Prognostic Nomogram for Percutaneous Balloon Compression in the Treatment of Trigeminal Neuralgia

Mingxing Liu

Department of Neurosurgery, Qingdao Municipal Hospital

Siwei Tang

Department of Neurosurgery, Qingdao Municipal Hospital

Tong Li

Department of Neurosurgery, Qingdao Municipal Hospital

Zhiming Xu

Department of Neurosurgery, Qingdao Municipal Hospital

Shengli Li

Department of Neurosurgery, Qingdao Municipal Hospital

Yong Zhou

Department of Neurosurgery, Qingdao Municipal Hospital

Luo Li

Department of Neurosurgery, Qingdao Municipal Hospital

Weimin Wang (✉ wangwm@sina.com)

Qingdao Municipal Hospital Group <https://orcid.org/0000-0002-0030-3146>

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Abstract

Because of its convenience and safety, percutaneous balloon compression (PBC) has become a more popular remedy for trigeminal neuralgia (TN) recently. The objective of this study was to establish a nomogram that can be used to preoperatively prognosticate the likelihood of pain-free based on preoperative disease characteristics. Clinical data were collected from those TN cases who had undergone PBC during the period of 2015 and 2020 in Qingdao municipal hospital. We excluded the cases caused by space-occupying lesion or had undergone MVD, Percutaneous glycerol rhizotomy (PGR) and glycerol rhizotomy (GR). A nomogram was established based on the results of multivariable logistic analysis. A receiver operating characteristic curve (ROC) analysis was applied to evaluate the reliability of models. The plotted decision curves were also used to assess the net benefit of nomogram-assisted decisions. Internal validation was performed using the ROC by bootstrap sampling. Finally, 16 cases and 69 cases were included into the ineffective and effective groups respectively. In the crude, adjust I and adjust II models, response to carbamazepine positively, the grade II or III compression severity score and classical TN type were all considered to be significant predictors of pain relief (BNI grades I-III) at 3 months follow-up. The AUC, accuracy, specificity, and sensitivity of the nomogram system was 0.83, 0.85, 0.75, 0.87 respectively for predicting patient outcomes. The decision curves showed good performance for the nomogram system in terms of clinical application. While, more research with validation in multiple, external independent patient populations is needed.

Introduction

Trigeminal neuralgia (TN) is a unilateral, sudden, recurrent pain in the distribution of the fifth cranial nerve. Several studies have reported the incidence rates of TN ranged between 5.9 and 12.6 per 100,000[5]. There is a wide range of medical and surgical treatments available for the TN[10, 5]. Although the microvascular decompression (MVD) has been widely accepted as an effective remedy for treatment of TN, it needs open-brain surgery and the mortality has been quoted as 0.22–2%[27, 11, 8, 23]. Percutaneous balloon compression (PBC) of a trigeminal ganglion (TG) is an acknowledged alternative with a relatively high pain relief rate, ranging from 70% to over 90%[25, 21, 18]. Because of its convenience and safety, PBC has become a more popular remedy for trigeminal neuralgia recently.

Since the pathogenesis of TN and the mechanism of PBC treatment were not clear, some of the patients have not achieved a perfect postoperative outcome. In addition to the balloon shape and volume as well as compression time, several factors, such as the TN type and radiographic data etc., may be related to the outcome[17, 16, 1]. Until now, there has been no preoperative grading system which would be helpful for counseling patients regarding individual disease-specific prognosis. The objective of this study was to establish a predictive scoring system that can be used to preoperatively prognosticate the likelihood of pain-free based on preoperative disease characteristics.

Materials And Methods

Patients

Clinical data were collected from those trigeminal neuralgia cases who had undergone PBC during the period of January 2015 and January 2020 in Qingdao municipal hospital. Those with incomplete clinical data or had undergone MVD, Percutaneous glycerol rhizotomy (PGR) and glycerol rhizotomy (GR) were excluded. Finally, 85 cases were included in our studies. Each patient underwent a pre-operative 3.0 T MRI (General Electric Vectra, Milwaukee, Wisconsin, USA) to get the sequence of three-dimensional time-of-flight (3D-TOF). The symptomatic TN caused by space-occupying lesion in the cerebellopontine angle were excluded from the study.

