



## Association Between Radiofrequency Rhizotomy Parameters and Duration of Pain Relief in Trigeminal Neuralgia Patients with Recurrent Pain

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**BACKGROUND:** Radiofrequency rhizotomy (RFR) is a commonly used, effective procedure for trigeminal neuralgia (TN), but a subset of patients experiences pain recurrence and requires subsequent surgeries. Currently, the rhizotomy temperature and duration of application are empirically determined, and there is no consensus on what settings are most beneficial. In this study, we analyzed patients who underwent trigeminal RFR and had subsequent surgeries to identify whether rhizotomy parameters were associated with the duration of pain relief.

**METHODS:** Single-center, retrospective analysis of patients undergoing RFR for TN from 1995 to 2016. The primary endpoint was subsequent procedure. Associations with rhizotomy parameters and covariates were assessed using Cox regression analysis.

**RESULTS:** The study included 338 patients, average age 65 years; 61% were women. Temperature was significantly associated with both the degree of immediate post-operative pain relief and the duration of pain relief, and in subgroup analyses by multiple sclerosis status and RFR procedural count. Ablation duration was also independently significant, though not when analyzed alongside age, sex, and race. Duration of pain relief was generally shorter in patients with multiple sclerosis and in repeated RFR.

**CONCLUSIONS:** Higher temperatures may be necessary to achieve pain relief in some patients, given the progressive nature of the facial pain, but they are not associated with longer duration of pain relief in patients who have recurrent pain. Modulation of the ablation duration

does not seem to affect the short-term or long-term outcomes.

### INTRODUCTION

Trigeminal neuralgia (TN) is a chronic pain disorder affecting the trigeminal nerve. It is estimated that the incidence of new cases is roughly 12 per 100,000 people each year.<sup>1</sup> The presentation is highly variable, with 2 sub-classifications, ranging from sporadic attacks of extremely severe pain (type I) to a constant undulating pain punctuated by paroxysms of severe pain (type II).<sup>2</sup> The disease progression is equally variable. Some patients experience spontaneous resolution, whereas many patients experience gradual disease progression, sometimes between nerve branches or even to the contralateral side.<sup>3</sup> Empiric evidence suggests that the majority of cases of TN are associated with vascular compression of the nerve root, although the pathophysiology is still poorly understood.<sup>4</sup>

First-line therapy for TN typically includes anticonvulsants, most classically carbamazepine or oxcarbazepine.<sup>5,6</sup> As the disease progresses, drug therapy often becomes insufficient for treatment of symptoms, and procedural interventions are commonly used.<sup>7</sup> Percutaneous radiofrequency rhizotomy (RFR) provides high rates of pain relief for individuals experiencing nerve pain by use of thermal ablation.<sup>8</sup> The nerve is heated by a percutaneous electrode until sensation is dulled sufficiently to mitigate pain in a mechanism that is believed to be predominated by thermal neurolysis.<sup>9</sup> This treatment is typically effective for several years, although half of patients experience recurrence of pain approximately 5 years after therapy.<sup>10,11</sup> As such, repeated procedures are often required.<sup>12</sup> One question that is yet to be fully addressed in the literature is the optimal ablation parameters

#### Key words

- Pain relief
- Radiofrequency rhizotomy
- Temperature
- Trigeminal neuralgia

#### Abbreviations and Acronyms

- MS:** Multiple sclerosis
- RF:** Radiofrequency
- RFR:** Radiofrequency rhizotomy
- TN:** Trigeminal neuralgia

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Citation: *World Neurosurg.* (2019) 129:e128-e133.  
<https://doi.org/10.1016/j.wneu.2019.05.059>

Journal homepage: [www.journals.elsevier.com/world-neurosurgery](http://www.journals.elsevier.com/world-neurosurgery)

Available online: [www.sciencedirect.com](http://www.sciencedirect.com)

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(applied current, achieved temperature, duration of exposure). Currently, surgeons have individual preferences for these parameters, typically basing them on empiric evidence.

