

Comparison of the short-term outcomes after low-temperature plasma radiofrequency ablation (coblation) in the Gasserian ganglion for the treatment of idiopathic trigeminal neuralgia

This article was published in the following Dove Press journal:
Journal of Pain Research

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Background: Low-temperature plasma radiofrequency ablation (coblation) is a relatively novel technique with promising applications in neuropathic pain. A nerve stimulator was modified and connected to a plasma knife head to solve the problem of accessing the Gasserian ganglion for treatment of trigeminal neuralgia (TN).

Objective: To compare the therapeutic effects and short-term outcomes of coblation vs radiofrequency thermocoagulation for the treatment of primary TN.

Methods: This was a retrospective cohort study of 217 inpatients who had undergone surgical treatment for primary TN between September 2017 and June 2018 at the Xuanwu Hospital, Capital Medical University. The patients were grouped according to the procedure they selected after an informed comprehensive discussion with their surgeon: the coblation group and the radiofrequency group. Pain, numbness, and muscle atrophy were evaluated before surgery, on the day of surgery, and at 3 days, 5 days, and 3 months after surgery.

Results: In the coblation and radiofrequency groups, the pain relief rates were 74.7% and 85.5% on day 1 ($P=0.066$), 85.3% and 97.3% on day 3 ($P=0.003$), and 97.7% and 88.2% at 3 months ($P=0.134$). At 3 months after surgery, 69.3% of the patients in the coblation group and 42.7% in the radiofrequency group had no pain ($P<0.001$). The multivariable analysis showed that the risk of numbness in the coblation group was independently lower than in the radiofrequency group at 3 months after surgery and (OR=0.243, 95%CI: 0.122–0.484, $P<0.001$). Three months after the surgery, no recurrence was found in both of the coblation group and the radiofrequency group. Postoperative pain score ≥ 4 points was considered as a sign of failure this series at 3 months after surgery. The failure rate in coblation group is 2.7% ($n=2$) and a radiofrequency group is 4.5% ($n=5$), but there was no statistical difference between the two groups ($P=0.703$).

Conclusion: Coblation could reduce the risk of postoperative numbness in patients with primary TN.

Keywords: trigeminal neuralgia, low-temperature plasma radiofrequency ablation (coblation), radiofrequency thermocoagulation, Gasserian ganglion

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Introduction

Trigeminal neuralgia (TN) is a unilateral facial pain syndrome originating from the cranial nerve V and is often accompanied by a facial spasm. It may become recurrent and chronic.^{1–4} TN is more common in women than men (1.74:1)² and in patients >50 years of age.¹ The annual incidence is 5.9 for 100,000 women and

3.4–5 per 100,000 men.⁵ The prevalence of TN is higher in patients with multiple sclerosis compared with the general population.⁶ Other causes of TN may include a structural disease or neurovascular compression, leading to demyelination, abnormal polarization, and abnormal neural impulses.^{1–3}

The classical treatment of TN includes antiepileptic medications^{2,7} and nonantiepileptic medications.⁸ Early surgery may be considered for patients with TN refractory to medical therapy and include percutaneous procedures on the Gasserian ganglion, gamma knife, and microvascular decompression.² Nevertheless, there is currently limited evidence for the effect of surgery on pain relief at 1 year.⁹ A variety of interventions on the Gasserian ganglion have been described, including percutaneous balloon microdecompression, percutaneous glycerol rhizolysis, and percutaneous radiofrequency. Conventional radiofrequency appears effective for pain relief in TN,^{10,11} as well as peripheral division radiofrequency thermocoagulation,¹¹ and neuronavigator-guided percutaneous thermocoagulation.¹² Nevertheless, the recurrence rates are still significant, with 25% at 3 years¹¹ and 15–23% per year.¹²

Low-temperature plasma radiofrequency ablation (coblation) is a relatively novel technique with promising applications in neuropathic pain. It has been suggested effective for the treatment of phantom limb pain,¹³ lumbar discogenic pain,¹⁴ and thoracic neuropathic pain,¹⁵ among others. Nevertheless, the use of coblation for TN is limited by the plasma knife head that cannot be located in the Gasserian ganglion. In the present study, a nerve stimulator was modified and connected to a plasma knife head to solve this problem of location.

