

Efficacy and safety of continuous radiofrequency thermocoagulation plus pulsed radiofrequency for treatment of V1 trigeminal neuralgia

A prospective cohort study

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Abstract

Patients may develop serious eye complications after continuous radiofrequency thermocoagulation (CRF) for V1 (ophthalmic division) trigeminal neuralgia (TN) at a higher temperature. Therefore, the temperature of clinical CRF for V1 TN has long been disputed, but there have few reports been found about how to achieve satisfactory pain relief, reduce the incidence rates of complications, and shorten the recovery time after CRF for V1 TN.

To observe whether pulsed radiofrequency (PRF) can lead to increased rate in pain relief, reduced rate of complications, or shortened recovery time after CRF is used to treat V1 idiopathic trigeminal neuralgia (ITN).

The prospective cohort study enrolled 56 patients with V1 ITN from May 2012 to April 2015. The patients were randomized into 2 treatment groups as follows: CRF only (group A, n=28) and CRF plus PRF (group B, n=28). The patients were followed 3 years up for pain relief, complications, and health-related quality of life (HRQoL).

All the patients in either group achieved satisfactory pain relief at discharge. After treatment, patients completely pain free in group A and group B accounted for 81.6%, 92.0% at 1 year, 68.4%, 92.0% at 2 years, and 68.4%, 83.6% at 3 years, respectively. The pain relief rate was higher in group B patients than in group A, but the difference was not statistically significant. During the follow-up period, 9 (32.1%) patients in group A and 2 (7.1%) patients in group B developed recurrence ($P < 0.05$). Eleven patients in group A occurred corneal hypoesthesia and with recovery time was 11.9 ± 7.5 (4–18) months versus 3 patients in group B with recovery time was 3.4 ± 2.5 (2–6) months, the differences of incidence rate and recovery times were all significant ($P < 0.05$) between groups A and B. The mean scores of HRQoL in group B patients were higher than that in group A patients ($P < 0.05$).

PRF after CRF results in decreased recurrence of V1 TN, reduced numbers of corneal hypoesthesia, shortened recovery time, and increased HRQoL scores. Its clinical use is recommended.

Abbreviations: CRF = continuous radiofrequency thermocoagulation, HRQoL = health-related quality of life, PRF = pulsed radiofrequency, TN = trigeminal neuralgia, V1 TN = ophthalmic division of trigeminal nerve.

Keywords: complications, pulsed radiofrequency, radiofrequency thermocoagulation, recurrence rate, trigeminal neuralgia

1. Introduction

Trigeminal neuralgia (TN) is a common neuropathic pain. The incidence is 4.3 to 28.9/100,000 people annually in worldwide,^[1,2]

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and it also occurs in China, but no epidemiological data are available. TN can be effectively treated by minimally invasive techniques that use microvascular decompression,^[3] balloon compression,^[4] continuous radiofrequency thermocoagulation (CRF), and gamma knife radiosurgery.^[5] CRF is widely used for the clinical treatment of TN with a pain relief rate of 90% to 100%,^[6–7] but problem is that serious complications often occur at a temperature $\geq 70^\circ\text{C}$ and lower temperatures lead to bad pain relief.^[8–10]

Pulsed radiofrequency (PRF) is widely used for the treatment of neuropathic pain,^[11,12] but its efficacy for pain relief efficacy in TN remains controversial. Some studies have reported that PRF was effective for TN,^[13–15] whereas other studies reported that it has limited efficacy.^[16–18] However, the results of recent studies suggest that PRF can effectively reduce the complication rate or shorten the recovery time of complications that occurred after CRF.^[19–21] In addition, Luo et al^[22] performed a retrospective study that found that PRF used at higher voltage and larger pulse width for TN obtained an increased rate of pain relief.

In those previous studies showing positive PRF efficacy for TN,^[13–15,19–22] the focus was pain relief or the effects of PRF on complications after CRF for V2 and/or V3 TN such as facial numbness. To the best of our knowledge, there are seldom specialized published study reports on PRF or CRF only for V1 branch TN.

The aim of this study was to determine if PRF for the treatment of V1 idiopathic trigeminal neuralgia (ITN) could lead to an increased rate of pain relief, reduced complication rate, and shortened recovery time after CRF.

2. Materials and methods

2.1. Patient

This prospective cohort study enrolled 56 patients with V1 ITN, who were seen at the Department of Pain Management of Shengjing Hospital, China Medical University, from May 2012 to April 2015. A random number table was used to randomize the patients into 2 treatment groups as follows: CRF only (group A, n=28) and CRF plus PRF (group B, n=28). This study was approved by the Ethics Committee of Shengjing Hospital, China Medical University.

