Retrospective Study

Efficacy and Complications of Percutaneous Balloon Compression for Patients With Trigeminal Neuralgia With and Without Concomitant Continuous Pain

Shuo Li, MBBS, Chenlong Liao, MD, PhD, Guangyu Wang, MMed, Yuanjie Zhang, MMed, Yiwei Wu, MD, PhD, and Wenchuan Zhang, MD, PhD

From: Department of Neurosurgery, Shanghai Ninth People's Hospital, affiliated with Shanghai JiaoTong University School of Medicine, Shanghai, People's Republic of China

Address Correspondence: Wenchuan Zhang, MD, PhD Department of Neurosurgery, Shanghai Ninth People's Hospital No.639, Zhizaoju Road Huangpu District, Shanghai, People's Republic of China E-mail: zhangwench88@sjtu.edu.cn

Disclaimer: Shuo Li and Chenlong Liao are co-first authors. There was no external funding in the preparation of this manuscript.

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 04-24-2023
Revised manuscript received: 06-17-2023
Accepted for publication: 07-19-2023

Free full manuscript: www.painphysicianjournal.com

Background: Percutaneous balloon compression (PBC) has become one of the most common and effective minimally invasive treatments for trigeminal neuralgia (TN). However, the initial and long-term pain outcomes, as well as the complication rates of PBC for patients with TN with concomitant continuous pain (CCP) have yet to be specifically documented.

Objective: In this clinical study, we aimed to evaluate and compare the results of PBC in treating TN with and without CCP.

Study Design: Retrospective study.

Methods: This research retrospectively analyzed the pain outcomes and complications of 57 patients with TN with CCP and 118 patients with TN without CCP who had undergone PBC at our institution from January 2019 through June 2022. Procedures were performed by one senior neurosurgeon in a single center. The postdischarge follow-up and the collection of clinical data, including immediate and long-term pain relief, time to recurrence, and complications, were completed through phone contact by an independent neurosurgeon blind to the patients' information. Then, the results of the 2 groups were compared; demographic and clinical data were evaluated for possible predictive factors for poor pain outcomes.

Results: In this study, PBC immediately resulted in complete pain relief in 70.2% of patients with CCP and significant pain relief in 84.2% of patients with CCP. For patients without CCP, the rates were 73.7% for complete pain relief and 85.6% for significant pain relief. After a minimum 6-month follow-up period, the rates decreased to 52.6% for complete pain relief and 73.7% for significant pain relief in patients with CCP, compared to 54.2% and 75.4% in those without CCP. The initial and long-term pain control rates in patients without CCP were slightly higher than those with CCP, but the differences were not statistically significant ($P = 0.878$, $P = 0.968$, respectively). The incidences of postoperative complications were similar between patients with and without CCP (21.1% vs 22.0%, $P = 0.883$), whereas the remission rate of complications in patients with CCP was significantly lower than that in patients without CCP (25.0% vs 69.2%, $P = 0.011$). A longer symptoms duration and having a history of neurodestructive procedures were predictive factors for poor outcomes following PBC.

Limitations: The study was performed in a single-center. The nature of this research is retrospective instead of prospective and randomized, with the inability to control completely for variables. Additionally, the follow-up duration was not long enough to observe recurrence in some patients.

Conclusions: This is the first specifically reported experience treating TN with CCP with PBC. PBC can result in significant relief of both episodic and constant pain from TN with CCP. Patients with a longer duration of pain and prior neurodestructive procedures have a higher risk of poor outcomes. The presence of CCP is not associated with pain outcomes and should not be considered a contraindication to PBC.