Although RF has been commonplace for over 40 years, there is limited literature on the effects of RF parameters on the surgical outcome. Selection of ablation temperature is often empiric.<sup>13</sup> In a prospective study of RF rhizotomy, Yao et al.<sup>14</sup> assessed the efficacy and safety of temperatures from 62° to 68° and noted superior long-term outcomes at 68°. In a related prospective study, the same group assessed patients undergoing bilateral rhizotomy at 68° and 75° and did not find any difference in the rate of pain relief at either temperature but noted fewer complications at 68°. <sup>15</sup> These studies involved a fixed duration of ablation (180 seconds) and did not assess any higher temperatures as are frequently used in the United States. A retrospective study by Tang et al.<sup>16</sup> assessed a wide range of temperatures, 55° to 90°. Their findings suggested that pain relief was maximized and side effects were minimized at 75°, but did not note ablation duration.

In this study, we sought to determine the association between different RFR temperatures and durations with durability of pain control in TN patients who required subsequent procedures for recurrent pain. The time until subsequent procedure was used to represent the duration of pain relief. To our knowledge, this is the first study in which duration of ablation has been studied in addition to ablation temperature.

## MATERIALS AND METHODS

### Patients

This was a retrospective cohort study performed among all patients who underwent trigeminal nerve radiofrequency rhizotomy at Johns Hopkins Hospital from January 1995 through August 2016. This study was reviewed and exempted by the institutional review board (NA\_0041684) and was compliant with the Health Insurance Portability and Accountability Act. Patients were included if they underwent more than one radiofrequency rhizotomy at our institution and had documentation of the temperature and duration parameters used for ablation. We studied patients with multiple sclerosis (MS) because one of our goals was to assess whether that subgroup had different outcomes either in the duration of pain relief or with respect to surgical parameters.

### Operative Technique

The protocol for RFR is classically described by Taha and Tew.<sup>17</sup> In our protocol, all patients had conventional RFR performed under laryngeal mask anesthesia. Using anatomic landmarks, fluoroscopic guidance, and stimulation of the motor branch, the trigeminal nerve was identified at the foramen ovale, and a radiofrequency needle was inserted percutaneously. We observed for return of cerebrospinal fluid, although this was not required in all cases. One milliliter of air was injected under fluoroscopic imaging to visualize the trigeminal cistern. The head of the bed was elevated to 60°, and a Radionics stylet was passed through the needle. The stylet was 20 gauge, and the length of the uninsulated tip was 10 cm. The nerve was again stimulated, and once confirmed, the patient underwent ablation with duration and temperature as predetermined by the surgeon. Stimulation

intensity was not incorporated into the determination of duration or temperature, and the procedure was terminated when the predetermined criteria were achieved.

### Data Collection

Temperature and duration data were obtained from the surgeon's notes. In cases where multiple temperatures were used for different durations, we recorded the temperature as a weighted average and the duration as the total duration of ablation.

Follow-up data were collected from the patient record and comprised appointments, surveys, telephone calls, and admissions. Demographic information and medical history were also obtained in this manner. The duration of pain relief was defined as the time until any subsequent surgery for TN (e.g., repeated rhizotomy, microvascular decompression, or other). We used this definition because other strategies for adjudicating pain recurrence were highly dependent on patient reporting and were found to be imprecise because perception and tolerance of pain varied greatly. Subsequent procedures as an endpoint was the most reliable metric available to us and eliminated significant variability in reporting. Patient charts were reviewed from the time of procedure up to the time of data collection.

Postoperative pain relief was typically assessed at the first follow-up appointment, typically 2 weeks after the procedure. Outcomes were categorized into a scale from 1 to 4 derived from the Barrow Neurological Institute pain scale to incorporate both subjective reporting of pain and objective pain requirements:

- 1) Pain relief without TN medications
- 2) Pain relief with TN medications
- 3) Partial pain relief with or without medications
- 4) No pain relief

### Statistical Analysis

Statistical analysis was conducted with Stata software (Stata Corp, Texas). Continuous data are presented as mean  $\pm$  standard deviation and were assessed with the Student *t* test. Categorical data are presented as percentages and were assessed with the  $\chi^2$  test. For graphic presentation, ablation temperature was grouped into approximate terciles. A 2-way proportion test was used to assess for differences in side effect rates by ablation temperature and duration. Kaplan-Meier survival curves were used for representation of time until pain recurrence, which is represented by the interprocedural time. Cox proportionate hazards regression was used to model the relationship between our independent variables and demographic covariates (age, sex, race). Bilateral procedures on the same individual were treated as separate procedures in the analysis. A *P* value of <0.05 was considered to indicate statistical significance.