2.2. Diagnostic criteria

The diagnostic criteria for TN were based on the principle of International Classification of Headache Disorders (IHS)-II (2004)^[23] and IHS-III (2013).^[24] Patients were enrolled based on the following inclusion criteria: >30 years old; pretreatment pain >6 (visual analogue scale, VAS); and signed a written informed consent that included awareness of possible complications; and systematic application of carbamazepine, gabapentin, or pregabalin for ≥ 3 months analgesic treatment prior to surgery, poor response to conventional medication, or serious side effects occurred.

Patients were excluded based on the following exclusion criteria: V2 (maxillary division) and/or V3 (mandibular division) TN or V1 combined with V2 and/or V3 TN; eye diseases (diagnosed by ophthalmologists); secondary TN caused by tumors, intracranial lesions, multiple sclerosis, or herpes zoster; severe organ disease; coagulation disorder; mental disorders; or could not accept any possible procedure-related complications.

At 30 minutes before the procedure, the patient was infused intravenously (IV) with ceftriaxone sodium 1.0g (Shanghai Roche Pharmaceuticals Co. Ltd., China). Immediately before the procedure, the patient was slowly injected IV with fentanyl 0.05 mg plus droperidol 2.5 mg (Innovar 2 mL; Yichang Humanwell Pharmaceuticals Co. Ltd., China), which was also administered during the procedure for severe pain.

2.3. Operation procedure

The procedures were performed with the patient lying supine on the computer tomography (CT) table, using the Härtel anterior approach under CT guidance. The point of puncture was marked at a distance of 3.5 cm lateral to the angle of mouth. After the patient received local anesthesia using 0.5% lidocaine, and CT scanning was finished, a 22G 10-cm puncture cannula with a 5-mm active tip was introduced into the foramen ovale a distance of 0.5 cm, as confirmed by CT. If there was no blood return, the radiofrequency electrode was connected for testing, and then radiating pain in the region of distribution of the ophthalmic division was induced at 0.1 to 0.2 V for 1 ms at 50 Hz. If cerebrospinal fluid (CSF) returned through the puncture cannula, its position was adjusted, depending on the results of the radiofrequency test parameters. Thereafter, 1.5% lidocaine (0.2 mL) was injected for local anesthesia (not used for patients with CSF return).

For group A patients, the temperature was gradually increased from 50°C to the preset value of 62°C over 240 to 360 seconds, followed by 180 seconds of CRF. If the patient still felt pain in the distribution region, the position of the puncture cannula was adjusted, and then CRF was performed again. For group B patients, PRF was performed following CRF. Parameters previously reported for PRF were used,^[22] as follows: output voltage 45 V, pulse width 10 ms, temperature 42°C, and duration time 8 minutes. At the end of the procedure, the puncture needle was withdrawn, the patient was sent back to the wards on a stretcher, and ceftriaxone sodium 1.0g was administered twice.

2.4. Follow-up and observations

Follow up of the patients was performed as an outpatient visit, by telephone, or home visit once per month during the first 6 months and thereafter once every 3 months during the next 2.5 years follow-up. The investigators performing the follow ups were blinded to the types of treatment and patients. Information on postprocedural relief of pain, the patients required medication for pain relief, complications, and patient satisfaction was recorded.

Pain was evaluated using VAS before the procedure, and after the procedure, relief of pain was evaluated using the Barrow Neurological Institute (BNI) pain scale.^[25] The BNI pain scale has 5 levels: I (excellent), complete disappearance of pain and no medication required; II mild pain, no medication required; III, moderate pain, medication required for complete control; IV, moderate pain, medication required but incomplete control; V, severe or unrelieved pain. A BNI score of I to III indicated satisfactory pain relief, while a BNI score of IV to V indicated poor pain relief, which served as a criterion for evaluating recurrence after surgery. The initial BNI score was obtained at discharge.

The corneal reflex was assessed as follows: with the patient staring to the side and unable to observe the activity of the tester, a piece of cotton was applied gently to the lateral-inferior side of the homolateral cornea in a lateral-to-medial direction, and whether or not contraction of bilateral musculus orbicularis oculi occurred was noted. I, no corneal hypoesthesia; II, corneal hypoesthesia; III, severe corneal hypoesthesia, absense corneal reflex.

Facial numbness was evaluated using the BNI facial numbness scale,^[25] as follows: I, no facial numbness; II, mild facial numbness; III, moderate facial numbness; IV, severe numbness.

2.5. Health-related quality of life (HRQoL) score

HRQoL was evaluated with using the Short Form-36 questionnaire (SF-36).^[26] The scores were summed separately for the physical and mental items to determine the physical component summary (PCS) and mental component summary (MCS). A complete score was 100. Higher scores indicated better HRQoL.