Therefore, the present study aimed to compare the therapeutic effects and short-term outcomes of coblation vs radiofrequency thermocoagulation for the treatment of primary TN.

Methods

Study design and patients

This was a retrospective cohort study of 217 inpatients who had undergone surgical treatment for primary TN between September 2017 and June 2018 at the Xuanwu Hospital, Capital Medical University. The study was approved by the ethics committee of Xuanwu Hospital, Capital Medical University. The need for informed consent was waived by the Medical Ethics Committee because the study was an observational, retrospective

study using a database from which the patients' identifying information had been removed. All the staff involved in the study must not use or disclose the information of the patients except for this study. This study was conducted in accordance with the Declaration of Helsinki. The inclusion criteria were: 1) patient with primary TN and 2) first lifetime surgery for TN. The exclusion criteria were: 1) incomplete data or 2) lost to follow-up.

The diagnostic criteria for primary TN were [2,16,17]: 1) paroxysmal facial pain lasting for a few seconds to 1 min; 2) five criteria for pain: i) pain limited to one or more branches of the trigeminal nerve; ii) pain is sudden, intense, sharp, like prickle on the skin surface, knife cutting, or burning pain; iii) severe pain; iv) trigger points on the face that can induce pain; and v) intermittent facial spasms; 3) every spasm attack is rigid; and 4) other diseases that cause facial pain are excluded.

Grouping

The patients were grouped according to the procedure they selected after an informed comprehensive discussion with their surgeon: the coblation group and the radiofrequency group.

Radiofrequency thermocoagulation

Radiofrequency thermocoagulation was performed using a Cosman radiofrequency thermocoagulation apparatus (Cosman Medical, Inc., Burlington, MA, USA) that included a four-electrode radiofrequency generator (G4). The approach was based on the technique by Sweet & Wepsic [18]. Computed tomography (CT) was first performed to confirm the needle trajectory and the position of the Gasserian ganglion at the junction of the lines between the clivus and the petrous apex. The patient received local anesthesia and sedation, and the needle was inserted while taking care not to damage the oral mucosa. CT was used to confirm the needle position (Figures 1 and 2), followed by confirmation using an electrical impulsion. Upon satisfactory positioning, intravenous anesthesia was achieved and an airway mask was used. Thermocoagulation was performed at 70°C for 180 s.

Coblation

For the coblation group, the Stimuplex HNS11 Nerve Stimulator (B. Braun Co., Ltd., Melsungen, Germany) was connected to a low-temperature plasma multifunction operating system (SM-D380C; Xi'an Surgical Medical

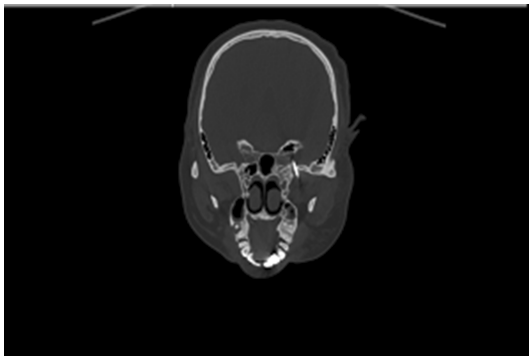


Figure 1 Computed tomography for confirmation of the needle position in the Gasserian ganglion.

Technology Co., Ltd., Xi'an, China) (Figures 3 and 5B). The puncture and localization methods were the same as in the radiofrequency group. When the needle was located in the foramen ovale, the positive electrode of the nerve stimulator was connected with the anode of the tail end of the cryogenic plasma ablation needle (DXR-G1100-A185; Xi'an Surgical Medical Technology Co., Ltd., Xi'an, China), corresponding to the needle core. The negative electrode was connected with the patient's skin (Figure 3). The nerve stimulator was turned on, adjusted to 2 Hz and 0.1 ms, and the stimulus intensity was gradually increased until inducing reproducible pain at 0.5 mV (Figure 4). The positive electrode of the nerve stimulator was disconnected from the tail electrode of the plasma ablation. The plasma ablation needle was connected to the plasma generator (Figure 5A). After intravenous anesthesia, ablation for 30 s at 45 W, and again for 30 s after a 30-s pause (Figure 6).