Key words: Percutaneous balloon compression, trigeminal neuralgia, concomitant continuous pain, pain relief, comparison, efficacy, complication, predictive factor

Clinical trial registration number and Registry URL: SH9H-2022-T258-2

Pain Physician 2023: 26:E823-E832

It is known that the characteristic pain of trigeminal neuralgia (TN) is paroxysmal and sharp, as well as superficial, commonly lasting from one second to 2 minutes (1). However, a significant percentage of patients with TN (20% - 60%) have an atypical clinical picture, with constant, burning, and dull background pain in the trigeminal nerve distribution area (2-5). According to the latest International Headache Society classification criteria, TN is classified into TN, purely paroxysmal; and TN with concomitant continuous pain (CCP), formerly called atypical TN (6). The atypical condition may evolve from the classic symptom and rarely responds to medications, including carbamazepine, phenytoin, or baclofen, representing a great diagnostic and treatment challenge for clinicians (7,8). In addition, the etiology of CCP has also not been well understood; no theory fully elucidates how the continuous dull pain develops. Some studies indicate that peripheral or central sensitization or trigeminal nerve atrophy may be involved, but substantial evidence is lacking (9-12).

Surgical management of TN with CCP is particularly challenging but fairly significant, considering that a large body of patients with CCP have a poor response to medications and have to seek surgical interventions. With the development and application of surgical procedures and medicines in clinical practice, the intense pain can be controlled effectively in a majority of patients with TN. However, an increasing number of studies focusing on the predictive factors for pain recurrence have suggested that the presence of CCP is a poor prognostic factor in patients with TN treated with microvascular decompression (MVD) (13,14). In addition, multiple studies have reported that patients with TN with CCP tend to benefit less from current surgical procedures like MVD and gamma-knife radiosurgery, representing an intractable issue that needs to be urgently solved (15-20).

Commonly performed percutaneous procedures treating TN by means of directly injuring the pain fibers in the trigeminal nerve include percutaneous glycerol rhizotomy, percutaneous balloon compression (PBC), and percutaneous radiofrequency thermocoagulation. Percutaneous procedures may be considered the first option for patients without apparent neurovascular compression based on preoperative magnetic resonance imaging or for patients with poor general conditions (21). Previous studies have confirmed the effective pain relief of all 3 procedures for patients with TN (22-24).

Nevertheless, some clinical studies have also suggested that this atypical symptom was a sensitive predictive factor for pain recurrence after percutaneous procedures. A study by Zakrzewska, et al (25) showed that patients with TN with CCP were more likely to suffer from pain recurrence and postoperative complications after radiofrequency thermocoagulation (25). The literature abounds with reports on the efficacy of PBC for pain control in classic TN, but unfortunately the pain outcomes and complications of patients with TN with CCP following PBC remain unclear. In addition, it is still controversial whether the occurrence of CCP is predictive of poor pain outcomes after PBC. For this purpose, we recorded the clinical information of the 2 patient populations who underwent PBC at our institute and followed-up with them for at least 6 months.

Methods

Patient Characteristics

A total of 393 patients with TN visited our department and underwent surgical interventions from January 2019 through June 2022. Patients presenting with characteristic recurrent pain and no symptoms between attacks fulfilling criteria for 13.1.1.1.1 or 13.1.1.3.1 of The International Classification of Headache Disorders, 3rd Edition (ICHD-3) were classified as the TN without CCP group. Patients presenting with both paroxysmal facial pain and CCP or near-CCP in the affected trigeminal distribution between attacks fulfilling criteria for 13.1.1.1.2 or 13.1.1.3.2 were classified as the TN with CCP group (6).

Patients with secondary TN, multiple sclerosis, injury to the trigeminal nerve, other paroxysmal or constant facial pains, and < 6 months of follow-up were excluded from this study. In addition, patients presenting with trigeminal deafferentation pain after prior neurodestructive procedures were also excluded.

After the screening, 57 patients with TN with CCP and 118 patients with TN without CCP were included in this clinical study. Preoperative demographic data and clinical characteristics were recorded in detail and are presented in Table 1.

Procedure Description

The procedures were performed under general anesthesia with patients supine on the operating table. A site parallel to the ipsilateral pupil 3 cm anterior to the external auditory canal and a skin puncture point 2.5 cm lateral to the corner of the mouth were then landmarked (26). A 14G introducing cannula and a No. 4 balloon catheter (Yinluo Medical Equipment Co., Ltd) were prepared. The 14G needle was inserted along the target trajectory, and punctured to 8 cm in depth. The foramen ovale was then entered and confirmed with the outflow of cerebrospinal fluid or via fluoroscopy. The balloon was inserted and inflated by injection of 0.7 mL iohexol contrast medium. In general, a pear-shaped configuration of the balloon was formulated and presented by fluoroscopy (Fig. 1). After 4 minutes, the balloon was deflated and the catheter and cannula were removed.

