60-90 seconds, emptying the contrast medium, slightly adjusting catheter depth, followed by immediately refilling the balloon to achieve compression again. The duration of compression can be adjusted between 60 and 90 seconds based on the patient's preoperative disease duration and recurrence frequency. Upon completion of compression, the puncture needle cannula and balloon were extracted, followed by manual compression of the puncture site and application of a bandage to cover the wound. Following anesthesia recovery and extubation, patients were transferred to the general ward if no complications arose, and postoperative records were documented.

Table 1. *General information about patients*.

General Information	Single-Compression Group	Double-Compression Group
Number of patients	65	125
Gender (men/women)	27 (41.5)/38 (58.5)	49 (39.2)/76 (60.8)
Age (years, range)	62.29 ± 10.25 (37-86)	62.56 ± 11.12 (35-89)
Pain Area		
Side (left/right)	29 (43.0)/36 (57.0)	55 (44.0)/70 (56.0)
I	5 (7.7)	5 (4.0)
II	10 (15.4)	25 (20.0)
III	14 (21.5)	26 (20.8)
I + II	3 (4.6)	9 (7.2)
II + III	27 (41.5)	49 (39.2)
I + III	1 (1.5)	1 (0.8)
I + II + III	5 (7.7)	10 (8.0)
Type of Prior Procedure		
MVD	11	27
PRT	30	63
PBC	8	13
GKRS	9	10
Others	7	12

Abbreviations: MVD: microvascular decompression; PRT: percutaneous radiofrequency thermocoagulation; PBC: percutaneous balloon compression; GKRS: gamma knife radiosurgery.

Follow-up and Effect Evaluation

Postoperative pain and facial numbness were assessed using the BNI-P and the BNI-N, respectively (12) (Table 2). Follow-up visits were conducted and documented at preoperative (T0) and postoperative one-day (T1), one-month (T2), 3-month (T3), 6-month (T4), and 12-month (T5) intervals through outpatient or telephone consultations. Patients were categorized into single- or double-compression groups based on the surgical approach employed, with a comparison of the effectiveness between the 2 compression methods.

Statistical Analyses

SPSS 26.0 statistical software was used to process the data, and the measurement data were expressed as ($x \pm s$) and compared by t test; the count data were

expressed as number of cases and percentages and compared by chi-squared test. Differences were considered statistically significant at $P < 0.05$.

Results

Changes in BNI-P and BNI-N Scores Pre- and Post-PBC Treatment

The BNI-P and BNI-N scores before and after PBC treatment are presented in Tables 3 and 4. There was no significant difference in BNI-P scores between the two groups at T0; however, the BNI-P scores of the double-compression group were significantly lower than those of the single-compression group at T1-T4 ($P < 0.05$). No significant difference in BNI-P scores was observed between the two groups at T5. At T1-T4, the BNI-N scores of the double-compression group exhibited a statistically significant decrease compared to that of the single-compression group ($P < 0.05$). However, at T5, there was no significant difference in BNI-N scores between the double- and single-compression groups. In the single-compression group, one patient (1.5%) experienced insignificant pain relief on postoperative day one, while two patients (3.1%) suffered from pain recurrence during the 1-4-year follow-up period. Similarly, in the double-compression groups, one patient (0.8%) had inadequate pain relief on postoperative day one, and three patients (2.4%) experienced pain recurrence during the same follow-up period. The remaining patients did not require repeat surgery but continued with regular oral analgesia.

Postoperative Complications Experienced by Patients

No intracranial infections, bleeding, or other serious complications were observed in this patient cohort. Any remaining complications were resolved to varying degrees within a certain period. The postoperative hospital stay ranged from one to 12 days with an average of 4.7 days (Table 5).

Typical Cases

Case 1: The initial puncture injection of a balloon filled with 0.5 mL of iodophor resulted in a pear-shaped configuration (Fig. 1A). Following minor adjustments, the balloon was advanced slightly deeper and filled with 0.7 mL of iodophor, resulting in a dumbbell shape (Fig. 1B). Contrast agent release occurred after compression for 60 seconds and 75 seconds respectively, totaling 135 seconds.

Case 2: The first pear-shaped balloon filled with 0.65 mL of iodophor (Fig. 1C) released the contrast

Table 2. *BNI-P and BNI-N scores.*

Score	BNI-P	Score	BNI-N
1	The pain was completely alleviated without the use of medication.	1	No facial numbness was present.
2	Occasional pain was experienced, but it remained manageable without the need for medication.	2	Mild facial numbness was observed, but it did not significantly impact daily activities.
3	Pain is sometimes present but can be effectively controlled with medication.	3	Facial numbness was noted and had an effect on daily life.
4	Despite medical therapy, there is still some degree of uncontrolled pain.	4	Facial numbness was severe and greatly impacted daily life.
5	The persistence of pain remains unresolved.		

