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Predictive Nomogram for the Durability of Pain Relief From Gamma Knife Radiation Surgery in the Treatment of Trigeminal Neuralgia

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Abstract

Purpose—To determine factors associated with the durability of stereotactic radiation surgery (SRS) for treatment of trigeminal neuralgia (TN).

Methods and Materials—Between 1999 and 2008, 446 of 777 patients with TN underwent SRS and had evaluable follow-up in our electronic medical records and phone interview records. The median follow-up was 21.2 months. The Barrow Neurologic Institute (BNI) pain scale was used to determine pre- and post-SRS pain. Dose-volume anatomical measurements, Burchiel pain subtype, pain quality, prior procedures, and medication usage were included in this retrospective cohort to identify factors impacting the time to BNI 4-5 pain relapse by using Cox proportional hazard regression. An internet-based nomogram was constructed based on predictive factors of durable relief pre- and posttreatment at 6-month intervals.

Results—Rates of freedom from BNI 4-5 failure at 1, 3, and 5 years were 84.5%, 70.4%, and 46.9%, respectively. Pain relief was BNI 1-3 at 1, 3, and 5 years in 86.1%, 74.3%, and 51.3% of type 1 patients; 79.3%, 46.2%, and 29.3% of type 2 patients; and 62.7%, 50.2%, and 25% of atypical facial pain patients. BNI type 1 pain score was achieved at 1, 3, and 5 years in 62.9%, 43.5%, and 22.0% of patients with type 1 pain and in 47.5%, 25.2%, and 9.2% of type 2 patients,

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respectively. Only 13% of patients with atypical facial pain achieved BNI 1 response; 42% of patients developed post-Gamma Knife radiation surgery (GKRS) trigeminal dysfunction. Multivariate analysis revealed that post-SRS numbness (hazard ratio [HR], 0.47; $P<.0001$), type 1 (vs type 2) TN (HR, 0.6; $P=.02$), and improved post-SRS BNI score at 6 months (HR, 0.009; $P<.0001$) were predictive of a durable pain response.

Conclusions—The durability of SRS for TN depends on the presenting Burchiel pain type, the post-SRS BNI score, and the presence of post-SRS facial numbness. The durability of pain relief can be estimated pre- and posttreatment by using our nomogram for situations when the potential of relapse may guide the decision for initial intervention.

Introduction

Although stereotactic radiation surgery (SRS) is an effective treatment for trigeminal neuralgia (TN), between 6% and 19% of TN patients who undergo SRS will have pain relapse by 24 months posttreatment and require either an additional procedure or reinitiation of medical management. The factors influencing the durability of SRS-related pain relief for TN are not well characterized (2).

Multiple factors have been identified as possibly contributing to the variable response rates after stereotactic surgery to treat TN, including facial pain type, radiation surgery technique, and posttherapy complications (8). Patient factors beyond facial pain type that may contribute include age, pain character, and symptoms atypical to TN. Radiation surgery factors influencing response rate may include target location along the nerve and maximum dose prescribed to the nerve (7). While SRS is considered controversial, modifications in patient selection, technique, target, and dosimetry have been explored as possible factors that may modify treatment response of TN to SRS (1).

Although a number of factors may predict treatment success at first assessment (6 months), no long-term predictors of treatment durability are known for SRS. In our initial report, we identified a number of patient and treatment factors that predicted treatment success at 6 months, including short nerve length and postsurgical numbness (8). Factors associated with reduced SRS efficacy included prior radiation frequency ablation (RFA), and diabetes. Given that the durability of pain response of microvascular decompression (MVD) can be on the order of decades (3), a major factor in the decision analysis for radiosurgical versus surgical management of TN would be the pretreatment factors that led to a more durable response from radiation surgery. Currently, patients with shorter life expectancies and medical comorbidities are considered acceptable candidates for SRS.

Here, we report a single-institution retrospective analysis of 448 patients who underwent SRS, to identify factors predictive of response durability of response and complications which were used in the development of a predictive nomogram.

Methods and Materials

Patients

Between September 1999 and December 2008, 777 SRS procedures were performed for patients with facial pain who were had clinical diagnosis of trigeminal neuralgia at Wake Forest University. Adequate follow-up data were obtainable for 446 patients (Table 1). Median follow-up time was 21.2 months. This study was approved by the institutional review board.