## RESULTS

A total of 550 patients were identified with a diagnosis of TN who underwent an RF procedure. We reviewed 1246 procedures, of which 1187 had documentation of the temperature and duration parameters used for ablation. Of these, 1008 had documentation of postoperative follow-up. A total of 677 procedures among

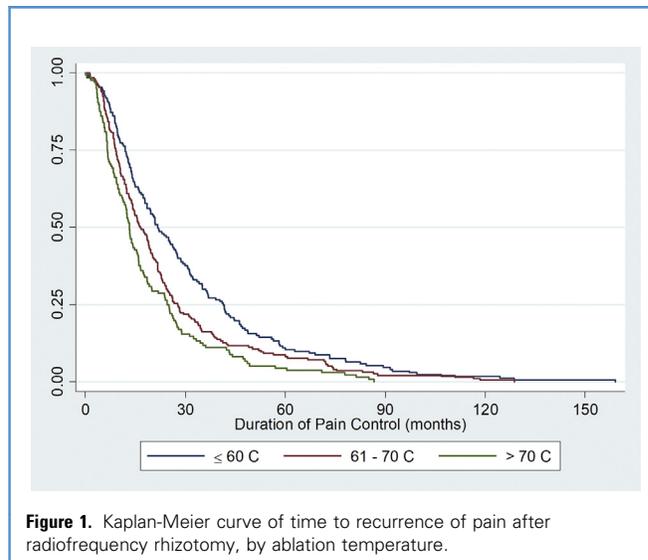
**Table 1.** Characteristics of Patients With Effective Pain Control after Radiofrequency Rhizotomy

Characteristic	Value
Patients, number	338
Sex (F), number	206 (61%)
Age (mean $\pm$ SD), years	64.8 $\pm$ 15
Race, number	
White	255 (75%)
Black	51 (15%)
Other	31 (9%)
MS, number	56 (17%)
Bilateral symptoms, number	13 (4%)
Radiofrequency temperature	
Average $\pm$ SD	67.9 $\pm$ 8.2°C
Maximum	90°C
Minimum	55°C
Radiofrequency duration	
Average $\pm$ SD	78.3 $\pm$ 35 seconds
Maximum	300 seconds
Minimum	60 seconds
Duration of pain relief	24.4 $\pm$ 23.3 months

Values are given as numbers (%) for categoric data or mean  $\pm$  SD for continuous data. SD, standard deviation; MS, multiple sclerosis.

338 patients had documentation of a subsequent procedure and were included in our analysis. The rate of reported postprocedural pain relief was 87% among included patients. The demographic, clinical, and operation information of these patients, along with the distribution of the treatment parameters, are shown in **Table 1**. The average duration of pain relief was 24.4  $\pm$  23.3 months. Among 304 procedures that were initial RFR, subsequent procedures were 19% microvascular decompression, 13% radiosurgery, and 68% repeated RFR.

Data on surgical complications were available on 499 of the 677 procedures; in the remaining cases, we could not determine with certainty the presence or absence of side effects using available records. Some degree of facial numbness was reported in 194 cases (39%), by far the most common side effect. Corneal numbness was reported in 12 cases (2.5%), chewing dysfunction in 10 cases (2%), anesthesia dolorosa in 6 cases (1.2%), and hearing difficulty in 3 cases (0.6%). Postprocedural facial numbness was reported in 43% of patients in the  $\leq 60^\circ\text{C}$  group, 37% of patients in the  $61^\circ\text{C}$  to  $70^\circ\text{C}$  group, and 44% of patients in the  $>70^\circ\text{C}$  group. Statistically, there was no significant difference in proportion. There was no significant difference in facial numbness by ablation duration, reported by 40% of patients in the  $\leq 60$ -second group and 42% in the  $>60$ -second group. With the exception of facial numbness, other side effects were too infrequent for statistical analysis to be appropriate.

