ORIGINAL RESEARCH

Effect of Percutaneous Balloon Compression on Trigeminal Neuralgia and Clinical Significance of NLRP3 Before and After Treatment

Jun Li, MM; Wenhao Wang, MM; Wei Huang, MM; Junming Lin, MM; Xuefeng Zheng, MM; Mingsheng Zhang, MM; Zhikun Lin, BS

ABSTRACT

Objective • Trigeminal neuralgia (TN) is very common in the middle-aged and elderly population and seriously affects the normal life of patients. This study aims to analyze the therapeutic effect of percutaneous balloon compression (PBC) on TN and to explore the clinical significance of NOD-like receptor thermal protein domain associated protein 3 (NLRP3), which not only can provide a reference for the clinical treatment of TN in the future, but also can help the clinic to find a reliable indicator for the assessment of TN condition.

Methods • The length of stay, total cost of hospitalization, and adverse reactions during treatment were compared between the two groups. Patients were subjected to assessments or investigations of the Barrow Neurological Institute (BNI) scale, Pittsburgh Sleep Quality Index (PSQI), Self-rating Anxiety Scale (SAS), and Self-rating Depression Scale (SDS) before and after treatment. In addition, NLRP3 in the peripheral blood of patients in the research group was measured, and the correlation of NLRP3 with BNI score and prognosis for recurrence was analyzed.

Results • The length of stay and the total cost of hospitalization were respectively (12.10±2.20) d and (26445.96±5553.78) yuan in the research group, significantly reduced than those in the control group ($P < .05$). And the BNI score, PSQI and SAS/SDS were lower in the research group after treatment ($P < .05$), but the incidence of facial numbness, herpes orofacialis and masticatory muscle weakness were higher in the research group than in the control group ($P < .05$). After treatment, NLRP3 decreased in the research group, which was positively correlated with BNI score ($P < .05$). In addition, NLRP3 showed an excellent effect in predicting recurrence.

Conclusion • PBC effectively improved the pain and negative psychological status of patients with TN, and NLRP3 was closely related to the pain of patients with TN. In the future, PBC is used in the clinic to treat TN and improve the prognosis of patients. (*Altern Ther Health Med.* 2024;30(10):212-217).

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INTRODUCTION

Trigeminal neuralgia (TN) is characterized by intermittent shooting pain or causalgia; the pain reaches its peak immediately upon onset and may radiate to the entire side of the face, and is described as a sensation of being stabbed, cut with a knife, or electric shock-like; it occurs without any specific pattern and can be triggered by activities such as brushing teeth, eating, or chewing; the intense pain often makes it difficult for patients to fall asleep, significantly affecting their quality of life.[1,2] TN is an extremely common type of degenerative chronic disease worldwide, with an average of more than 3 million new cases per year.[3] Finding effective diagnosis and treatment options is currently a hot topic in clinical research on TN. However, the pathogenesis of TN is still unclear, and nerve damage, genetics, mental stress, and immune factors are considered to be common factors triggering the disease.[4] Surgical treatment is the most direct and effective approach, with microvascular decompression (MVD) being a commonly used one.[5] MVD provides pain relief without causing sensory or motor disorder and has been proven to have excellent outcomes.[6,7] With advancements in medical technology, percutaneous balloon compression (PBC) is also being widely used due to its advantages of simplicity, short procedure time, minimal trauma, and quick recovery (for patients). Patients receiving PBC avoid the risk of craniotomy, which reduces the incidence of serious complications and safeguards the middle-aged and elderly people to a certain extent.[8,9] However, the application of PBC is still controversial given the lack of unified guideline for TN treatment.

It has been reported that NOD-like receptor thermal protein domain associated protein 3 (NLRP3) inflammasome is expressed in many pain-related nerve and immune cells, e.g. osteoarthritis, herniated disc, etc.[10,11] NLRP3 is also regarded as a new clinical diagnosis and treatment marker for TN in the future.[12] However, no study has confirmed the clinical significance of NLRP3 in TN. However, relevant studies on NLRP3 and TN are still relatively rare, and more experiments are needed to demonstrate the specific relationship between the two.

In order to explore the effect of PBC in improving TN and further clarify the clinical significance of NLRP3 in TN, a preliminary analysis was conducted. These results can provide updated references and guidelines for future clinics in the treatment of TN, thus protecting the health of TN patients more effectively.

MATERIALS AND METHODS

Sample size calculation

The sample size was obtained according to the formula: $N=Z^2\times[P\times(1-P)]/E2$. The sample size (Z) was set to 1.96, the probability value (P) was set to 0.5, and the error value (E) was set to 10%, this is also the minimum standard parameter for sample size calculation. The sample size (N) = 96.