Table 1. *Demographic and clinical characteristics of patients with TN with CCP and without CCP.*

Characteristic	TN without CCP (n = 118)	TN with CCP (n = 57)	*P* value
mean age in years	57.3 ± 10.8 (32-94)	57.1 ± 11.5 (32-88)	0.821
mean follow-up in months	26.9 (6-50)	26.2 (6-48)	0.701
men/women	38:80	22:35	0.746
left/right (%)	56:62	18:39	0.156
mean disease duration in months	74.6 ± 73.1 (1-428)	60.1 ± 53.4 (1-242)	0.248
involvement of trigeminal divisions (% of cases)			
1st division	16 (16.1%)	7 (12.3%)	0.863
2nd division	99 (83.9%)	42 (73.7%)	
3rd division	60 (41.5%)	32 (52.6%)	
Response to medication			0.015*
Yes	98 (83.1%)	38 (66.7%)	
No	20 (16.9%)	19 (33.3%)	
Previous operations (% of cases)			0.852
PRF	17 (14.4%)	8 (14.0%)	
PBC	7 (5.9%)	5 (8.8%)	
MVD	34 (28.8%)	26 (45.6%)	
Gamma Knife	3 (2.5%)	2 (3.5%)	

Values are expressed as number (%) or as mean ± SD, unless indicated otherwise. *: $P < 0.05$; TN: trigeminal neuralgia; CCP: concomitant continuous pain; PRF: percutaneous radiofrequency thermocoagulation; PBC: percutaneous balloon compression; MVD: microvascular decompression

Clinical Follow-up and Outcome Assessment

To avoid selection bias, an independent neurosurgeon with no role in patient management during the study period was responsible for following up by phone with patients and assessing their pain relief. During calls, the patients were requested to indicate whether their facial pain disappeared, when pain recurrence occurred if it did, and whether there were any complications. The follow-up duration ranged from 6 months to 48 months in 6-month intervals. The degree of facial pain and numbness were assessed using the Barrow Neurological Institute (BNI) pain intensity and numbness scales, respectively (Table 2). Pain outcomes were defined as complete (BNI I), significant (BNI II), and poor (BNI III-V). Recurrence was defined as the re-

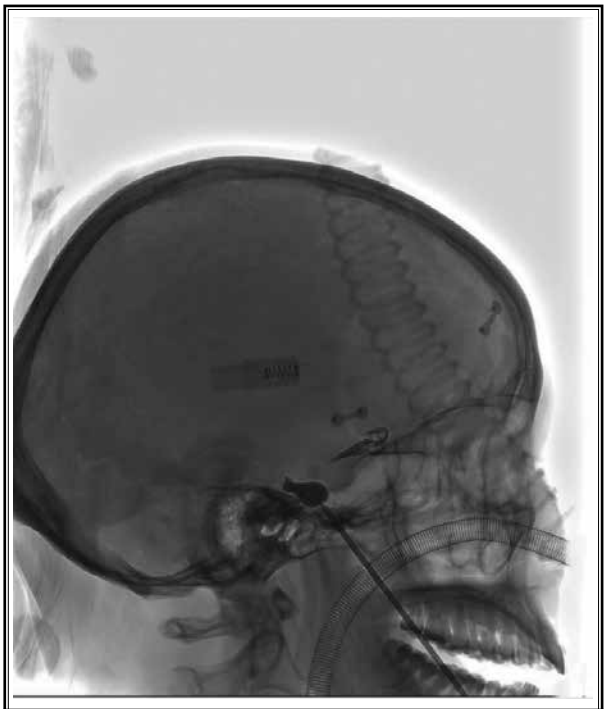

Fig. 1. *The foramen ovale was successfully penetrated and contrast media was injected into the balloon. The obtained "pear" shape was visualized on the lateral fluoroscopic image.*

Table 2. *Barrow Neurological Institute facial pain and numbness intensity scale.*

Grade	Description
Pain	
I	no pain, no medication
II	occasional pain, no medication
IIIa	no pain, continue medication
IIIb	persistent pain, controlled with medication
IV	some pain, not controlled with medication
V	severe pain or no relief
Numbness	
I	no numbness
II	mild numbness that is not bothersome
III	somewhat bothersome numbness
IV	very bothersome numbness

appearance of pain after initial improvement and with an intensity of BNI III-V. BNI numbness scale scores of III-IV were considered as the presence of bothersome facial numbness (27).