The quality of pain experienced by each patient was subclassified using the system previously proposed by Burchiel et al (4) as previous data have suggested differences in pain relief outcomes based on Burchiel pain type (5). In summary, Burchiel type 1 pain was defined as pain in which greater than 50% of symptoms are episodic, whereas Burchiel type 2 pain was defined as having greater than 50% constant pain. Atypical facial pain was defined as facial pain that was possibly derived from a somatoform cause. In those with atypical facial pain, radiation surgery was offered only if some component of the patient's pain was episodic. Patients with multiple sclerosis-related TN, trigeminal neuropathic pain, and post-herpetic neuralgia were excluded because these disorders likely have different pain mechanisms.

Radiation surgery technique

Radiation surgery treatment was performed with the Gamma Knife model B (1999-2004) or 4C (2005-2008) unit (Elekta, Norcross, GA). The radiation surgery procedure was done as described previously (2). In brief, the patient underwent placement of a Leksell model G stereotactic head frame (Elekta) and then a high-resolution stereotactic magnetic resonance imaging (MRI) study on the day of treatment. Patients requiring CT alone for treatment planning were excluded from this study because precise dosimetric assessment of the dorsal root entry zone (DREZ) and pons surface was not possible without MRI. A treatment plan was generated using the Leksell GammaPlan treatment planning system (Elekta), using a 4-mm collimator to target the trigeminal nerve. The radiation dose was prescribed at the 100% isodose line for all patients. Treatment philosophy regarding isocenter location changed during the study, based on new reports in the literature describing advantages to more distal shot placement along the trigeminal nerve (9). Patients treated earlier in the study had the isocenter placed proximally, such that the 50% isodose line was tangential to the pons. Later, the isocenter was placed distally, commonly at the pars triangularis, because higher doses to the brainstem were considered to be related to higher rates of treatment-related numbness. The mean prescription dose was 88.06 Gy (range, 80-97 Gy); most patients received 90 Gy (see Supplementary Table S1). The collimator output factor for the 4-mm collimator was 0.87.

Follow-up

Patients were generally seen in follow-up at approximately 3 months after SRS. If they had satisfactory pain relief at that point, they were subsequently seen on an as-needed basis. Outcome data were determined from patient electronic medical records as well as through a standardized telephone questionnaire that assessed pain outcomes, medication outcomes,

and toxicity. Pain relief was categorized using the Barrow Neurologic Institute (BNI) pain intensity score as this scale is commonly used in modern radiosurgical literature for TN treatment and has the advantage that outcomes can commonly be determined from the medical record (14). In short, the BNI pain score scale is as follows: BNI 1 = complete pain relief without medications; BNI 2 = some pain but not requiring medications; BNI 3 = some pain but adequately controlled with medications; BNI 4 = some pain not adequately controlled with medications; BNI 5 = continued severe pain or no pain relief. An initial treatment response was considered a BNI score of 1 to 3 at 3 months postradiation surgery. BNI score was also obtained at time of last follow-up. Date of treatment failure was considered to be the date at which pain became a BNI 4 or 5 score, based on medical records or telephone interview.

At the time of the analysis, follow-up notes or phone survey results were unobtainable for 195 patients; they were excluded from further analysis. For patients undergoing multiple SRS procedures, only the results and dosimetry of their first radiosurgical procedure were included in the study.

Dosimetric assessment

Dosimetric variables were obtained retrospectively using Leksell GammaPlan software and the 448 patients' archived treatment plans with stereotactic MR images (see Supplementary Table S1), as previously described by Marshall et al. The DREZ was defined on MRI as the point at which the center of the nerve intersected the brainstem. The maximum point dose to the pons was calculated by the GammaPlan software after the pons was contoured. The point dose at which the nerve came into contact with the petrous dura was used as the surrogate marker for the distal portion of the trigeminal nerve. The anatomy used for dosimetric assessment is shown in Figure 2.

Statistical analysis

Two-tailed paired *t* tests were used to compare mean doses between patient groups. The χ^2 and Fisher exact tests were used to test for heterogeneity between treatment groups. Time to BNI 4 to 5 pain relapse was calculated using the Kaplan-Meier method. Log-rank tests were performed to determine statistical differences between pain relapse curves. Univariate analysis was used to generate hazard ratios and check the assumptions of the Cox proportional hazards model (see Supplementary Table S3). Covariate selection took place using backwards stepwise selection of covariates that met diagnostic criteria and $P < .02$. Interactions were assessed with product terms.