Patient data

A total of 108 patients with primary TN who were treated in the Pain Medicine Department of our hospital from January 2022 to January 2023 were selected for this study and analyzed retrospectively. Depending on the patient's symptoms and willingness to make their own choices, they received different TN treatments. The research group consisted of 58 patients who received PBC, and the control group consisted of the other 50 patients who received MVD. Statistical analysis of age, course of disease, gender, and other data showed no statistical difference between the two groups ($P > .05$), indicating comparability. Table 1. This study was to be conducted in strict accordance with the *Declaration of Helsinki*, and all the study subjects had signed the informed consent form.

Table 1. Clinical data

	Control group (n = 50)	Research group (n = 58)	χ^2 or *t*/	*P* value
Age	57.6±5.3	58.5±5.1	0.898	.371
Course of disease (years)	3.4±1.4	3.1±1.7	0.991	.324
Gender			0.023	.881
male	24 (48.00)	27 (46.55)		
female	26 (52.00)	31 (53.45)		
Place of residence			0.681	.409
rural	22 (44.00)	21 (36.21)		
town	28 (56.00)	37 (63.79)		
Location of pain			0.904	.342
left side	27 (54.00)	26 (44.83)		
right side	23 (46.00)	32 (55.17)		
Ethnicity			0.339	.561
han Chinese	45 (90.00)	54 (93.10)		
minority	5 (10.00)	4 (6.90)		

Inclusion and exclusion criteria

Inclusion criteria: Patients who met the diagnostic criteria for TN[13] and were diagnosed in our hospital; patients with indications for MVD and PBC[14,15] who were about to receive surgery for the first time; patients who themselves and their families were informed and signed an informed consent form; patients with complete data and high compliance.

Exclusion criteria: Patients with secondary TN caused by other reasons (e.g., tumor, hemangioma, multiple sclerosis); patients with severe heart, liver, or kidney dysfunction; patients with speech or communication disorders; patients with infectious diseases; patients withdrawing from the study halfway.

Treatment methods

MVD: Under general anesthesia, a 4 cm longitudinal incision was made behind the ear and within the hairline on the affected side of the patients. The skin and muscles were separated to expose the root of the mastoid, and a 3 cm diameter bone window was drilled. The dura mater was cut and cerebrospinal fluid was drained under a microscope. The arachnoid membrane was then dissected to locate the root of the trigeminal nerve and identify the responsible blood vessel causing compression. The compressing segment of the blood vessel was removed, and a Teflon pad was used to isolate the nerve. Finally, the dura mater was closed and carefully sutured layer by layer. PBC: The patient was placed in the supine position, and surgical site disinfection and draping were routinely performed. Under fluoroscopy monitoring, a facial percutaneous puncture was performed, and a specific balloon was inserted under the guidance at the location of the trigeminal ganglion. Then, a contrast agent was injected to inflate the balloon, aiming to relieve the compression of the trigeminal nerve root causing TN. After puncture site compression, sterile dressing was applied to cover the puncture site to complete the treatment.

Sample collection and testing

Three mL of peripheral venous blood was collected from patients in the research group in fasting state and stored in procoagulant tubes before and at 1 month after surgery. The samples were allowed to stand at room temperature for 30 min, followed by centrifugation to obtain serum. The NLRP3 level was then measured according to the instructions of the enzyme-linked immunosorbent assay (ELISA) kit. The kits were purchased from Shanghai Jihe Biotechnology Co., Ltd (China).

Prognosis follow-up

Patients in the research group were followed up for 6 years by regular review once a month to statistically analyze the recurrence of TN during the follow-up period. Relapse was defined as the patient's re-emergence of TN symptoms and confirmation of TN recurrence after diagnosis by a physician.

Outcome measures

The length of stay, total cost of hospitalization, and adverse effects during treatment were statistically analyzed for both groups. Pain intensity was assessed by the Barrow Neurological Institute (BNI) scale[16] before and at 1 month after surgery, with grade I as no pain and no medication needed; grade II as occasional pain without the need for medication;

grade III as pain that can be controlled with medication; grade IV as slight relief in pain after medication, but not controlled; grade V as no relief from pain after medication. The Pittsburgh Sleep Quality Index (PSQI)[17] was applied to evaluate patients' sleep, consisting of 18 entries, each scored on a 0-3 scale. The higher the score, the worse the sleep quality. The Self-rating Anxiety Scale (SAS) and Self-rating Depression Scale (SDS)[18] were applied to assess the psychological status of patients, each questionnaire consisted of 20 questions out of 100, with a standardized score of 53, and depression/anxiety was considered to be present with a score of 53 or higher. Besides, the correlation of NLRP3 with BNI score and prognosis for recurrence was analyzed.