Surgery

Under general anesthesia, the PBC was carried out with the patient. The lateral cranial images were obtained using A C-arm fluoroscopy image intensifier. A stab wound was created with an 11# blade about 2.5 cm lateral to the corner of the mouth as the entry point. The integrity of 8# balloon catheter (QK-08S50 Matreneu®, Qingyuan Medical Equipment Co. LTD, Shenzhen) was checked. We removed air bubbles during balloon inflation using omnipaque. With the assistance of lateral fluoroscopy images, a noncutting 15-gauge needle was advanced slowly toward the foramen ovale. As soon as the needle just passed the foramen ovale, it was not advanced further, the obturator was withdrawn, and a thinner stylet 1.5 cm longer than the needle was employed to penetrate the Meckel's capsule followed by a thicker stylet with the same length to make a tunnel in the cavity. Then, the balloon catheter was advanced until it protrudes 17 mm from the needle's mouth. Omnipaque (300 mg iodine/mL; GE Health Care, Sweden) was used to inflate the balloon. A proper position of the balloon was inspected with tentative inflation. We inflated the balloon with about 0.75 mL of omnipaque until the balloon presented a pear shape and remained for about 60 seconds. The needle was withdrawn and repositioned if the balloon shape was not satisfactory. The balloon was inflated for 60 seconds at the obtained shape (elliptical, round, or irregular) after several attempts without acquiring a pear shape. The balloon was deflated and the catheter and needle were removed after compression. The wound was compressed with firm pressure for 10 minutes.

Balloon shape

By the term typical pear shape, we describe balloon shapes with a minimal protrusion toward the porus trigeminus. The balloon shapes were assessed by 2 authors independently (blinded to the outcome). If there was disagreement in assessment result, the final decision was judged by the senior author independently. The balloon shape was classified as pear balloon shape and non-pear balloon shape (Fig. 1). The cases with non-pear balloon shape in our study were excluded.

Compression severity score

Degree of vascular compression was analyzed and divided into grades I, II, and III respectively depending the sequence of 3D-TOF. Grade I indicate that either there was not any vessel in the vicinity of the nerve or a vessel was near but not in direct contact. Grade II denotes that a vessel was compressing the nerve, but not enough to distort the nerve. Grade III denotes that the vessel was distorting the normal course of the

nerve(Fig. 2). The scoring was completed by two authors (Dr.TL and Dr.ST) after a period of training with the senior author (Dr.ZX) and after obtaining high inter- and intra-reliability score between paired data sets. Examiners were blinded to clinical outcome. If an exam was felt to be between score, it was downgraded to the lower score. To simplify, the degree of vascular compression was divided into three levels: grade I vs grade II or grade III.

Tn type

The diagnosis of TN was carried out depending on The International Classification of Headache Disorders, 3rd edition[13]. The subtype of TN was classified as classical TN or all other forms in accordance with criteria established by the International Association for the Study of Pain.

Outcome evaluation

The degree of pain relief was assessed by the Barrow Neurological Institute (BNI) criteria. The outcomes were evaluated at 3 months postoperatively. For simplification, we defined BNI grades I to III as pain relief and BNI grades IV and V as ineffectiveness of pain relief.

Statistical analysis

The study included the following variables: age, gender, symptom duration, affected side, trigeminal division, response to the carbamazepine, balloon shape, trigeminal cardiac reflex, NRS, facial numbness, weak chewing, keratitis, compression severity score, TN type. Those enumeration data are expressed as percentage and measurement data are expressed as mean $\pm$ SD. Differences between the groups are statistically analyzed using the t test or the χ^2 test depending on different variables. Unadjusted and adjusted logistic regression models were used to determine the association of variables with TN outcomes. The results were shown as odds ratios (ORs) and p value. A nomogram was established based on the results of multivariable analysis. A receiver operating characteristic curve (ROC) analysis and area under the ROC curve (AUC) were applied to evaluate the reliability of models for predicting patient outcomes. The plotted decision curves were also used to assess the net benefit of nomogram-assisted decisions. The nomogram was validated using bootstrapping (1,000 bootstrap resamples) to calculate a relatively corrected AUC. The p value less than 0.05 is considered statistically significant. Data were analyzed with the use of the statistical packages R (The R Foundation; <http://www.r-project.org>; version 3.4.3) and Empower (R) (www.empowerstats.com, X&Y solutions, inc. Boston, Massachusetts).