Table 3. *Comparison of BNP-P scores before and after surgery.*

BNP-P Score	Single-Compression Group (n = 65)	Double-Compression Group (n = 125)	Statistics	*P* Values
T0	3.00 ± 0.00	3.00 ± 0.00	F = 0.00	1.000
T1	0.34 ± 0.71	0.18 ± 0.44	F = 14.65	0.000
T2	0.15 ± 0.56	0.04 ± 0.29	F = 12.79	0.000
T3	0.14 ± 0.55	0.03 ± 0.28	F = 11.99	0.001
T4	0.20 ± 0.73	0.07 ± 0.46	F = 8.50	0.004
T5	0.20 ± 0.73	0.11 ± 0.55	F = 3.28	0.072

Table 4. *Comparison of BNP-N scores before and after surgery.*

BNP-N Score	Single-Compression Group (n = 65)	Double-Compression Group (n = 125)	Statistics	*P* Values
T0	1.00 ± 0.00	1.00 ± 0.00	F = 0.00	1.000
T1	3.83 ± 0.73	3.74 ± 0.43	F = 8.27	0.004
T2	3.09 ± 0.29	3.04 ± 0.19	F = 8.62	0.004
T3	2.06 ± 0.24	2.02 ± 0.12	F = 11.99	0.001
T4	1.05 ± 0.21	1.02 ± 0.12	F = 6.12	0.014
T5	1.02 ± 0.12	1.02 ± 0.12	F = 0.00	0.949

agent after a compression time of 85 seconds; upon a slightly deeper adjustment, the dumbbell-shaped balloon filled with 0.7 mL of iodophor (Fig. 1D) released the contrast agent after a compression time of 60 seconds, resulting in a total compression time of 145 seconds.

Case 3: The pear-shaped balloon filled with 0.6 mL of iodophor released the contrast agent after 90 seconds of compression upon first puncture (Fig. 1E), while the pear-shaped balloon filled with 0.8 mL of iodophor released the contrast agent after 75 seconds of compression at a small depth of fine-tuning (Fig. 1F), totaling 155 seconds.

Case 4: The balloon was filled to a pear shape with 0.6 mL of iodophoresis during the first puncture (Fig. 1G). After the balloon was compressed for 90 seconds and fine-tuned slightly deeper, an additional 0.8 mL of iodophoresis was injected to achieve the desired shape (Fig. 1H). The contrast agent was then released after compressing for a total of 155 seconds.

Discussion

PBC has been utilized as a safe and effective treatment for primary TN in clinical practice for over three decades (13,14). The mechanism of pain relief achieved by PBC involves mechanical compression of the semilunar ganglion, which often results in facial sensory deficits. Severe facial numbness is frequently associated with superior pain relief and lower recurrence rates; however, numbness may also persist for an extended period. Therefore, there is an urgent need to improve pain relief and reduce facial numbness. For this reason, it is imperative to enhance analgesia and alleviate facial hypoesthesia.

Recurrent TN often results in local tissue adhesions. To address this, we employ the PBC double compression method: first, we fill the balloon to dilate the adherent tissue in Meckel's cavity and compress for 60-90 seconds; then, we empty the contrast, micro-adjust the catheter to go slightly deeper, refill the balloon, and compress again for 60-90 seconds. The compression duration was appropriately adjusted between 60 and 90 seconds based on the patient's disease length and recurrence frequency. The results indicated that the BNI-P scores of the double-compression group at T1-T4

Table 5. *Postoperative complications experienced by patients.*

Symptom	Single-Compression Group (%)	Double-Compression Group (%)
Chew muscle weakness	50 (76.9)	92 (73.6)
Perioral herpes	4 (6.1)	6 (4.8)
Facial hematoma	7 (10.8)	13 (10.4)
Diplopia	1 (1.5)	1 (0.8)