Statistical analysis

Statistical software SPSS 22.0 was used for data processing and analysis. Counting data were expressed as (%), with a chi-square test for inter-group comparison. Measurement data were expressed as ($\bar{x} \pm s$), with independent samples t test for inter-group comparison and paired t test for intra-group comparison. Correlation was analyzed by the Spearman correlation coefficient. $P < .05$ was considered statistically significant. Predictive value by receiver operating characteristic (ROC) curve, when $P<.05$, the diagnostic effect was judged by the area under curve (AUC), with an AUC closer to 1 indicating higher diagnostic accuracy.

RESULTS

Hospitalization

The length of stay and the total cost of hospitalization were respectively (12.10±2.20) d and (26445.96±5553.78) yuan in the research group, significantly reduced than those in the control group ($P < .05$). Figure 1

Pain before and after treatment

Before treatment, there was no significant difference in BNI scores between the two groups ($P > .05$). After treatment, the number of patients with grade IV and grade V decreased notably in both groups, while the number of patients with grade I and grade II increased ($P < .05$), and was larger in the research group ($P < .05$). Table 2

Sleep before and after treatment

Before treatment, there was no difference in PSQI scores between the two groups ($P > .05$). After treatment, the PSQI score of the research group decreased to (6.24±0.78), lower than that of the control group (6.24±0.78) ($P < .05$). Figure 2

Psychological status before and after treatment

The results of SAS and SDS showed that the scores decreased remarkably in both groups after treatment ($P < .05$), which were respectively (30.91±3.93) and (27.28±3.83) in the research group, considerably lower than those in the control group ($P < .05$).

Figure 1. Comparison of hospitalizations. A) Length of stay. B) Total cost of hospitalization. The length of stay and total hospitalization costs were lower in the research group than in the control group.

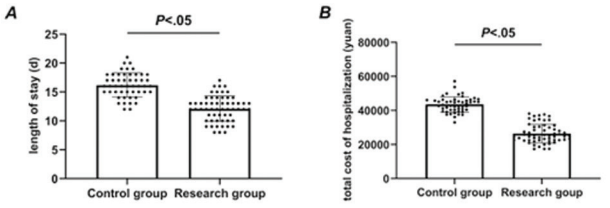


Table 2. Changes in BNI score

BNI score		Control group (n = 50)	Research group (n = 58)	χ^2	*P* value
Before treatment	I	0 (0.0)	0 (0.0)	-	-
	II	0 (0.0)	0 (0.0)	-	-
	III	1 (2.00)	3 (5.17)	0.758	.384
	IV	28 (56.00)	25 (43.10)	1.787	.181
	V	21 (42.00)	30 (51.72)	1.019	.313
After treatment	I	13 (26.00)[a]	43 (74.14)[a]	24.920	<.001
	II	31 (62.00)[a]	10 (17.24)[a]	22.840	.0001
	III	6 (12.00)	5 (8.62)	0.335	.563
	IV	0 (0.0)[a]	0 (0.0)[a]	-	-
	V	0 (0.0)[a]	0 (0.0)[a]	-	-

[a]indicates a statistically significant difference from before treatment.

Figure 2. Changes in PSQI scores before and after treatment**.** PSQI was reduced in both groups after treatment and was more lower in the research group than in the control group.

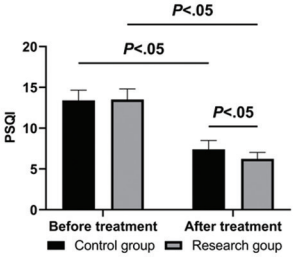
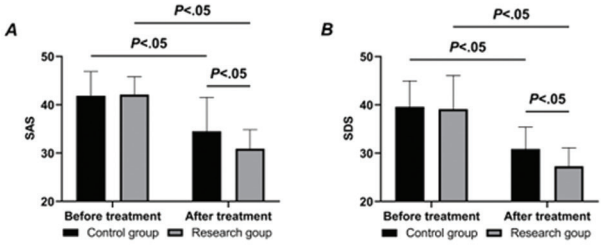


Figure 3. Changes in psychological status. A) SAS. B) SDS. SAS and SDS were reduced in both groups after treatment and were lower in the research group than in the control group.