Figure 3 When the needle was located in the foramen ovale, the positive electrode of the Stimuplex HNS11 Nerve Stimulator (B. Braun Co., Ltd., Melsungen, Germany) was connected with the anode of the tail end of the cryogenic plasma ablation needle (DXR-G1100-A185; Xi'an Surgical Medical Technology Co., Ltd., Xi'an, China), corresponding to the needle core. The negative electrode was connected with the patient's skin.

Data collection and follow-up

Physical examination was conducted routinely before surgery and 3 days after surgery. Follow-up over the phone was conducted routinely 3 months after surgery. Postoperative complications included pain, hypoesthesia, numbness, and whether muscle atrophy occurred.

For pain, VAS scoring was conducted before surgery, on the day of surgery, 3 days after surgery, and 5 days after

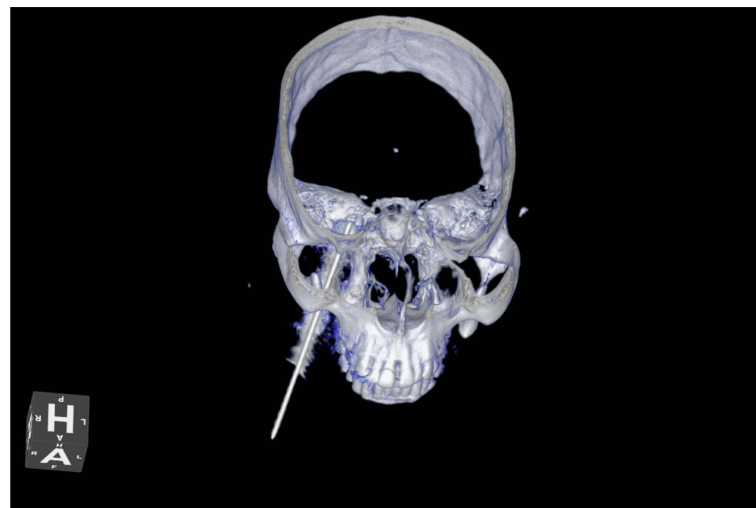


Figure 2 Three-dimensional reconstruction of the computed tomography for confirmation of the needle position in the Gasserian ganglion.
Abbreviations: A, anterior; H, head; P, posterior; L, left; F, foot.



Figure 4 The nerve stimulator was turned on, adjusted to 2 Hz and 0.1 ms, and the stimulus intensity was gradually increased until inducing reproducible pain at 0.5 mV.

surgery. 0=no pain; 10=intolerable pain. Patients were asked about pain, whether it affected their lives (including sleeping and chewing) and whether communication with others was impaired or limited.

For numbness, on the day of surgery and on the 3rd day after surgery, the patients were enquired whether they had a feeling of numbness (numbness or numb pain). Hypoesthesia during hospitalization was tested through physical examination and inquiry. A cotton swab was used to lightly touch patients' cheeks on both sides and the patients were enquired whether the cheeks on both sides had the same feeling, and whether numbness affected speaking, chewing, etc.

For muscle atrophy, the patients were mainly enquired whether their faces were symmetrical and whether there was muscle collapse or atrophy.



Figure 6 Trigeminal ganglion was ablated by the plasma generator.

Statistical analysis

All statistical analyses were conducted with SPSS 21.0 (IBM, Armonk, NY, USA). The Chi-square test was used for categorical data analysis. For continuous data, the independent-sample t test or the paired-sample t test was used for analysis when normal distribution was satisfied; otherwise, nonparametric analysis was used. The association of factors with postoperative numbness was analyzed by a binary logistic regression model. The regression factors entered into the model included the significant variables in the univariate analyses. Two-sided P -values <0.05 were considered statistically significant.



Figure 5 (A) The positive electrode of the nerve stimulator was disconnected from the tail electrode of the plasma ablation and connected to the plasma generator. **(B)** The low-temperature plasma multifunction operating system (SM-D380C; Xi'an Surgical Medical Technology Co., Ltd., Xi'an, China).