Results

Clinical Characteristics of Patients

According to the outcome, 16 cases and 69 cases were included into the ineffective and effective groups respectively. There was no significant differences in aspects of age, symptom duration, gender, affected side, trigeminal division, NRS, trigeminal cardiac reflex, facial numbness, and keratitis between the two groups (table 1).

In the effective group, the response to carbamazepine was positive in 53(76.8%) cases, which was significantly higher than that in the ineffective group (5, 31.2%). In the effective group, the weak chewing was positive in 7(10.1%) cases, which was significantly lower than that in the ineffective group (5, 31.2%). In the effective group, the compression severity score was grade II or III in 57(82.6%) cases, which was significantly higher than that in the ineffective group (6, 37.5%). In the effective group, the TN type was classical in 62(89.9%) cases, which was significantly higher than that in the ineffective group (5, 31.2%).

Univariate analysis for TN outcome

Univariate logistic regression was used to determine the association between response to carbamazepine, weak chewing, compression severity score, TN type and TN outcome. As showed in Table 2, we observed a significant correlation between response to carbamazepine, weak chewing, compression severity score, TN type and TN outcome ($P < 0.05$). The results showed response to carbamazepine positively, grade II or III compression severity score and classical TN type were all significant predictors of immediate TN relief (OR 7.3, 95%CI 2.2–24.1; OR 7.9, 95%CI 2.4–26.0 and OR 19.5, 95%CI 5.2–72.6 respectively) (table2).

Relationship between preoperative variables and TN outcome in different models

We also employed multivariate logistic regression to demonstrate the association between response to carbamazepine, compression severity score, TN type and TN outcome (Table 3). In the crude model, response to carbamazepine positively, the grade II or III compression severity score and classical TN type were all considered to be significant predictors of pain relief (BNI grades I-III) at 3 months follow-up (OR 7.3, 7.9 and 19.5 respectively).

In the adjust I (adjusting for age and gender) and II (adjusting for age, gender, symptomatic side, trigeminal division, symptom duration, trigeminal cardiac reflex, NRS, facial numbness and keratitis) models, the three preoperative variables above were all considered to be significant predictors of pain relief (BNI grades I-III) at 3 months follow-up (Adjust I, OR 7.2, 8.1 and 19.8 respectively; Adjust II, OR 46.6, 14.2 and 1717.3 respectively).

Establish and Assess Nomogram

We included the preoperative variables, including response to carbamazepine, compression severity score and TN type to model for predicting TN outcome. Based on the independent risk factors selected, we developed a nomogram (Fig. 3) to predict the probability of effective outcome after PBC surgery for TN patients based on the logistic model: $\text{logit}(\text{outcome}) = -1.11 + 1.46 \times \text{response to medication} + 0.17 \times \text{compression severity score} + 2.57 \times \text{TN type}$.

The calibration curve demonstrated satisfactory agreement (Fig. 4A). The decision curves for effective outcome probability in the nomogram, showed relatively good performance in terms of clinical

application. The decision curve shows that if the threshold probability is > 25% and < 95%, respectively, meaning the nomogram in study to predict effective outcome risk adds more benefits than the All or None scheme (Fig. 4B). An ROC analysis and AUC were applied to evaluate the reliability of model for predicting patient outcomes (Fig. 4C). The AUC, accuracy, specificity, and sensitivity was 0.83, 0.85, 0.75, 0.87 respectively (table4). The nomogram was validated using bootstrapping (1,000 bootstrap resamples) to calculate AUC. The AUC for the prediction nomogram was confirmed to be 0.84 through bootstrapping validation, which indicated appropriate model discrimination (Fig. 4D).

Discussion

Although a sizable body of studies demonstrated the importance of objective clinical predictors of curative effect, the selection of TN patients for PBC was still subjective[24, 21, 18]. Until now, there was no objective scale established for the prediction of TN patients' after PBC. Some may doubt whether such a scale would be complicated or offer any additional value. While, in our study, we developed a nomogram, including response to carbamazepine, compression severity score and TN type, to predict the probability of effective outcome for TN patients following PBC. Moreover, the ROC analysis and decision curves demonstrated relatively good performance for the model in terms of clinical application. In more practical terms, our results revealed that applying the nomogram added significant clinical value above the current paradigm of subjective consideration of clinical factors.