Adverse reactions

Compared with the control group, the research group exhibited a higher incidence of facial numbness, cold sore mouth, and masticatory muscular weakness ($P < .05$), consistent incidence of diplopia ($P > .05$), and notably lower incidence of vertigo ($P < .05$). Table 3

Table 3. Adverse reactions

Group	Facial numbness	Cold sore mouth	Diplopia	Masticatory muscular weakness	Vertigo
Control group (n = 50)	2 (4.00)	1 (2.00)	0 (0.00)	1 (2.00)	11 (22.00)
Research group (n = 58)	9 (15.52)	8 (13.79)	1 (1.72)	9 (15.52)	1 (1.72)
χ^2	3.894	4.889	0.870	5.839	11.18
P value	.048	.027	.351	.016	.001

Figure 4. Relationship between NLRP3 and BNI scores. A) Changes in NLRP3 before and after treatment. B) Correlation analysis of NLRP3 and BNI scores before treatment. C) Correlation analysis of NLRP3 and BNI scores after treatment. NLRP3 was reduced after treatment in the research group, and there was a positive correlation between NLRP3 and BNI scores before and after treatment.

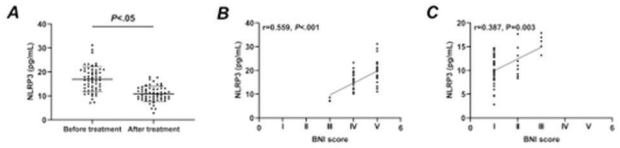
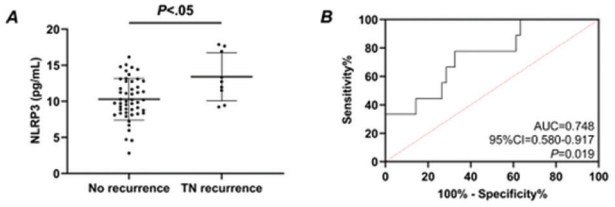


Figure 5. ROC curves evaluating the diagnostic performance of NLRP3 for TN prognostic recurrence**.** A) Comparison of NLRP3 after treatment in patients with and without TN recurrence. B) ROC curves of NLRP3 diagnosis of TN prognostic recurrence. NLRP3 was higher in patients with TN recurrence than in patients without recurrence, and NLRP3 showed excellent predictive value for TN prognostic recurrence.



Changes in NLRP3 before and after treatment and its relationship with BNI scores

The level of NLRP-3 in peripheral blood was (16.71±3.59) pg/mL in the research group before treatment, and it was significantly reduced after treatment ($P < .05$). According to the Spearman correlation coefficient analysis, NLRP3 was positively correlated with BNI scores in the research group before and after treatment ($P < .05$), i.e., the higher the BNI score, the higher the NLRP3. Figure 4

Value of NLRP3 in predicting prognosis for recurrence of TN

During the 6-month prognosis, all the patients in the research group were successfully followed up, 9 of whom had TN recurrence. Patients with and without the recurrence of TN were compared for post-treatment NLRP3 levels, which were considerably higher in those with TN recurrence ($P<.05$). The ROC curve showed that when post-treatment NLRP3 was > 11.44 pg/mL, the sensitivity and specificity for predicting TN recurrence in 6 months were respectively 77.78% and 67.35% ($P<.05$). Figure 5

DISCUSSION

In this study, we found that PBC is excellent in improving TN, and the change in NLRP3 before and after treatment is of great clinical significance, which provides an important reference for TN treatment in the future.

First, pain relief was compared between the two groups before and after treatment. It was observed that patients receiving PBC showed a greater decrease in BNI scores compared with those receiving MVD, confirming that PBC was more effective in relieving the pain of patients with TN, which was consistent with the results of previous studies.[19,20] PBC was first reported by Mullan in 1983. With the development of modern medical technology, the approach has been gradually improved, with a postoperative pain relief rate of up to 88%-97% according to reports.[21] In recent years, it has also been demonstrated that PBC has good efficacy in recurrent TN after MVD,[22] along with the advantages below: (1) As the puncture needle is inserted next to the patient's mouth, a small trauma with the size of a pinhole will be made. Besides, since the procedure is minimally invasive, the patient's recovery period is notably shortened, and the patient can be discharged from the hospital within 1-2 days, which reduces medical costs. This was also confirmed by shorter lengths of stay and lower hospitalization costs in the research group. (2) The duration of the procedure is short, usually only 20 minutes, making it possible to avoid stress injury caused by mechanically invasive operation. (3) Patients of all age groups can tolerate the entire procedure under general anesthesia. Such may be the reason for notably lower PSQI scores in the research group. (4) By selectively preserving the unmyelinated nerve fibers that transmit corneal sensation, the incidence of postoperative complications such as keratitis and corneal ulceration significantly decreases compared to radiofrequency thermocoagulation, so it is particularly suitable for patients with TN involving the first branch.[23]