Results

Characteristics of the patients

Among the patients identified for possible inclusion, 14 did not undergo surgical treatment and 18 underwent coblation or radiofrequency thermocoagulation, but they were without TN; they were excluded. Finally, 185 patients were included in this study, including 75 patients in the coblation group and 110 in the radiofrequency thermocoagulation group. The patients with TN were 62.5 ± 11.2 years of age and there was a majority of female (63.8%) (Table 1). The course of disease was 1 month to 31 years (median of 48 months).

Clinical outcomes

Postoperative pain score ≤ 3 points was considered as pain being relieved. On the 1st day after surgery, the pain relief rate was 74.7% (n=56) in the coblation group and 85.5% (n=94) in the radiofrequency group ($P=0.066$). On the 3rd day after surgery, the pain relief rate was 85.3% (n=64) in the coblation group and 97.3% (n=107) in the radiofrequency group ($P=0.003$). At 3 months after surgery, the pain relief rate was 94.7% (n=71) in the coblation group and 88.2% (n=97) in the radiofrequency group ($P=0.134$). At 3 months after surgery, 69.3% of the patients in the coblation group and 42.7% in the radiofrequency group had no pain ($P<0.001$). Three months after the surgery, no recurrence was found in

both of the coblation group and the radiofrequency group. Postoperative pain score ≥ 4 points was considered as a sign of failure this series at 3 months after surgery. The failure rate in the coblation group is 2.7% (n=2), radiofrequency group is 4.5% (n=5), but there was no statistical difference between the two groups ($P=0.703$). In the coblation group, the mean pain score on the 1st day after surgery was significantly lower than before surgery ($P<0.001$) (Figure 7). There was no significant difference between the mean pain scores on the 3rd and 1st day after surgery ($P=0.095$). The mean pain score at 3 months was significantly lower than on the 3rd day ($P<0.001$). In the radiofrequency group, the mean pain score on the 1st day after surgery was significantly lower than before surgery ($P<0.001$) (Figure 7). The mean pain score on the 3rd day after surgery was significantly lower than on the 1st day ($P<0.001$). There was no significant difference between the mean pain score at 3 months and on the 3rd day after surgery ($P=0.595$). Compared with the radiofrequency group, pain was higher in the coblation on day 3, but lower at 3 months (Figure 7). At 3 months after surgery, no recurrence was found in both of the coblation group and the radiofrequency group. Postoperative pain score ≥ 4 points was considered as a sign of failure this series at 3 months after surgery. The failure rate in coblation group is 2.7% (n=2) and radiofrequency group is 4.5% (n=5), but there was no statistical difference between the two groups ($P=0.703$).

Table 1 Characteristics of the patients

	All	Coblation	Radiofrequency	P-value
	n=185	n=75	n=110	
Age (years)	62.5 ± 11.2	62.1 ± 12.3	62.9 ± 10.4	0.638
Gender, female, n (%)	118 (63.8)	49 (65.3)	69 (62.7)	0.717
Duration of symptoms (months)	68.1 ± 70.4	68.2 ± 65.5	68.1 ± 73.9	0.804
Side affected, n (%)				0.354
Left	64 (34.4)	23 (30.7)	41 (37.3)	
Right	121 (65.4)	52 (69.3)	69 (62.7)	
Division of trigeminal nerve, n (%)				0.152
V2	29 (15.7)	11 (14.7)	18 (16.4)	
V3	27 (14.6)	11 (14.7)	16 (14.5)	
V2 and V3	79 (42.7)	39 (52.0)	40 (36.4)	
V1, V2, and V3	27 (14.6)	6 (8.0)	21 (19.1)	
V1 and V2	23 (12.4)	8 (10.7)	15 (13.6)	
Trigger stimuli, n (%)	70 (37.8)	22 (29.3)	48 (43.6)	0.049
Pain, n (%)				0.854
Persistent	14 (7.6)	6 (8.0)	8 (7.3)	
Intermittent	171 (92.4)	69 (92.0)	102 (92.7)	