Even though the TN was not life-threatening, it influenced the life and work of patients seriously. PBC of trigeminal ganglion (TG) is an acknowledged minimally invasive treatment for TN, which was firstly reported by Mullan and Lichtor[20, 19]. PBC can block the abnormally discharging "short circuit" by compressing the demyelinating A β fiber selectively. Subsequently, the pain relieved by generating new myelin sheath[17]. Previous studies showed that the rates of pain relief ranged from 80–100% and the rate of complications was about 20%[18, 9, 6]. The complications of PBC included facial numbness, weak chewing, keratitis, act[28, 25]. In our study, we found the pain relief rate of PBC was 81.2% at 3 months follow-up which was parallel with previous studies. Previous studies showed the preoperative factors, such as TN type, response to medication, radiographic data and symptom duration, and intra-operative factors such as compression time, balloon shape and volume were associated with the TN patients' outcome after PBC[24, 16]. While, in our study, we focused on the preoperative factors which would influence prognosis and drawn different conclusions.

For the intra-operative factors, such as compression time, balloon shape and volume, were reported influenced the outcome after PBC. Meckel cave is a cleft-like dural pocket extending from the posterior fossa into the middle cranial fossa through the porus trigeminus which is a natural connection between the two fossae. The anatomical features were basics of the pear-shaped balloon during PBC. A pear-shaped balloon appears when the balloon extends into the pontine cistern after filling the Meckel cave through the porus trigeminus[3, 2]. Numerous clinical studies have classified the shape of the balloon into pear-shaped, oval, round, irregular and inverted pear-shaped. Round shape indicates that the balloon has not entered or did not completely enter the Meckel cave and is inflated in the epidural cavity. A balloon

with this shape may not produce effective treatment or may be associated with early recurrence. According to Asplund et al. a pear-shaped balloon results in longer pain relief and lower risk for pain recurrence than non-pear-shaped balloons[4]. Several previous studies showed the parallel conclusion. Consequently, in our study, we exclude the cases with non-pear balloon shape to reduce errors of our score system. Mullan and Lichtor concluded that 1 minute of compression was enough to relieve the pain after analyzed 100 cases of TN following PBC[19]. Brown and Gouda reported a series of TN cases treated by PBC[7]. During the operation, the volume of balloon was between 0.75 to 1 mL and compression duration was 1 to 1.5 minutes. While, in the study, they found that there was no significant difference between different balloon volume or compression duration. They concluded that 0.75 mL of contrast medium and 60-second compression was enough for getting satisfactory results which was also demonstrated by other studies. Consequently, in our study, we used the 0.75 mL of balloon volume and 60-second compression as the standard treatment during the PBC operation.

Several previous studies showed clinical factors such as symptom duration, preoperative NRS, previous surgery, TN type and compression severity score of TN nerve may influence the curative effect. Previous studies showed that atypical pain was associated with a poorer prognosis not only in ablative procedures such as GR and SRS, but also in non-ablative procedures such as MVD[22, 12]. Tyler-Kabara et al. showed that 74% of patients with typical pain had excellent outcomes following MVD, compared with only 35% of patients with atypical pain[26]. In our study, we found similar results that the atypical TN patients achieved a lower rate of excellent pain relief. Previous studies showed that vascular contact with the trigeminal nerve is universal (occurring in 82 to 92%)[15]. Nevertheless, several papers showed that neurovascular compression on MRI remains important for predicting postoperative outcome following MVD[22, 29]. A meta-analysis showed that artery compression to be an independent predictor of pain relief following MVD (OR 3.35, 95% CI 1.91–5.88)[14]. In our study, we found parallel results that the grade II or III compression severity score had a 14.2 times risk against the no vessel or grade I compression severity score of pain relief at 3 months follow-up. Until now, the carbamazepine was still the preferred drug for TN patients, which provides pain relief in 70% of patients. Previous study showed that response to carbamazepine positively remains significant for prognosis of TN following MVD[22]. In our study, we found parallel results that response to carbamazepine positively significantly predicted satisfying outcome following PBC. In my opinion, response to carbamazepine negatively means the nerve was compressed for a long time and injured seriously. The curative effect of other therapy, including MVD, PBC and radiofrequency rhizotomy (RFT), would be limited because of the serious lesion of nerve.

The nomogram system provides an objective means to select TN patients for PBC. While, the simplicity is critical for the nomogram system readily adopted. The complex disease factors which was validated in previous studies were simplified in our nomogram system. The TN type was simplified to classical vs nonclassical. Responsiveness to medication was divided into response to carbamazepine positively or negatively. The degree of vascular compression was divided into two levels: grade I vs grade II or grade III. The ROC analysis and decision curves indicated that the nomogram system was reliable for clinical application. The TN nomogram system realize the goal of being simple to be used without sacrificing predictive ability.