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics 26.0 (IBM Corporation). Comparisons between groups were performed using an independent samples t test or Wilcoxon's rank-sum test for continuous data and Pearson's χ^2 test or Fisher's exact test for categorized data as appropriate. The duration from surgery to a poor outcome (ineffective or recurrence) for various patient populations was plotted using Kaplan-Meier survival analyses. The identification of factors predicting the outcomes was performed by univariate analyses. Then a multivariate Cox proportional hazards model was used to assess the variables in pain relief. Only variables with a P value < 0.2 on univariate analysis were entered into the multivariate model to avoid overfitting.

Predictive factors included 9 categorized variables: gender, age (more than 60 years old or not), symptoms side, distributions (involvement in more than multiple branches or not), symptoms duration (more than 3 years or not), type of pain, a history of MVD, a history of neurodestructive procedures, and response to medication. The results were presented as hazard ratios (HRs), corresponding 95% CIs, and corresponding P value. Significance was accepted at the 0.05 level. The study was approved by our institutional review board.

Results

Patient Characteristics

The patient data included a total of 175 PBC procedures. Patients having a poor response or no response to PBC were treated with percutaneous radiofrequency thermocoagulation instead of repeated PBC. PBC procedures were performed for patients with TN without CCP in 67.4% and patients with TN with CCP in 32.6%. Demographic and clinical preoperative data are shown in Table 1. There were no significant differences between the 2 patient groups regarding age, side, distribution, duration of pain before PBC, or duration of follow-up after PBC (P > 0.05). No significant difference in the number of previous operations was observed between patients (P = 0.852). The response rate to medications in patients with CCP was significantly lower than that in patients without CCP (66.7% vs 83.1%, P = 0.015).

Pain Outcomes

During the follow-up, 14 patients were lost to contact (i.e., a 92.6% response rate), leaving a total of 175 patients. The mean follow-up period was 26.8 months (range, 6 – 50 months) for patients without CCP and 26.2 months (range, 6 – 48 months) for patients with CCP.

When visiting our center, all patients categorized their paroxysmal pain and continuous or near-continuous pain as severe (BNI III - V). The initial and long-term outcomes of all patients are shown in Fig. 2 and Fig. 3, respectively. For all patients, 85.1% reported good outcomes (BNI I, 72.6%; BNI II, 12.6%) immediately following PBC. The remaining 14.9% reported poor or no pain relief. At the last follow-up, 74.8% of the patients still reported complete and good outcomes (BNI I, 53.7%; BNI II, 21.1%). The Kaplan- Meier plot depicts the pain recurrence following PBC for all patients over time (Fig. 4).

The Kaplan- Meier plots generated for both patient groups following PBC were highly similar (χ^2 = 0.563, P = 0.453) (Fig. 5). Twelve patients without CCP (mean 7.5 months, 2 - 24 months) and 6 patients with CCP experienced a recurrence of paroxysmal pain (mean 6.0 months, 2 - 12 months) during follow-up. The pain recurrence most frequently occurred within 12 months after initial relief (88.9%). The difference in the time-to-recurrence between groups was not statistically significant (P = 0.627).