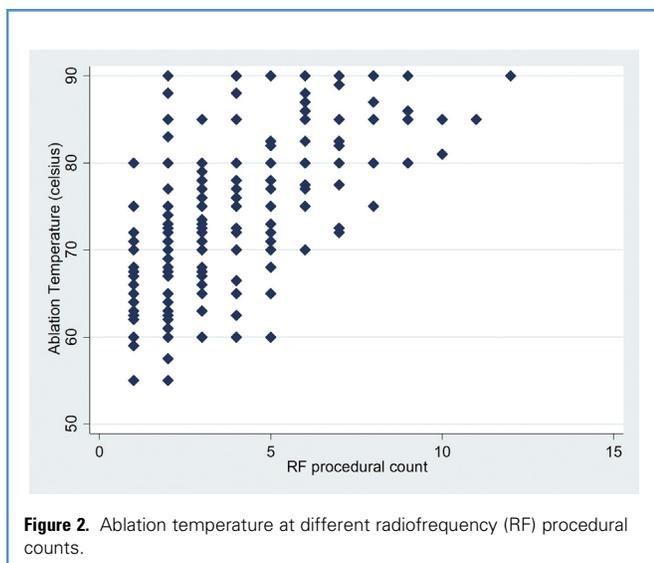


Kaplan-Meier survival curves are presented by approximately tercile temperature groups ( $\leq 60^\circ\text{C}$ ,  $61^\circ\text{C}$ – $70^\circ\text{C}$ ,  $>70^\circ\text{C}$ ) in **Figure 1**. In the Cox regression model, ablation temperature, ablation duration, and RF procedural count are analyzed as continuous variables to preserve the resolution of our data. Ablation temperature, ablation duration, procedural count, and MS status were individually associated with duration of pain relief ( $P < 0.05$ ). The interactions between predictors were also assessed for significance, but none was found relative to their individual effects. From these analyses, we defined a complete model of predictors and used Cox proportionate hazards regression to determine the relative contribution of each variable to the outcome (**Table 2**). After full adjustment for covariates, ablation temperature was significantly associated with duration of pain relief. The effects of ablation temperature in the multivariate model predominated over the effects of other variables and comparatively, ablation duration was not significant.

**Table 2.** Cox Proportional Hazards Model of Predictors of Duration of Pain Relief

Predictor	HR	P Value	95% CI
Ablation temp ( $^\circ\text{C}$ ), per SD	1.23	0.001	(1.1, 1.38)
Ablation duration (seconds), per SD	0.97	0.51	(0.89, 1.06)
RFR procedure count	1.02	0.49	(0.96, 1.08)
MS status	1.26	0.12	(0.96, 1.39)
Age	1.00	0.42	(0.99, 1.01)
Sex	0.87	0.14	(0.73, 1.05)
Race	1.08	0.57	(0.83, 1.41)

HR, hazard ratio; CI, confidence interval; SD, standard deviation; RFR, radiofrequency rhizotomy; MS, multiple sclerosis.