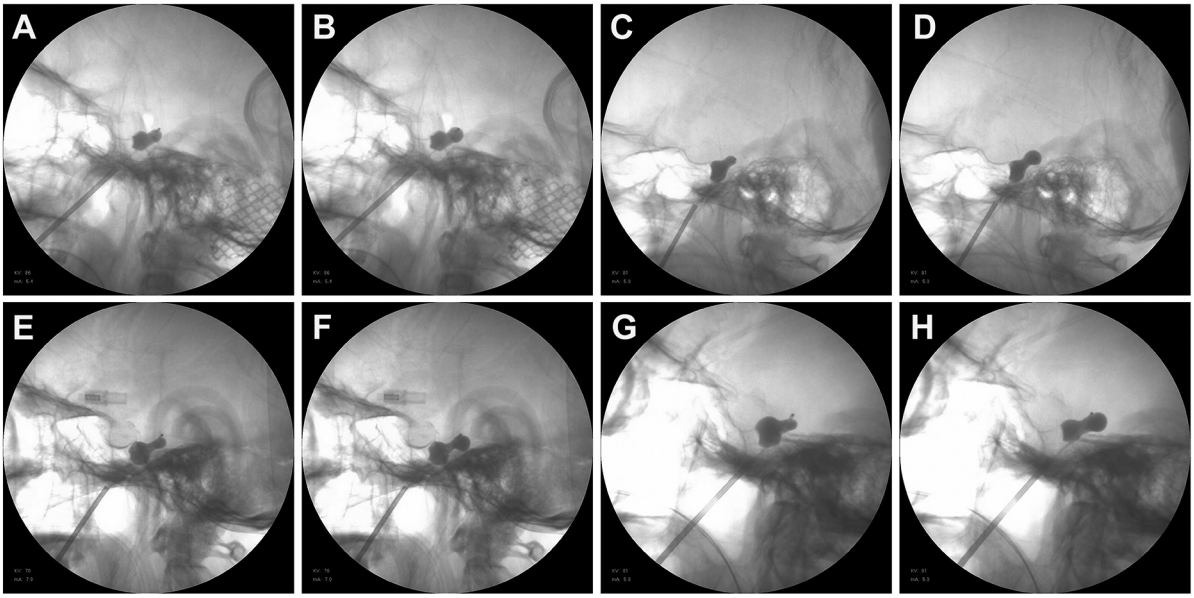

Fig. 1. *Representative images of PBC double-compression method.*

were significantly lower than those of the single-compression group ($P < 0.05$). Furthermore, the effective rates for the double-compression group were 99.2%, 99.2%, 99.2% and 98.4%, respectively, which exceeded those of the single-compression group (96.9%, 96.9%, 96.9% and 95.8%). The incidence of postoperative pain recurrence was 2.4%, which demonstrated a lower rate compared to the single-compression group (3%) and previous studies (15,16). However, there was no significant difference in BNI-P scores between the 2 treatment groups at T5 ($P > 0.05$). The BNI-N score exhibited a significant decrease in the double-compression group compared to the single-compression group from T1 to T4 ($P < 0.05$). However, there was no statistically significant difference in the BNI-N score between the 2 groups at T5 ($P > 0.05$). Therefore, the PBC double-compression method has demonstrated the ability to enhance pain relief rates, diminish pain recurrence rates, and mitigate early facial numbness without extending compression duration and potentially even shortening it.

Masticatory weakness, perioral herpes, and diplopia are common complications following PBC surgery. However, this study demonstrates that the incidence of complications was lower in the double-compression group compared to the single-compression group. Masticatory muscle weakness typically resolves within three months, while the low occurrence of perioral herpes is attributed to routine use of acyclovir antiviral therapy before and after surgery (17).

In the current investigation, 6 patients did not experience significant pain relief immediately postoperatively; however, the pain resolved within 12 days after surgery. This phenomenon is commonly referred to as "delayed relief" by some scholars and may be attributed to sequential postoperative changes in the nerve tissue of the balloon-compressed ganglion, selective destruction of myelinated nerve fibers, and the time required for demyelination (18). Brief instances of intraoperative asystole were observed in three cases, which resolved upon cessation of puncture or compression and were classified as trigeminal cardiac reflexes (19).

The implementation of "double compression" significantly reduced common postoperative complications associated with PBC without introducing new risk factors.

Limitations

The limitations of this study include its retrospective nature, single-center design, small sample size, and short follow-up period. Furthermore, the long-term efficacy and safety of the double-compression method of PBC require further evaluation in a large-scale multicenter trial with extended follow-up.

Conclusion

In conclusion, the double-compression method of PBC exhibits a high cure rate, low recurrence rate, and minimal complications, rendering it an appropriate treatment option for patients with recurrent TN and one deserving of clinical promotion and application.

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