Complications

No major complications occurred in both groups,

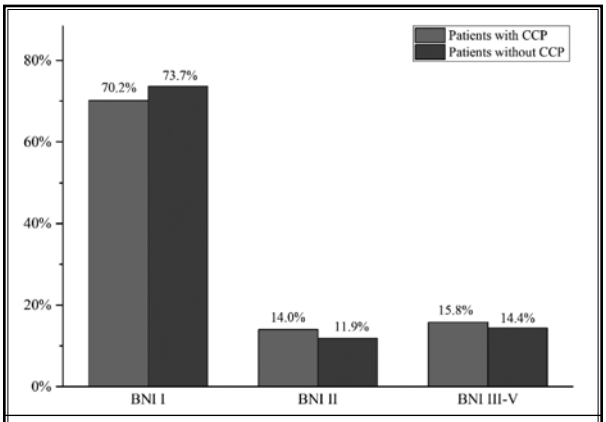

Fig. 2. *Initial pain relief rates in patients with and without concomitant continuous pain following percutaneous balloon compression.*

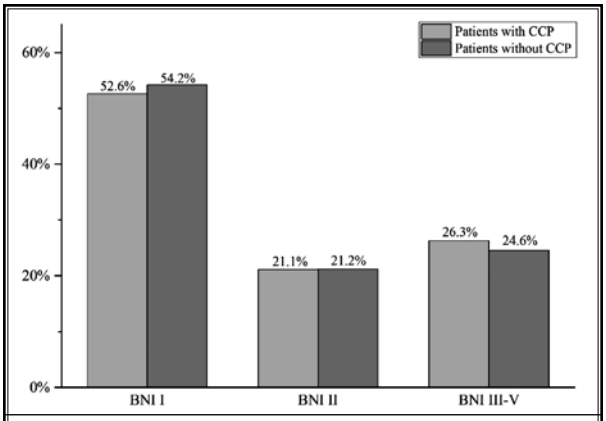

Fig. 3. *Long-term pain relief rates in patients with and without concomitant continuous pain following percutaneous balloon compression.*

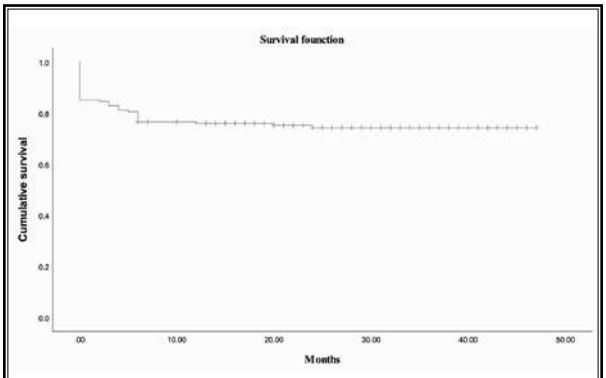

Fig. 4. *Illustration of pain recurrence following percutaneous balloon compression for trigeminal neuralgia over time.*

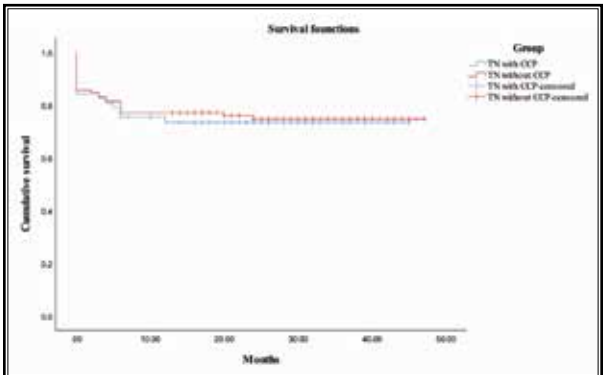

Fig. 5. *Kaplan-Meier survival curves for both patient groups are shown ($\chi^2 = 0.563$; $P = 0.453$).*

including cerebrospinal leak, meningitis, and death. Postoperative numbness in the trigeminal nerve distribution after PBC was experienced in 92.0% of all patients. Bothersome facial numbness (BNI III–IV) was reported in 16.9% of patients without CCP and 19.3% of patients with CCP. The postoperative complications of PBC are presented in Fig. 6. The difference in the rate of complications (excluding numbness) was not statistically significant between patients with and without CCP at the time of discharge (21.1% vs 22.0%, $P = 0.883$). Dysesthesia was the most common type of complication in both groups. At the last follow-up, there were 15.8% of patients with CCP and 6.8% of patients without CCP reporting complications after PBC. Although no significant difference in the lasting complication rates was found ($P = 0.059$), the remission rate of complications was statistically lower in patients