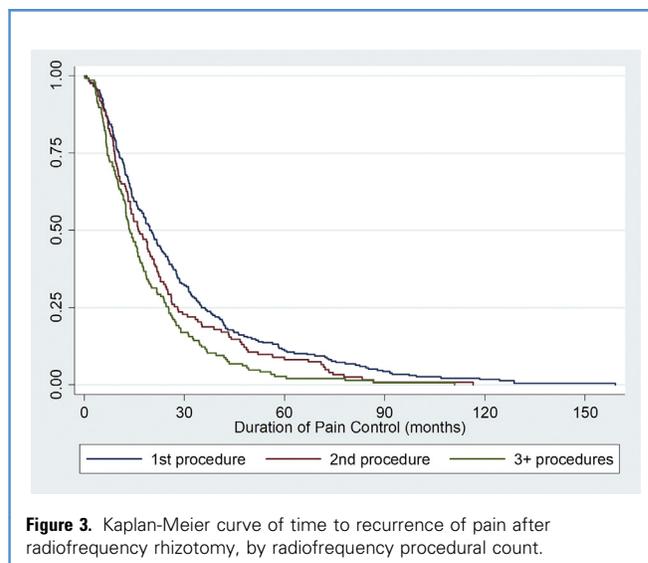
We performed subgroup analysis by RF procedural count because surgeons often select sequentially higher temperatures with each subsequent RF rhizotomy (Figure 2). Duration of pain control was compared at different RF procedure counts (Figure 3). Interestingly, when we assessed our hazards model for patients on their first or second procedure, we found that none of our predictors were significant. However, for patients on their third or higher procedure, a significant relationship with ablation temperature was present ( $P = 0.03$ ).

We also performed analysis based on patient MS status. The survival curves are shown (Figure 4). As noted previously, MS status was individually associated with a significant difference in duration of pain relief ( $P = 0.04$ ). In subgroup analysis of patients with and without MS, ablation temperature was the only significant predictor of the duration of pain relief ( $P = 0.01$  and  $P = 0.01$ , respectively).

## DISCUSSION

This study encompasses a broad range of RF temperatures from 55° to 90°C and treatment durations from 60 to 300 seconds in a diverse population of patients. We describe the association of ablation parameters with long-term pain relief in patients experiencing pain recurrence. This is a more medically challenging subset of patients than those in previous reports, because rates of reoperation among all patients receiving RF rhizotomy are described as roughly 10% to 12% in various studies.<sup>16,18,19</sup> We are not surprised, therefore, that some of our findings are different from those in the few reports currently in the literature. One such difference is the duration of pain relief, which averaged 24.4 months in our patients but has been reported variously from 24 to 48 months in other studies,<sup>7,20,21</sup> although we report similar rates of postsurgical pain relief. Similarly, our side effect rates are comparable to previous reports.

Relative to a similar retrospective study of RF temperature in the literature,<sup>16</sup> our participants were of similar age and gender

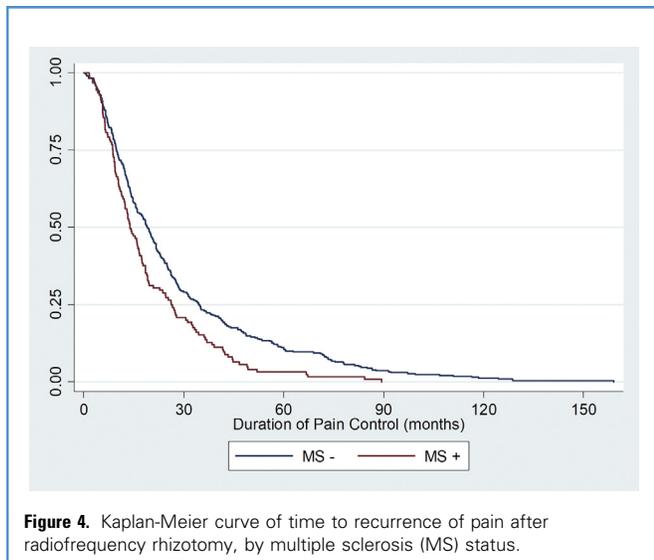


distribution, but of markedly different racial and cultural backgrounds. In contrast with existing studies reporting that rates of postoperative pain relief did not vary with temperature,<sup>14,16</sup> we noted a significantly higher rate of pain relief at lower temperatures. Our results also differ in our findings of the association between ablation temperature and duration of pain relief. One study suggested “optimal” outcomes (meaning longest pain relief with fewest side effects) at 75°C, the center of the study temperatures.<sup>16</sup> Another found optimal outcomes at the highest of the study temperatures: 68°C.<sup>14</sup> By contrast, we identified a monotonic inverse relationship between ablation temperature and duration of pain relief across a broad range of temperatures. We also found that ablation duration was insignificant in our models unless analyzed in isolation.