The original observed data used to create the database for nomogram construction included 446 observations. We used bootstrap sampling to create 1000 new datasets, each with 446 observations. Length of pain relief was analyzed in each of these bootstrap samples using 2 regression models. One model was based only on pretreatment variables (age at treatment, sex, laterality, Burchiel type pain, and prior surgical procedure). The other model (posttreatment model) included all variables used in the pretreatment model as well as measures for posttreatment facial numbness or paresthesia and 6-month pain response. Predicted probabilities of pain response were output for each combination of covariates in

both models at 6-month intervals. Age was used as a continuous measure in the models and predicted at 5-year intervals. For the pre-treatment model, there were 416 unique combinations of covariates and 3328 combinations for the posttreatment model. We used the 50th percentile of the bootstrap results as the median and the 5th and 95th percentiles to create 95% confidence intervals (CI). These medians and confidence intervals were stored in a database and accessed using the internet site (Fig. 4). The internet-based application that allows users to select the covariates that represent the patient's state and, once selected, the predicted rates for monthly time points both before and after the Gamma Knife radiation surgery (GKRS) procedure are displayed. Statistical analyses were performed using SAS software (SAS Institute, Inc, Cary, NC).

Calibration plots were created as a diagnostic tool by using the rms package available in the analytical program R (6). We used 80 patients per subgroup and 150 repetitions to evaluate 1 year time to pain recurrence results.

Results

Pain outcomes

The median times to pain relapse in the type 1 and 2 and atypical facial pain groups were 55.2, 20.75, and 7.89 months, respectively. The median duration of symptoms prior to pain relief was similar between groups at 4 to 5 months (see Supplementary Table S2). Pain relapse at time of last follow-up occurred in 38.2%, 55.7%, and 62% of type 1, 2, and atypical facial pain groups, respectively. Overall, the 1-, 3-, and 5-year rates of BNI 1 to 3 pain relief were 84.5%, 70.4%, and 46.9%, respectively. Similarly, at 1, 3, and 5 years, pain relief was BNI 1 to 3 in 86.1%, 74.3%, and 51.3% in type 1; 79.3%, 46.2%, and 29.3% in type 2; and 62.7%, 50.2%, and 25% in the atypical facial pain patients, respectively. The proportion achieving BNI 1 pain relief at 1, 3, and 5 years was 62.9%, 43.5%, and 22.0% in type 1 patients; and 47.5%, 25.2%, and 9.2% in type 2 patients, respectively. The number of atypical facial pain patients who received a BNI 1 response was 13%. Of the 201 patients who experienced BNI grade 4 or 5 pain relapse, 62% underwent an additional GKRS procedure.

Predictors of durable pain relief

A pre- and posttreatment regression model was constructed to identify predictors of durability of response. The dominant predictors of durability in the pretreatment (Table 2) model included type of TN (type 2 vs 1: hazard ratio [HR], 1.56; 95% CI, 1.05-2.30), the presence of atypical facial pain (HR, 1.92; 95% CI, 1.15-3.23), and the number of procedures before GKRS (HR, 1.55; 95% CI, 1.06-2.26). The posttreatment model (Table 2) identified TN type (HR, 1.65; 95% CI, 1.08-2.51), the presence of GKRS-related sequelae (HR, 0.47; 95% CI, 0.34-0.66), and degree of pain relief at 3 to 6 months posttreatment as the dominant predictors of durability following treatment. The degree of posttreatment pain relief showed a graduated decrease in the risk for treatment failure, which was statistically significant at each level of patient-reported relief (Fig. 1). No dosimetric factors were independently predictive of durable pain response.

Nomogram creation and use

Based on the factors identified in the pre- and posttreatment settings, we constructed a nomogram by bootstrap sampling to create 1000 databases which could then be used to generate confidence intervals around the estimates for every possible combination of the identified covariates in the regression model. The resultant pre- and posttreatment calibration curves are displayed in Figure 3. The calibration curves show excellent agreement with the observed data in both the pre- and posttreatment setting, with the CIs narrowing in the posttreatment model due to the higher predictive value generated by including the 3- to 6-month pain assessment. The estimates were then populated into a searchable database (<http://ext-lamp.wakehealth.edu/nomograms/>) to return the estimated and associated confidence intervals for each combination of covariates at 6-month intervals.