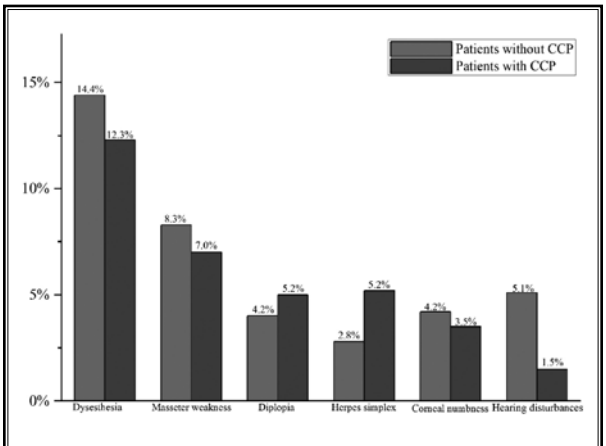

Fig. 6. *The incidence of postoperative complications after percutaneous balloon compression at discharge.*

with CCP than in patients without CCP (25.0% vs 69.2%, $P = 0.011$).

Preoperative Prognostic factors for Pain Outcomes

Overall preoperative predictors of poor outcomes were analyzed (Table 3). In the univariate analysis, only 2 variables were found to be associated with poor outcomes of pain following PBC: duration of presurgical symptoms > 3 years (hazard ratio [HR] 3.57; 95% CI, 1.71 – 7.42; $P < 0.001$) and a history of previous neurodestructive procedures (HR 4.07; 95% CI, 2.25 – 7.37; $P < 0.001$). Kaplan-Meier plots were designed (Fig. 7 and Fig. 8). A multivariate Cox hazards analysis was performed to determine which variables predicted an unfavorable outcome.

At the end of the stepwise selection process, the above 2 variables were still retained in the final model constructed on 175 patients: duration of presurgical symptoms > 3 years (HR 2.90; 95% CI, 1.31 – 6.42; $P = 0.008$) and a history of previous neurodestructive procedures (HR 3.84; 95% CI, 2.04 – 7.23; $P < 0.001$).

Table 3. *Hazard ratios (HR) associated with poor outcomes of the different variables included in the univariate model.*

Variable	HR (95% CI) (n = 175)	*P* Value
Age, yrs		
≤ 60	Ref	
> 60	0.95 (0.52 – 1.76)	0.875
Gender		
Men	Ref	
Women	0.88 (0.47 – 1.68)	0.714
Painful side		
Right	Ref	
Left	0.69 (0.37 – 1.29)	0.249
Distribution		
One branch	Ref	
multiple branches	0.88 (0.49 – 1.60)	0.682
Preop symptom duration, yrs		
≤ 3	Ref	
> 3	3.57 (1.71 – 7.42)	0.001***
Previous neurodestructive procedures		
No	Ref	
Yes	4.07 (2.25 – 7.37)	0.000***
Previous MVD		
No	Ref	
Yes	0.79 (0.42 – 1.49)	0.461
Response to medication		
No	Ref	
Yes	1.47 (0.82 – 2.62)	0.196
CCP		
No	Ref	
Yes	1.09 (0.59 – 2.04)	0.783

***: $P < 0.001$; MVD: microvascular decompression; CCP: concomitant continuous pain

Discussion

Few studies have focused on the efficacy of PBC for TN with CCP to date. Here, we present the long-term experience of a single institution's surgical outcomes of TN with CCP and without CCP following PBC and compare their pain outcomes and complications. The most

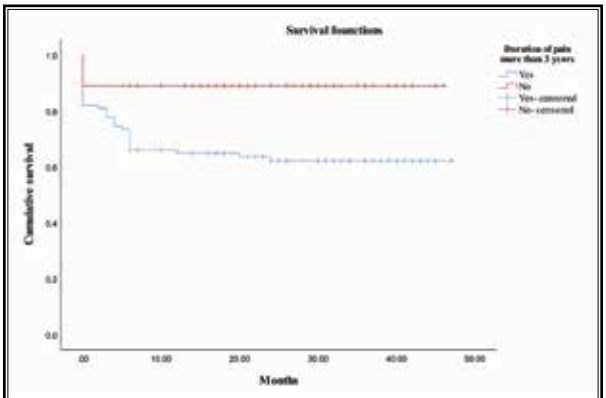

Fig. 7. *Kaplan-Meier plot illustrating survival curves for different duration of pain. The difference between groups was noticeable ($\chi^2 = 14.547$; $P < 0.001$).*

