

Clinical Efficacy of Percutaneous Balloon Compression Combined with Carbamazepine in the Treatment of Trigeminal Neuralgia: A Retrospective Study

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Objective: To investigate the effect of percutaneous balloon compression combined with carbamazepine on patients with Trigeminal Neuralgia (TN).

Methods: The clinical data of 126 patients with TN admitted to our hospital from January, 2021 to January, 2022 were retrospectively analyzed. All patients underwent percutaneous balloon compression in our hospital. The patients were divided into a control group and an observation group, according to whether they continued to take carbamazepine after surgery. The general demographic data of patients, such as gender, age, family income, education level, pain site, diseased nerve, course of disease, and duration of pain were collected. Propensity score matching was used to balance the baseline data of the two groups, and the quality of life, treatment effect, and complications of the two groups were compared after matching.

Results: After treatment, the total effective rate of the observation group (95.00%) was higher than that of the control group (70.00%) ($p < 0.05$). Before treatment, there were no significant differences in the scores for quality of life dimensions between the two groups ($p > 0.05$). After treatment, the scores for each quality of life dimension in the observation group were higher than those in the control group. After treatment, the incidence of complications in the observation group (7.50%) was lower than that in the control group (30.00%) ($p < 0.05$).

Conclusions: Percutaneous balloon compression combined with carbamazepine can effectively enhance the treatment of patients by improving their quality of life and reducing the occurrence of complications. These results can improve the clinical management of TN.

Keywords: percutaneous balloon compression; carbamazepine; Trigeminal Neuralgia; oxidative stress response

Introduction

Trigeminal Neuralgia (TN), a chronic disorder characterized by sudden and severe pain occurring mostly on the face, brings life burden to patients [1]. At present, Percutaneous Balloon Compression (PBC) and drug therapy, especially carbamazepine, are widely used in the management of TN [2]. Carbamazepine, as an antiepileptic drug, has been shown to be effective for pain relief in TN patients [3]. PBC, as an interventional treatment, exerts pressure on the blood vessels around the trigeminal nerve, thereby reducing the excessive excitation of the nerve and providing pain relief [4]. In past studies, PBC and carbamazepine have played active roles as separate treatments in the remission of TN [5]. However, there is still a lack of large-scale research support for the clinical effect of combination therapy and its application in TN patients. There are different clinical guidelines and practices regarding the continuation of carbamazepine after PBC [6]. Therefore, this study

aimed to comprehensively evaluate the differences in efficacy, safety, and patient quality of life between PBC plus carbamazepine treatment and PBC treatment alone in TN patients through a retrospective cohort study. The purpose of this study is to provide more objective and comprehensive evidence for the combined treatment of TN. Through this study, we hope to provide a more scientific basis for the individualized treatment of TN patients, promote a deeper understanding of the treatment of this disease, and bring better clinical results to patients.

Materials and Methods

General Information

This retrospective cohort study evaluated the clinical efficacy of PBC combined with carbamazepine in TN patients. A retrospective analysis was performed on 126 patients with TN admitted to our hospital from January, 2021 to January, 2022, and they were divided into two groups. The control group stopped taking carbamazepine after receiving PBC, and the observation group continued taking carbamazepine after receiving PBC. Clinical data for the two groups were collected, including gender, age, family income, education level, pain site, pathological nerve lesion, course of disease, and duration of pain.

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Inclusion criteria: (1) Patients that met the diagnostic criteria for TN in the International Classification of Headache Disorders [7]; (2) Patients that underwent PBC; (3) Patients that were treated with carbamazepine before the PBC operation; (4) Patient with complete medical records; (5) Patients aged 18 to 70 years.

Exclusion criteria: (1) Patients with combined cardiac, renal, or pulmonary dysfunction; (2) Patients that suffered from psychiatric disorders, cognitive disorders, or inability to communicate; (3) Patients with blood disorders or infectious diseases; (4) Patients that were allergic to medications; (5) Patients that experienced other neurologic disorders; (6) Patients with previous failed surgical treatments.

This trial, which was a retrospective cohort study, was approved by the Xiantao First People's Hospital ethics committee (No.202402002) and did not require patient consent because of the anonymity of the data.

Methods

Data Collection

In this study, general data were collected from patient medical records, including gender, age, family income status, education level, site of pain, diseased nerve, course of the disease, and pain duration.