Patient data including sex, laterality, Burchiel type, prior procedures, and age at treatment were entered for the pre-treatment nomogram. In the posttreatment nomogram, data for pain relief at 6 months and presence of numbness are also entered. The nomogram then generates a time-to-pain relapse curve specific to the patient's conditions, allowing patients to view their likelihood at being pain free after a certain time interval. A clinical case example of nomogram usage is illustrated in Figure 4.

Discussion

SRS represents a valuable noninvasive TN treatment option. However, pain response may not be long-lasting in a significant proportion of patients. A time-dependent failure pattern has been described after GKRS for TN showing that there does not appear to be a plateau in late treatment failures over time (13). The largest radiosurgical series report median pain-free intervals of 5 years (8, 12). The surgical alternative, MVD, does not have the same limit in durability of pain response and can lead to permanent pain relief in as many as 70% of patients. However, MVD may have a greater risk in elderly or medically frail patients. The goals of the current analysis were to assess factors that predicted for durability of radiosurgical pain response and to create a user-friendly clinical tool to help predict duration of pain response. The 2 resultant nomograms allow for pretreatment assessment of patients, to allow patients and caregivers to make treatment decisions by considering whether the predicted pain-relief interval is meaningful, given the patient's age and comorbidities (Fig. 4). Post-treatment assessment of pain relief durability will help to identify patients who will likely require closer follow-up given a higher potential rate of relapse.

The dominant factors affecting the pretreatment assessment of pain-free duration after SRS were age and Burchiel pain type. A dramatic difference between pain-free intervals would be predicted by our nomogram for a 40- and 80-year-old patient with all other factors equivalent with regard to their likelihood of being pain free at 5 years (10% vs 45%, respectively). Moreover, multiple series have reported that type 2 TN patients are at greater risk of pain relapse after both MVD (15) and radiation surgery (5). Our current series is the largest population of patients of type 2 pain treated with GKRS reported to date. Pain relief in higher-risk populations, such as those with type 2 TN, recurrent TN, or atypical facial pain may be less dependent on treatment technique and more dependent on an unidentified underlying pathology. We found that treatment-induced numbness was the major factor

predictive of posttreatment pain relief. In fact, the nomogram predicts that an 80-year-old patient with type 1 trigeminal neuralgia would have a 77% likelihood of being pain free at 5 years if she experienced numbness after treatment. This same patient would have 52% likelihood of being pain free if she did not experience posttreatment numbness.

The other dominant posttreatment factor identified in the current series for durability of pain response is a good initial response to SRS, including the need for fewer pain medications post-SRS. A positive initial treatment response has been used by some institutions as a criterion for offering a second GKRS procedure at time of pain failure (10).

This report represents the first attempt at constructing a nomogram that incorporates disease and patient factors, aimed at predicting the likelihood of treatment durability over time after SRS. An ideal decision analysis for treatment of TN would incorporate factors that predict response, durability of response, patient operative risk, and cost to society of both MVD and SRS. An economic analysis performed by the Mayo Clinic has identified MVD to have a greater cost effectiveness than SRS over time because of its superior treatment durability (11). However, some patients may not be candidates for MVD based on medical comorbidities or advanced age. The current nomogram estimates durability of SRS pain response may help to select populations in which SRS may be more beneficial given the health limitations of some patients. The clinical utility of the current nomogram lies in its ability to risk-stratify patients pretreatment, to aid in decision making about the optimal surgical modality for each individual. While this model is based on the largest series of patients with TN treated with SRS reported to date, it will need to be validated in other datasets.

Conclusions

The durability of GKRS for TN depends predominantly on Burchiel type at presentation, posttreatment BNI score, and development of facial numbness after GKRS. Creation of an online nomogram allows predictive factors to be queried by patients and practitioners. We found that patients with a history of procedures for TN were as likely to have durable relief as those who had not undergone GKRS.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Summary

We conducted a retrospective cohort review of all trigeminal neuralgia cases to identify pre- and posttreatment time to relapse of Barrow Neurologic Institute (BNI) pain scores 4/5, using pre- and posttreatment characteristics and BNI pain responses. Each Cox proportional hazards model was used to construct a nomogram for the durability of Gamma Knife radiation surgery for trigeminal neuralgia. This nomogram was converted to an Internet-based format for ease of use.