According to the results of the comparison of adverse reactions, the research group showed a higher incidence of facial numbness, masticatory muscular weakness and herpes, which were also frequently occurring PBC-related adverse reactions. Research has shown that facial numbness and masticatory muscular weakness may be caused by effective compression of the trigeminal ganglion and damage to the motor branches of the trigeminal nerve by the balloon, which is also one of the unavoidable injuries in PBC.[24] When the balloon catheter is close to the cavernous sinus or the balloon is inserted too deeply, it may compress and damage the abducens nerve, leading to diplopia.[25] In this study, however, diplopia was observed in only 2 patients, which is closely related to the high proficiency of doctors in our hospital in performing PBC. The outbreak of herpes is also common after PBC,[26] which may be the result of activation and infection of latent herpes simplex virus within the nerves during the puncture process. Antiviral treatment is usually not needed in this case, as the infection can resolve on its own.

The comparison of the psychological status between the two groups revealed lower SAS and SDS scores in the research group after treatment, indicating that PBC was also beneficial in improving the negative psychological status of patients with TN. Severe pain due to TN is usually recurrent.[27] According to psychological research, long-term pain can easily cause negative emotions such as rage, depression, and anxiety.[28] Prolonged exposure to such negative emotions is not only detrimental to patient compliance but may also lead to loss of confidence in treatment and the occurrence of depression.[29] Therefore, the psychological status of patients with TN is also worthy of attention in clinical treatment. Decreased SAS and SDS scores in the research group were also presumed to be the results of the enhanced pain relief by PBC, suggesting that PBC could be the preferred treatment option for TN in the future, thus providing patients with comprehensive physical and psychological treatment.

To provide a more comprehensive reference for the diagnosis and treatment of TN, the clinical significance of NLRP3 before and after treatment was further analyzed. The results showed that the NLRP3 levels of patients in the research group were remarkably reduced after PBC, which confirmed that NLRP3 may be involved in the occurrence and development of TN, consistent with the results of previous research.[30] Studies have shown that in patients with TN, compression on the nerve may lead to thinning of the myelin sheath, similar to other nerve disorders. Such can trigger inflammation in the trigeminal nerve, resulting in infiltration of glial cells, axonal degeneration, the proliferation of Schwann cells, and infiltration of inflammatory cells. The key transcription factor nuclear factor κB (NF-κB) in the inflammatory reaction of the trigeminal ganglion can induce the reaction of the NLRP3 inflammasome signaling pathway, which further promotes the release of various inflammatory factors by the body.[31] It was also found that the pain threshold of mice was significantly increased after NLRP3 silence in TN model mice,[32] proving the important role of NLRP3 in TN. In the present study, NLRP3 was also positively correlated with patients' BNI scores, which confirms the above-mentioned view. Furthermore, we have found that NLRP3 exhibited excellent predictive efficacy in the prognosis of TN recurrence, suggesting that NLRP3 may be used to evaluate the condition of TN one day. The underlying mechanism may be attributed to the accelerated release of inflammatory factors mediated by elevated levels of NLRP3 after treatment, which triggers TN recurrence. Nevertheless, more experimental evidence is still needed.

However, the small number of cases in this study and the short study period require a larger number of cases to further validate our results. Meanwhile, because the study was a retrospective analysis, our observational indicators were limited, and more objective indicators (e.g., inflammatory factors, immunoglobulins, etc.) are needed to assess the therapeutic effect of PBC on TN. In the follow-up study, we will carry out a follow-up controlled trial as soon as possible to refine the above limitations.

CONCLUSION

PBC has a significant effect in the treatment of TN, which effectively improves the pain and negative psychological status of patients, and is of great clinical significance. NLRP3 is closely related to the pain of patients with TN and is excellent in predicting the recurrence of TN, which is expected to become a new clinical assessment index for TN in the future.

ETHICAL APPROVAL

Not applicable.

COMPETING INTERESTS

The authors report no conflict of interest.

AUTHOR CONTRIBUTIONS

Jun Li and Wenhao Wang conceived and designed the project, and wrote the paper. Wei Huang generated the data. Junming Lin and Zhikun Lin analyzed the data. Xuefeng Zheng and Mingsheng Zhang modified the manuscript. All authors gave final approval of the version to be published, and agreed to be accountable for all aspects of the work.

AVAILABILITY OF DATA AND MATERIALS

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ACKNOWLEDGEMENTS

Not applicable.

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