Limitations

The main limitation of this study was that the sample size was small. Consequently, the predictive effect was susceptible to bias. Moreover, this is a retrospective study and as such provides only retrospective validity, so a prospective validation of the prognostication tool is still needed. The retrospective nature of the study creates the inherent bias. Depending on the best current understanding of the disease process, we selected three variables into the nomogram system. We excluded the cases caused by space-occupying lesion or had undergone MVD, Percutaneous glycerol rhizotomy (PGR) and glycerol rhizotomy (GR). Other factors not included or assessed in the nomogram system may also influence the prognosis of TN following the PBC. In addition, the long-term effects of PBC on TN need a longer patient follow-up period. At this stage, more research with validation in multiple, external independent patient populations is needed

Conclusions

The nomogram, including response to carbamazepine, compression severity score and TN type, can predict the probability of short-term effective outcome after PBC surgery for a TN patient. The ROC analysis and decision curves demonstrated relatively good performance of the nomogram system in terms of clinical application. While, more research with validation in multiple, external independent patient populations is needed.

Abbreviations

TN, Trigeminal neuralgia; PBC, percutaneous balloon compression; ROC, receiver operating characteristic curve; MVD, microvascular decompression; TG, trigeminal ganglion; AUC, area under the ROC curve; RFT, radiofrequency rhizotomy; PGR, Percutaneous glycerol rhizotomy; glycerol rhizotomy (GR), stereotactic radiosurgery (SRS).

Declarations

- **Funding (information that explains whether and by whom the research was supported)**

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- **Conflicts of interest/Competing interests (include appropriate disclosures)**

The authors declare no conflict of interests for this article.

- **Availability of data and material (data transparency)**

Not applicable

- **Code availability (software application or custom code)**

Data were analyzed with the use of the statistical packages R (The R Foundation; <http://www.r-project.org>; version 3.4.3) and Empower (R) (www.empowerstats.com, X&Y solutions, inc. Boston, Massachusetts).

- **Ethics approval (include appropriate approvals or waivers)**

Not applicable

- **Consent to participate (include appropriate statements)**

Not applicable

- **Consent for publication (include appropriate statements)**

Not applicable

- **Authors' contributions (All authors must be mentioned)**

All authors take responsibility for the integrity and the accuracy of this manuscript. Study concept and design: Weimin Wang and Luo Li; Draft of the manuscript: MingXing Liu, Siwei Tang and Tong Li; Acquisition of data: Yong Zhou and Shengli Li; Statistical analysis: Zhiming Xu; Edit: Weimin Wang.

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Tables

Tables 1-4 not available with this version.

Figures

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Figure 1

The fluoroscopy images of balloon shape By the term typical pear shape, we describe balloon shapes with a minimal protrusion toward the porus trigeminus.

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Figure 2

The degree of vascular compression Grade I indicate that either there was not any vessel in the vicinity of the trigeminal nerve (white arrow) or a vessel (black arrow) was near but not in direct contact (2a). Grade II denotes that a vessel (black arrow) was compressing the trigeminal nerve (white arrow), but not enough to distort the nerve (2b). Grade III denotes that the vessel (black arrow) was distorting the normal course of the trigeminal nerve (white arrow) (2c).

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Figure 3

The nomogram to predict the probability of effective outcome after PBC surgery for TN patients Based on the independent risk factors selected, we developed a nomogram to predict the probability of effective outcome after PBC surgery for TN patients based on the logistic model: $\text{logit}(\text{outcome}) = -1.11 + 1.46 \times \text{response to medication} + 0.17 \times \text{compression severity score} + 2.57 \times \text{TN type}$.

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Figure 4

Establish and Assess Nomogram The calibration curve demonstrated satisfactory agreement (figure 4A). The decision curve shows that if the threshold probability is >25% and <95%, respectively, meaning the nomogram in study to predict effective outcome risk adds more benefits than the All or None scheme (figure 4B). The ROC was applied to evaluate the reliability of model for predicting patient outcomes. The AUC was 0.83 which indicated that the model was reliable (figure 4C). The AUC for the prediction nomogram was confirmed to be 0.84 through bootstrapping validation, which indicated appropriate model discrimination (figure 4D).