We recommend interpreting our findings cautiously. Because this was a retrospective study, it is difficult to isolate the role of surgical decision making in determining the appropriate ablation parameters. RF temperature and duration are tied to the surgeon’s assessment of the disease severity. Better outcomes, both in immediate pain relief and in long-term pain control, at lower ablation temperatures may in fact reflect milder disease rather than the ablation parameters themselves. Furthermore, the natural history of TN is often understood to be a gradual increase in the severity of disease despite treatment,<sup>22,23</sup> and this is supported by our models. We demonstrate that with increasing RF procedure count the duration of pain relief falls, although its contribution in the model appears to be mediated by other variables. That is, temperature itself may serve as a proxy for procedure count, given that the surgeons in our study typically increased ablation temperatures with subsequent procedures.

## Procedural Count Analysis

The need for repeated procedures in TN patients is well established across different surgical modalities.<sup>24-26</sup> As noted previously, a key consideration of surgeons when performing RFR is



**Figure 4.** Kaplan-Meier curve of time to recurrence of pain after radiofrequency rhizotomy, by multiple sclerosis (MS) status.

the ablation parameters of previous procedures. Existing studies of optimal RF temperature were done only at the first procedure.<sup>14</sup> In an effort to address these factors, we modeled duration of pain relief by RF procedural count. For the first procedure, when surgical decision making could not be affected by prior RF parameters, we found the relationship between surgical parameters and outcomes was not significant. We theorize this further suggests that surgical decision making is the key factor in determining procedural success: different temperatures are used as needed to achieve pain relief, even in the absence of precedent. At the second procedure, we found the relationship of temperature to outcome was not significant either. Interestingly, at the third and subsequent procedural counts, the relationship between RF temperature and duration of pain relief becomes significant. We hypothesize that this may indicate reduced long-term efficacy as the temperature needed to achieve short-term pain relief increases, reflective of the progression of disease rather than the direct effects of RF temperature. This is in accordance with other reports in the literature that suggest recurrence of TN pain is more challenging to treat than the pain at initial presentation.

### MS Subgroups

This study included similar proportion of participants with MS (16%) as is reported in the literature,<sup>27,28</sup> although rates as low as 1% have been reported in some populations.<sup>29</sup> The pathophysiologic relationship between MS and TN remains uncertain,<sup>30</sup> but TN associated with MS is generally understood to be more difficult to treat than in patients without MS, with a shorter duration of pain relief after treatments and a greater number of treatments required.<sup>31-33</sup> These trends were borne out in our study. However, postprocedural pain relief was not different in patients with and without MS. This would suggest that when it comes to ablation parameters in MS patients, similar considerations should be made as in non-MS patients.

### Limitations

One of the limitations of our dataset is the limited follow-up, which prevented us from being able to reliably assess post-procedural side effects in our participants. Additionally, because we focused on a subset of patients who had more than one RFR, it may be difficult to generalize our findings to all patients receiving RFR. In addition, the data were collected in retrospective fashion, which limits the ability to draw causal relationships between findings observed in this series.

### CONCLUSION

Our data suggest that treating recurrent trigeminal neuralgia is challenging and that despite increasing ablation temperature, duration of pain relief with RFR decreases with time. This trend is seen only after an individual has had more than two RFR procedures, indicating that these patients have a severe and recurrent form of TN. This should be considered when counseling patients with multiply recurrent TN. Regarding ablation duration, we could find no difference in the range of 60 to 120 seconds used at our center. Some groups report using longer times, which is rarely done at our institution, although it merits further study. Of note, we did not identify any variation in the rate of side effects or procedural complications by ablation parameter. Future prospective studies will be required to further elucidate the optimal treatment paradigm for patients with recurrent TN.

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*Received 19 December 2018; accepted 7 May 2019*

*Citation: World Neurosurg. (2019) 129:e128-e133.*

*https://doi.org/10.1016/j.wneu.2019.05.059*

*Journal homepage: [www.journals.elsevier.com/world-neurosurgery](http://www.journals.elsevier.com/world-neurosurgery)*

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