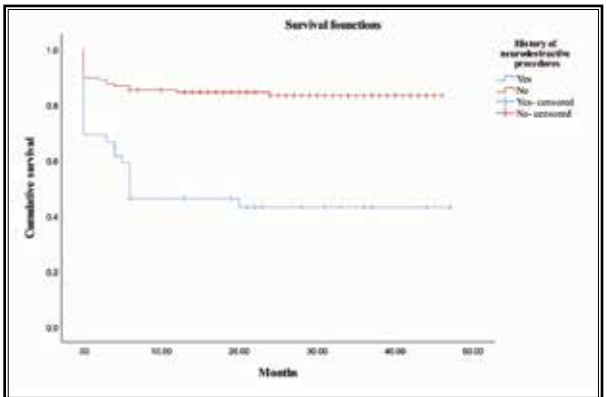

Fig. 8. *Kaplan-Meier plot illustrating survival curves for a different history of neurodestructive procedure. A statistically significant difference was obtained ($\chi^2 = 27.917$; $P < 0.001$).*

striking observation is that PBC has similar efficacy for TN with CCP as it does for TN without CCP.

Patient Characteristics

In this clinical study, TN without CCP accounted for 67.4%, and TN with CCP accounted for 32.6% of all cases. This proportion was consistent with the study by Sindou, et al (18) of 452 patients, consisting of 65.5% with typical TN and 35.5% with atypical TN (i.e., the presence of constant pain). In 71.9% of the patients with atypical TN, the continuous pain occurred at the onset of TN; the remaining patients developed this condition 6 months to 12 years after the paroxysmal pain. Almost all patients described the concomitant pain as persistent, dull, and not as violent as the paroxysmal pain (18).

Compared with patients with TN without CCP, patients with TN with CCP were not significantly older, and their paroxysmal pain did not last longer. Regarding gender and distribution, there was no significant difference. Patients with CCP sought surgical interventions earlier than patients without CCP, though the difference was not statistically significant ($P = 0.248$). The constant pain, which further reduces a patient's quality of life and is more difficult to control through medication treatments, may account for this phenomenon. Similar to the previous conclusion (19), patients with CCP responded more poorly to medication than those without CCP (66.7% vs 83.1%, $P = 0.015$). In addition, there was a slight, nonsignificant overrepresentation of prior procedures in patients with CCP.

Pain Outcomes in Patients With or Without CCP

A large number of studies have reported their experience treating TN with PBC (28-34). In our study, 85.6% of patients without CCP achieved significant pain relief immediately. The proportion of initial pain relief was similar to previous studies on PBC, with initial pain relief rates ranging from 83% - 100% (35), thus contributing to the widely accepted conclusion that PBC could result in immediate pain relief in a majority of patients.

Although the literature on PBC for TN is numerous, less attention has been paid to the efficacy of PBC for TN with CCP. Three previous studies have analyzed the effect of PBC on atypical pain (36-38), however, patients with deafferentation pain, symptomatic neuralgia in multiple sclerosis, postherpetic neuralgia, or other facial pains were also included. Consequently, no study has specifically evaluated the outcomes and complications of patients with TN with CCP so far.

Although the general view among neurosurgeons has been that surgical interventions are less effective for TN with CCP (39), the initial pain relief following PBC was observed in 84.2% of patients with CCP in our study. Although the pain relief rate was slightly lower than those in patients without CCP, no statistically significant difference was noted. It is worth noting that 5 patients with significant relief of paroxysmal pain reported their CCP was residual following PBC, but tolerable and did not require medications. Our results show that both paroxysmal pain and persistent pain can be relieved by PBC in patients with CCP.