Control Group Method

The percutaneous puncture balloon compression technique was chosen for this group. The patient was kept in the supine position and general anesthesia was performed. The vital signs of the patient were monitored during the entire operation. The Hartel puncture technique was used to puncture 2.5 cm lateral to the angle of the mouth, 3 cm anterior to the ipsilateral external auditory canal, and 1 cm below the pupil. Under fluorescent screen guidance, the positive direction was lowered until the foramen ovalis was entered. Under computed tomography guidance, the needle core was pulled out, a Fogarty balloon 4 was inserted into Meckel cavity through the puncture needle, the guide wire was withdrawn, and iodine containing non-ionic contrast agent was injected into the balloon for filling. The position and shape of the balloon were checked and judged according to the surrounding bone landmarks. The balloon was emptied if necessary, and the position of the catheter was readjusted to fill the balloon to 0.4–10 mL. After compressing the ganglion for 3–10 min, the balloon was emptied, the catheter was removed, and the puncture point was pressed for 5 min. The operation was usually completed within 15 min. After the patient underwent PBC, carbamazepine treatment was discontinued directly.

Observation Group Method

The observation group: the surgical method was the same as the control group, the two groups were treated with carbamazepine before surgery, and the observation group was treated with carbamazepine continuously af-

ter surgery (Shanghai Fudan Fuchina Pharmaceutical Co., LTD., Shanghai, China, code number approved by SFDA of China: H31021366, specification: 100 mg/tablet), 100–200 mg each time, 1–2 times a day, and adjusted according to the patient's tolerance and pain relief.

Observation Indicators

(1) General demographic and clinical data were extracted from the medical records of the included patients, including gender, age, family income, education level, pain location, lesion nerve, course of disease, pain duration, etc.

(2) The clinical efficacy of the two groups was compared through 1 month follow-up after surgical treatment. The Barrow Neurological Institute (BNI) [8] pain score was used to evaluate the degree of postoperative pain. BNI scores were divided into five levels: Grade I, no pain and no medication required; Grade II, patients have occasional pain but are not taking any medications; Grade III, patients displayed some pain, which could be controlled by drugs. The pain of Grade IV patients was reduced, but the dosage was not sufficiently controlled. Grade V indicates no relief of pain. Immediate failure was defined as postoperative TN, without facial anesthesia, requiring continued medical control of pain. Recurrence was defined as the absence of symptoms after PBC surgery for at least 3 months followed by recurrence, with or without medication.

(3) The quality of life of the two groups before and after treatment was compared using the general Quality of Life questionnaire 74 (GQOL-74) [9], which measures four dimensions: physical function, psychological function, social function, and material life. There are a total of 74 items, and the total score of each item is 100 points. The higher the score, the better the quality of life. The overall Cronbach's α coefficient of the scale was 0.895, and the split-half reliability coefficient was 0.904, which showed good reliability and validity.

(4) The postoperative complications of the two groups were observed, including oral and labial herpes, facial numbness, masticatory weakness, keratitis, etc.

Statistical Processing

IBM SPSS Statistics for Windows version 27.0 (IBM Corp, Armonk, NY, USA) was used for statistical analysis. Measures that conformed to the normal distribution were expressed as the mean and standard deviation ($\bar{x} \pm s$), and differences were evaluated using *t* tests. Measures that were not normally distributed were expressed using the median and interquartile range [M (P25, P75)], and differences were evaluated using the Mann–Whitney U test. Count data, expressed as [n (%)], were compared using the χ^2 test, and *p* values < 0.05 were considered statistically significant.

Table 1. Comparison of clinical data in each group.

Clinical data	Before matching				After matching			
	Control group (n = 65)	Observation group (n = 61)	χ^2/U	<i>p</i>	Control group (n = 40)	Observation group (n = 40)	χ^2/U	<i>p</i>
Gender								
Male	36 (55.38%)	34 (55.74%)	0.002	0.968	27 (67.50%)	25 (62.50%)	0.220	0.639
Female	29 (44.62%)	27 (44.26%)			13 (32.50%)	15 (37.50%)		
Age [years, M (P25, P75)]	49.00 (44.00, 51.00)	50.00 (47.50, 53.00)	-3.071	0.002	49.00 (47.00, 52.00)	48.00 (47.00, 52.00)	0.053	0.958
Family income situation								
<5000 CNY	28 (43.08%)	25 (40.98%)	0.057	0.812	21 (52.50%)	22 (55%)	0.050	0.823
≥5000 CNY	37 (56.92%)	36 (59.02%)			19 (47.50%)	18 (45%)		
Degree of education								
Primary and Junior High schools	30 (46.15%)	32 (52.46%)	0.761	0.684	15 (37.50%)	17 (42.50%)	0.464	0.793
High school	22 (33.85%)	20 (32.79%)			18 (45%)	15 (37.50%)		
College or above	13 (20%)	9 (14.75%)			7 (17.50%)	8 (20%)		
Location of pain								
Left side	35 (53.85%)	36 (59.02%)	0.342	0.559	24 (60%)	26 (65%)	0.213	0.644
Right side	30 (43.85%)	25 (40.98%)			16 (40%)	14 (35%)		
Diseased nerve								
Ophthalmic nerve	23 (35.38%)	18 (29.51%)	1.919	0.383	13 (32.50%)	15 (37.50%)	0.497	0.780
Maxillary nerve	20 (30.77%)	15 (24.59%)			11 (27.50%)	12 (30%)		
Mandibular nerve	22 (33.85%)	28 (45.90%)			16 (40%)	13 (32.50%)		
Course of disease [years, M (P25, P75)]	1.90 (1.50, 2.20)	2.30 (1.60, 2.60)	-2.442	0.015	2.10 (1.50, 2.50)	2.00 (1.60, 2.60)	0.463	0.644
Time of pain								
<5 min	35 (53.85%)	21 (34.43%)	4.806	0.03	22 (55%)	24 (60%)	0.205	0.651
≥5 min	30 (43.85%)	40 (65.57%)			18 (45%)	16 (40%)		