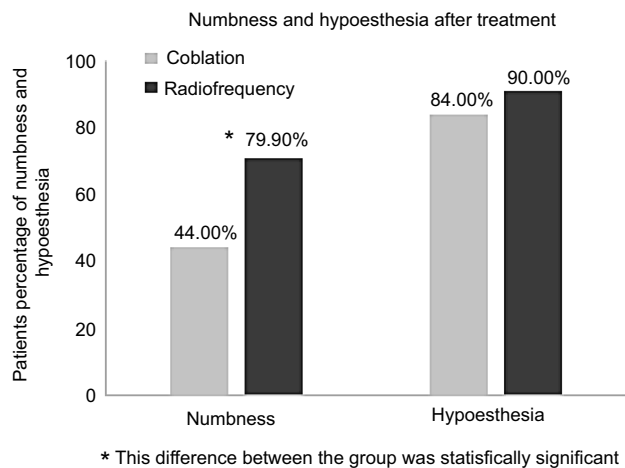


Figure 7 VAS analysis of pain after coblation or radiofrequency thermocoagulation for the treatment of idiopathic trigeminal neuralgia. * $P < 0.05$.

Adverse reactions

Table 2 presents the adverse reactions. There were no differences between the two groups regarding hypoesthesia, amyotrophy, and chewing weakness, but the frequency of numbness was smaller in the coblation group compared with the radiofrequency group (44.0% vs 70.9%, $P < 0.001$) (Figure 8).

Risk factors for postoperative numbness

The multivariable analysis showed that the risk of numbness in the coblation group was significantly lower than in the radiofrequency group at 3 months after surgery, and this effect was independent of gender, age, trigger stimuli, and pain score on day 3 after surgery, and pain score at 3 months after surgery (OR=0.243, 95% CI: 0.122–0.484, $P < 0.001$) (Table 3).

Table 2 Pain scores and symptoms after surgery

	Coblation n=75	Radiofrequency n=110	P-value
Pain			
Baseline	7.13±1.580	7.18±1.356	0.683
Day 1	2.48±1.131	2.39±1.093	0.772
Day 3	2.23±1.311	1.50±0.965	<0.001
3 months	0.81±1.513	1.39±1.930	0.003
Numbness, n (%)	33 (44.0)	78 (70.9)	<0.001
Hypoesthesia, n (%)	63 (84.0)	100 (90.9)	0.154
Amyotrophy, n (%)	9 (11.90)	7 (6.60)	0.252
Chewing weakness, n (%)	29 (39.50)	31 (28.40)	0.207

Discussion

Coblation is a relatively novel technique with promising applications in neuropathic pain.^{13–15} The surrounding tissue might be damaged by radiofrequency thermocoagulation at 70°C to 90°C¹⁴ In contrast, coblation will not cause tissue temperature to exceed 60°C to 70°C, as there is a space filled with saline between the ending tip and the tissue. The ions responsible for destruction of intercellular bonds in tissues. The principle action of coblation is based on molecular dissociation rather than thermal damage as in radiofrequency thermocoagulation. The coblator uses radiofrequency energy through a saline medium to create a plasma that breaks molecular bonds in the tissue, causing the tissue to dissolve at relatively low temperatures²⁰ In this study, a nerve

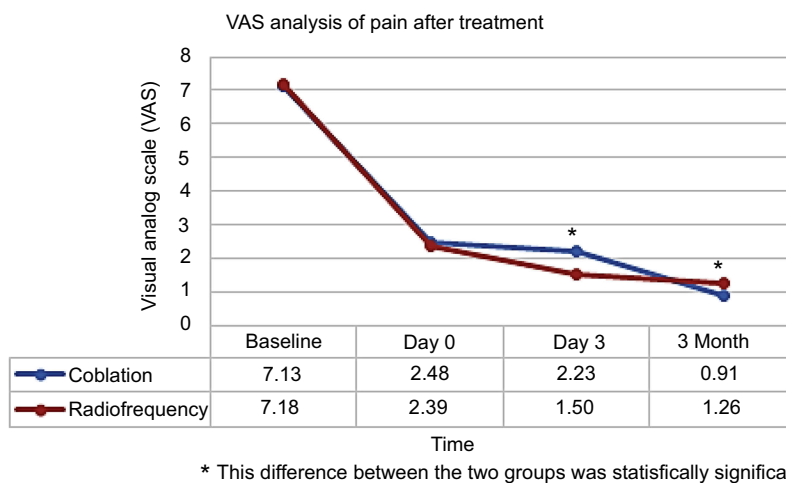


Figure 8 Frequencies of numbness and hypoesthesia after coblation or radiofrequency thermocoagulation for the treatment of idiopathic trigeminal neuralgia. * $P < 0.05$.