It has been reported that one of the major limitations of PBC is its high recurrence rate (40). However, in our study at the final follow-up, there were still 73.7% of patients with TN with CCP and 75.4% of patients with TN without CCP remained pain-free. Pain recurrence was noted in only 12 (10.2%) patients without CCP and 6 (10.5%) patients with CCP, indicating that the recurrence rates between the 2 patient groups were not significantly different. Importantly, we noticed that 88.9% of recurrence occurred within 12 months after PBC in both groups.

The tendency that relapses usually occur within postsurgical one year has also been found in several other studies. Sanjeet et al (36) found that pain most frequently returned one year post-PBC. Therefore, we inferred that if pain did not recur within one year, the probability of recurrence was greatly reduced. The recurrence rates post-PBC of our study were lower than prior results. Sanjeet et al (36) suggested that about 46% of patients with TN with atypical pains developed pain recurrence during the follow-up period. Kouzounias et al (41) reported that the patient success rate decreased from 85% to 36% with a mean follow-up of 20 months. The short follow-up duration and distinguishing CCP from other atypical pains of this study may account for the low recurrence rate.

Selecting appropriate patients who fulfill some criteria may improve PBC's curative effect. To further identify the potential predictive factors for poor outcomes of PBC for TN, we created a multivariate Cox model. At the end of the stepwise selection process, the following 2 variables were entered: duration of presurgical symptoms > 3 years ((HR 2.90; 95% CI, 1.31 – 6.42; $P = 0.008$)) and a history of neurodestructive procedures (HR 3.84; 95% CI, 2.04 – 7.23; $P < 0.001$).

Longer symptom durations associated with poor

outcomes have also been found with MVD and stereotactic radiosurgery in other studies (42-46), thus suggesting that patients receiving surgical interventions in the early stage of TN may have a better prognosis. Since existing procedures are aimed at the peripheral nerve, a possible mechanism for a poor prognosis is that central sensory transmission is overactivated (central sensitization) because of sustained and long-term compression. Because the underlying mechanisms of pain relieved by MVD and neurodestructive procedures are different, a history of MVD and a history of neurodestructive procedures are studied separately as different factors. Our results demonstrate that a history of neurodestructive procedures is associated with poor pain outcomes, whereas a history of prior MVD was not.

Therefore, we suggest that patients with prior neurodestructive surgeries should be treated with PBC carefully. Importantly, CCP had no effect on the outcomes post-PBC in our study, although the presence of CCP was commonly considered one of the most important predictors (38,47,48). In a multivariate analysis conducted by Kourilsky et al (47), atypical pain was identified as a sensitive factor for predicting pain recurrence. Additionally, several intraoperative factors, including the shape of the balloon, inflation pressures, and the compression's length of time, may also influence the effectiveness of PBC for TN. Given that the purpose of the prognostic model was to select appropriate patients for PBC, the intraoperative and postoperative factors were not taken into account.

Complications

PBC is relatively less invasive compared with MVD, but the rate of complications is higher. All patients with initial pain relief suffered from facial numbness; however, only 44% of our patients who had a poor or no immediate response to PBC experienced facial numbness. The presence of postoperative facial numbness may predict pain relief following PBC. Some surgeons consider postoperative numbness to be a positive indicator in patients who have received PBC (41,49). The incidence of bothersome facial numbness in patients with CCP was slightly higher than in patients without CCP, while the difference was not significant (19.3% vs 16.9%, $P = 0.703$). Although no severe complications were reported in this series, common postoperative complications were inevitable, with 21.1% of patients with CCP and 22.0% of patients without CCP suffering from one or more complications. At the end of the follow-up, complications still existed in 15.8% of patients with CCP and 6.8% of patients without CCP. The remission rate of complications in patients with CCP was statistically lower (25.0% vs 69.2%, $P = 0.011$), which meant that patients with CCP were more likely to suffer from long-term complications than patients without CCP.

Conclusion

PBC can result in significant relief for both episodic and constant pain for TN with CCP. Patients with CCP are more likely to suffer from durable complications. Patients with a longer duration of pain and prior neurodestructive procedures have a higher risk of poor outcomes. The presence of CCP is not associated with pain outcomes and should not be considered a contraindication to PBC.

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