Note: 1 CNY ≈ 0.1382 USD.

Table 2. Comparison of clinical outcomes between the two groups [n (%)].

Group	Number of cases	Conspicuous effect	Effective	Void of effect	Total effective rate
Control group	40	10 (25%)	18 (45%)	12 (30%)	28 (70.00)
Observation group	40	17 (42.50%)	21 (52.50%)	2 (5.00%)	38 (95.00)
χ^2	-	-	-	-	8.658
<i>p</i>	-	-	-	-	0.003

Results

Comparison of Clinical Data

A total of 126 patients were included in this study, including 65 cases in the control group and 61 cases in the observation group. Before PSM, there were statistically significant differences in age, course of disease, and pain duration between groups ($p < 0.05$). After 1:1 propensity score matching, 40 cases in the control group and 40 cases in the observation group were successfully matched, and the baseline characteristics of patients in each group were balanced. The results were comparable ($p > 0.05$). See Table 1 for details.

Comparison of Clinical Efficacy

After treatment, the total effective rate of the observation group (95.00%) was higher than that of the control group (70.00%) ($p < 0.05$). For details, see Table 2.

Comparison of Quality of Life

Before treatment, there were no significant differences in the scores for quality of life index between the two groups ($p > 0.05$). After treatment, the scores for all quality of life dimensions in the observation group were higher than those in the control group ($p < 0.05$). For details, see Table 3.

The Incidence of Complications was Compared between the Two Groups

Carbamazepine was stopped after PBC surgery in the control group. There were 12 cases of complications (30.00%) in the control group; 4 cases had oral and labial herpes, 3 cases had facial numbness, 3 cases had masticatory weakness, and 2 cases had keratitis. The observation group continued to take carbamazepine after surgery. The observation group had a total of 3 cases of complications, accounting for 7.50%; 2 cases of oral and labial herpes and 1 case

Table 3. Comparison of the quality of life of the two groups ($\bar{x} \pm s$, score).

Group	Number of cases	Physical function		Psychological function		Social Function		Material life	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group	40	63.45 ± 8.54	73.25 ± 7.35*	68.95 ± 6.43	72.83 ± 7.15*	70.15 ± 5.61	78.68 ± 6.55*	60.25 ± 5.23	70.23 ± 6.12*
Observation group	40	64.15 ± 8.67	79.55 ± 7.81*	69.15 ± 7.45	78.65 ± 7.04*	70.68 ± 5.92	86.25 ± 6.84*	61.23 ± 5.47	76.50 ± 6.58*
<i>t</i>	-	0.364	3.715	0.129	3.668	0.411	5.055	0.627	4.413
<i>p</i>	-	0.717	<0.001	0.898	<0.001	0.682	<0.001	0.533	<0.001

Note: Compared with pre-treatment, * $p < 0.05$.

Table 4. Occurrence of complications.

Variables	Control group (n = 40)	Observation group (n = 40)	χ^2	<i>p</i> value
Keratitis	2 (5%)	0 (0%)		
Masticatory weakness	3 (7.5%)	0 (0%)		
Oral and labial herpes	4 (10%)	2 (5%)		
Facial numbness	3 (7.5%)	1 (2.5%)		
All	12 (30%)	3 (7.5%)	6.646	0.01

of facial numbness. There were no cases of masticatory weakness or keratitis. The incidence of complications in the control group was higher than that in the observation group ($p < 0.05$). For details, see Table 4.

Discussion

The pathogenesis of TN is relatively complex. The initial pain of TN occurs in the face of the patient, and with the prolonging of disease course, the pain may radiate to the head, ears, shoulders and other parts, seriously affecting the quality of life of the patient. For this reason, active treatment is the key clinical goal [10,11].