Table 3 Multivariable regression analysis for the factors associated with postoperative numbness

Variables	OR (95% CI)	P-value
Sex	0.938 (0.488–1.803)	0.848
Age	0.998 (0.970–1.026)	0.866
Trigger stimuli	1.097 (0.567–2.123)	0.783
Pain on day 3	1.208 (0.909–1.605)	0.192
Pain at 3 months	0.824 (0.689–0.985)	0.033
Treatment	0.243 (0.122–0.484)	<0.001

stimulator was modified and connected to a plasma knife head to solve the problem of accessing the Gasserian ganglion for treatment of TN. Therefore, the objective was to compare the therapeutic effects and short-term outcomes of coblation vs radiofrequency thermocoagulation for the treatment of primary TN. The results suggest that coblation could reduce the risk of postoperative numbness in patients with primary TN.

Coblation is a relatively novel technique with promising applications in neuropathic pain.^{13–15} Nevertheless, the use of coblation for TN is limited because the plasma knife head is too large to reach the Gasserian ganglion. Therefore, in the present study, a nerve stimulator was modified and connected to a plasma knife head to solve this problem of location. The results showed that pain reduction relative to baseline was less important in the coblation group than in the radiofrequency group, but the proportion of patients without pain was higher in the coblation group than in the radiofrequency group. Our previous small sample study investigating coblation in the treatment of idiopathic TN with the third branches lesion found that coblation group had a significantly lower score of facial numbness and pain level of TN than the radiofrequency group. This study was conducted using coblation in patients with a third branch of TN.¹⁹ No study about using coblation to treat TN of V1, V2 and V3 branches has been reported. The present study is globally supported by studies performed in other types of neuropathic pain.^{13–15} Sun et al showed that coblation was more effective than radiofrequency for the treatment of lumbar discogenic pain.¹⁴

Facial numbness is one of the most common adverse reactions after radiofrequency ablation for TN.^{16,17} In the present study, there were no differences between the two groups regarding hypoesthesia, amyotrophy, and chewing weakness, but the frequency of numbness was smaller in the coblation group compared with the radiofrequency. The multivariable analysis showed that the lower frequency of numbness in the coblation group was

independent of gender, age, trigger stimuli, pain score on day 3 after surgery, and pain score at 3 months after surgery. Broggi et al¹⁸ also showed that those factors were not associated with the outcomes of radiofrequency for TN. On day 3, the pain score in the coblation group was higher than in the radiofrequency group. A possible reason is that the needle (diameter 1.1 mm, DXR-G1100-A185; Xi'an Surgical Medical Technology Co., Ltd., Xi'an, China) used for coblation is thicker than the needle (diameter 0.7 mm, 20G radiofrequency puncture needle, Cosman Medical, Inc., Burlington, MA, USA) for radiofrequency thermocoagulation. Therefore, the puncture injury in the coblation group can be more severe. Nevertheless, the difference was not important and the difference was reversed at 3 months, the coblation group reporting significantly less pain. Therefore, pain should not be an issue against the use of coblation.

The main innovation of this study is that the nerve stimulator was modified to connect to the plasma knife head, allowing the use of coblation on the Gasserian ganglion for the treatment of TN. Nevertheless, this was a preliminary study and additional studies are necessary to confirm the outcomes.

Limitations

The present study is not without limitations. It was a single-center retrospective study with a small sample size. Long-term follow-up was not conducted. Future studies will address these issues.

Conclusion

Coblation could reduce the risk of postoperative numbness in patients with primary TN. This was a preliminary study that requires confirmation. Nevertheless, the results suggest an innovative method for the treatment of primary TN that could possibly result in less adverse effects than the traditional approaches.

Acknowledgments

This work was supported by Beijing Postdoctoral Research Foundation the Capital [2018-ZZ-108,2018], Capital Medical University [16JL50,2016] [H0690], Beijing Health and Family Planning Commission [2015-3-067], and Beijing Municipal Administration of Hospitals [ZYLX201507,2015].

Disclosure

The authors declared that they have no conflicts of interest in this work.

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