Fig. 1. Time to BNI 4/5 pain relapse is shown by (A) the presence of treatment-related sequelae and (B) posttreatment BNI response.

Fig. 2.
Anatomical depiction of derivation of dosimetric factors is shown. DREZ = dorsal root entry zone.

Fig. 3.
Observed versus expected values are shown plotted against a perfect agreement line.

A

Predictor of Durability of Pain Relief following Stereotactic Radiosurgery for Trigeminal Neuralgia

This model is intended to provide both a pre and posttreatment assessment of likelihood of obtaining pain relief following stereotactic radiosurgery for Trigeminal Neuralgia. The posttreatment model is intended to help with assessment of treatment prognosis/durability of response while the pretreatment model is intended to help with patient selection for stereotactic radiosurgery.

Gender:

Laterality:

Trigeminal Neuralgia Type:

Atypical Facial Pain:

Prior Procedure for Trigeminal Neuralgia Type:

Age At Treatment:

Pain Relief at 6 months:

Post Treatment Facial Numbness or paresthesias:

Submit Form:

B

C

Fig. 4.

Nomogram is shown for durability of pain response following treatment (A) mode of entry for patient and treatment related factors, (B) resultant nomogram output for an 80-year-old patient, and for a 40-year-old patient (C).

Table 1

Patient characteristics and prior treatment

Patient and prior treatment characteristics	Trigeminal neuralgia	
	No. of patients	Median (IQR)/column %
Follow-up		
Months	446	21.1 (9.7-43.0)
Age		
Years	446	67.5 (56.6-75.8)
Sex		
Male	173	38.8%
Female	273	61.2%
Hypertension		
No	226	50.7%
Yes	220	49.3%
Diabetes		
No	400	89.7%
Yes	46	10.3%
Burchiel class		
3	26	5.83%
4	102	22.9%
5	318	71.3%
Pain distribution		
V1	18	4.0%
V2	122	27.4%
V3	62	13.9%
V1+V2	78	17.5%
V1+V3	7	1.57%
V2+V3	96	21.8%
V1+V2+V3	62	13.9%
Laterality		
Left	181	40.6%
Right	265	59.4%
Medications		
Current	446	2 (1-2)
Prior	446	3 (2-4)
Prior procedure		
No	308	69.1%
Yes	138	30.9%
Glycerol rhizotomy	43	9.64%
MVD	43	9.64%
RFA	54	12.1%
TN type		

Patient and prior treatment characteristics	Trigeminal neuralgia	
	No. of patients	Median (IQR)/column %
1	385	86.3%
2	61	13.7%
Atypical facial pain		
No	414	92.8%
Yes	32	7.2%

Abbreviations: IQR = interquartile range; RFA = radiofrequency ablation; V1 to V3 = trigeminal branch.

Table 2

Pre- and posttreatment predictors of durability

		95% CI		
	Hazard ratio	Lower	Upper	P value
Pretreatment covariate				
Age	0.97	0.96	0.98	.0001
Sex (female vs male)	1.22	0.90	1.66	.21
Laterality (left vs right)	0.74	0.55	0.99	.05
TN type (2 vs 1)	1.56	1.05	2.30	.03
Atypical facial pain (yes vs no)	1.92	1.15	3.23	.01
No. of prior procedures	1.55	1.06	2.26	.02
Posttreatment covariate				
Age	1.00	0.99	1.02	.95
Sex (female vs male)	1.20	0.87	1.65	.26
Laterality (left vs right)	0.79	0.58	1.08	.13
TN type (2 vs 1)	1.65	1.08	2.51	.02
Atypical facial pain (yes vs no)	1.55	0.92	2.60	.10
BNI 2/3 (moderate) vs BNI 4/5	0.05	0.03	0.09	<.0001
BNI 2/3 (minimal) vs BNI 4/5	0.02	0.01	0.05	<.0001
BNI 1 vs BNI 4/5	0.01	0.00	0.02	<.0001
No. of prior procedures	1.26	0.92	1.75	.16
Gamma Knife–related numbness	0.47	0.34	0.66	<.0001

Abbreviations: BNI = Barrow Neurologic Institute; CI = confidence interval; TN = trigeminal neuralgia.