The results of the present study showed that after treatment, the total effective rate of the observation group (95.00%) was higher than that of the control group (70.00%) ($p < 0.05$), indicating that the clinical efficacy of PBC combined with carbamazepine treatment was superior. Dagnino APA and Campos MM [12] reported that carbamazepine is the preferred drug for relieving trigeminal neuralgia. In recent years, TN patients have been treated with carbamazepine to relieve pain, and PBC and other surgical methods have been adopted after the drug gradually failed to work. After the operation, the repair of cells and tissues plays a crucial role in recovery. However, in order to achieve the ideal postoperative effect, to prevent the rebound caused by sudden withdrawal after surgery, to improve the long-term efficacy and relieve pain, it is better to continue to combine carbamazepine after surgery [13,14]. Yoon SY and Oh J [15] said that carbamazepine, a sodium channel blocker, has achieved significant effect in the treatment of TN. Carbamazepine can avoid inflammation and reduce the postoperative stress response. As an auxiliary drug, it can control the patient's condition and relieve pain by inhibiting neu-

rons. Therefore, percutaneous puncture microballoon compression combined with carbamazepine provides a superior therapeutic effect [16,17].

This study found that, before treatment, there were no significant differences in the quality of life scores between the two groups ($p > 0.05$). After treatment, the quality of life scores of the observation group were higher than those of the control group ($p < 0.05$), indicating that continuing to take carbamazepine after PBC can effectively improve the quality of life of patients. According to the study of Cao C *et al.* [18], TN is a common neurosurgical problem, which seriously affects the quality of life of patients. PBC treatment is a safe procedure that can block the trigeminal nerve conduction pathway, inhibit the pain trigger point, and relieve the local compression of the trigeminal nerve. Carbamazepine can stabilize over-excited nerve cells, inhibit repeated nerve discharge, effectively reduce the synaptic transmission of excitatory impulses, and has a strong anti-epileptic effect. It can significantly improve the blood supply of the nervous system of patients, effectively protect nerve cells, and reduce the duration and frequency of pain in patients [14,19]. The dosage of the drug is mainly low. Administration of carbamazepine after PBC has a stronger combination effect, which can effectively relieve the degree of pain and improve the quality of life of patients [20].

Zhi D *et al.* [21] reported that PBC provides an effective and relatively safe option for the treatment of trigeminal neuralgia; however, PBC surgery is performed under general anesthesia, which may cause complications. In the present study, the incidence of complications in the observation group (7.50%) was lower than that in the control group (30.00%) ($p < 0.05$). PBC can effectively destroy the large nerve fibers that mainly contribute to trigeminal neu-

ralgia, but the small nerve fibers are not as easily affected by the procedure. However, the nerve fibers can regenerate repeatedly, which may be the cause of recurrent pain in TN patients after successful compression. In the early stage, in order to achieve a good curative effect, a long duration of compression is often used, but postoperative follow-up indicates that the postoperative numbness symptoms of patients with a long period of compression are significantly increased [22]. Song D *et al.* [23] have stated that carbamazepine has a positive effect on microvascular decompression in TN. PBC combined with carbamazepine treatment can reduce the compression time by 1–2 minutes, and continuing to take carbamazepine after surgery can reduce the postoperative numbness symptoms and the occurrence of complications [24].

However, the present study still has some limitations. This was a retrospective cohort study, which could not completely exclude potential confounding factors and information bias. However, we analyzed additional information for the two groups, and demonstrated that the two groups were comparable. The number of subjects selected was small and all were admitted to our hospital, resulting in weak generalizability for the conclusions; moreover, there was no evaluation of the long-term effect of the intervention in patients after surgery. Therefore, in the future, the clinic should expand the scope of sample selection, as well as carry out long-term follow-up observation, considering the limitations in the trial. Future studies should also adopt a more rigorous design in order to obtain more objective and accurate research results, with a view to promoting the further development of the field.

Conclusions

In conclusion, PBC combined with carbamazepine treatment has a significant effect on TN patients, which can promote recovery, improve quality of life, and reduce the occurrence of complications. These results have significant clinical potential for improving the prognosis of TN patients.

Availability of Data and Materials

Data to support the findings of this study are available on reasonable request from the corresponding author.

Author Contributions

XY: Writing—original draft, Investigation, Methodology, Formal analysis, Conceptualization, Writing—review & editing. YL: Writing—original draft, Formal analysis, Visualization, Conceptualization, Writing—review & editing. Both authors read and approved the final manuscript. Both authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

This study has been approved by Xiantao First People's Hospital ethics committee (No.202402002) and Xiantao First People's Hospital ethics committee exempted patient consent because of the anonymity of the data. The study is in accordance with the Declaration of Helsinki.

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Conflict of Interest

The authors declare no conflict of interest.

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