2.6. Statistical analysis

All data were analyzed using IBM-SPSS ver. 19.0 software (IBM Corp., Armonk, NY). Quantitative data of normal distribution and with homogeneity of variance were analyzed by pair-wise *t* tests; otherwise, data were analyzed by the 2-sample Wilcoxon rank-sum test. Rate data were analyzed by the Fisher exact test, and other ranked data were analyzed by the Wilcoxon Mann-Whitney test. Postprocedure pain relief data were analyzed by the Kaplan-Meier method and log-rank test. The effects of relevant

Table 1
Patients characteristics.

Group	A	B
Patients (n)	28	28
Sex (F/M%)	16 (57.1)/12 (42.9)	15 (53.6)/13 (46.4)
Mean age (Y, range)	55.6 ± 10.4 (32–74)	56.1 ± 12.4 (35–75)
Left/right side (%)	15 (53.6)/13 (46.4)	14 (50.0)/14 (50.0)
Presurgery pain duration (M, range)	9.4 ± 6.3 (5–23)	10.2 ± 6.8 (4–28)
Follow up duration (M, range)	25.6 ± 12.3 (6–36)	26.3 ± 11.8 (4–36)
Hospital duration, d	4.6 ± 1.2 (4–7)	4.3 ± 1.4 (4–7)
Presurgery drug dosage		
Carbamazepine, mg/d, n	563.5 ± 87.2 (16)	529.4 ± 78.5 (15)
Pregabalin, mg/d, n	416.4 ± 71.5 (7)	424.1 ± 81.2 (6)
Gabapentin, g/d, n	1.9 ± 0.4 (5)	2.1 ± 0.5 (7)
Presurgery VAS	7.6 ± 1.9	7.7 ± 1.7

VAS=visual analogue scale.

factors (e.g., age, pain duration before surgery and duration of procedure surgery) were analyzed using the Cox proportional hazards regression model. Censored follow-up was defined as loss of follow-up, patient death, the use of other treatments after recurrence. The censored date was the date of last visit before loss follow-up or death, $P < 0.05$ indicated statistical significance.

3. Results

3.1. Patient characteristics

Patient characteristics are shown in Table 1. A total of 56 patients with V1 ITN fulfilled the inclusion criteria. After the procedure, 1 patient in group A was lost to follow up at 27 months. All the other cases completed follow up, and there were no deaths during follow-up. The duration of hospitalization, the duration of follow up, differences in sex and age between groups A and B patients were not significant. Five group A patients and 1 group B patient received secondary surgery or other treatments, and the date of last visit before secondary treatment served as the censor date.

3.2. Intraoperative and in-hospital data and complications

Table 2 shows that all patients successfully completed CRF and CRF plus PRF. Facial hematoma developed in 6 group A and 5 group B patients. The hematomas were treated by compression during the procedure and cold compresses applied for 15 minutes every 3 hours at 1 day after the procedure. All facial hematomas resolved by 7 days. A total of 7 patients (4 and 3 in groups A and B) experienced mouth penetration during administration of local

Table 2
Intraoperative and in-hospital duration data.

Group	A	B
Surgery time, min	24.2 ± 4.3	29.1 ± 5.6
Facial hematoma, n (%)	6 (21.4)	5 (17.9)
Mouth penetration, n (%)	4 (14.3)	3 (10.7)
Intracranial hypotension headache	4 (14.3)	5 (17.9)
Foramen ovale penetration with blood return, n (%)	3 (10.7)	4 (14.3)
Foramen ovale penetration with CSF return, n (%)	9 (32.1)	8 (28.6)
Facial numbness, n (%)	3 (10.7)	2 (7.1)
Nausea and vomiting, n (%)	2 (7.1)	3 (10.7)

CSF=cerebrospinal fluid.

anesthesia or use of the puncture cannula, the procedures were continued after the puncture cannula was replaced. After delivery of the puncture cannula into the foramen ovale, blood return was observed in 3 and 4 patients of groups A and B, respectively, the puncture cannula was adjusted 5 mm forward or backward to prevent thermocoagulation injury to the vascular wall and avoid subsequent postprocedural bleeding. Nine and 8 patients of groups A and B had CSF return, the position of the needle tip was adjusted based on its location, as determined by CT and region stimulated by the radiofrequency current. Nausea and vomiting was treated by antiemetics and relieved within 6 hours. Intracranial hypotension headache occurred in 4 and 5 of groups A and B, respectively, which was manifested as headache and dizziness after the patients stood upright. The headache was relieved by absolute bed rest and fluid replacement, with a recovery time of 4.1 ± 1.2 (2–7) days. Twelve and 3 patients of groups A and B developed corneal hypoesthesia immediately after surgery and 1 case recovered before discharged in group A. Facial numbness (V2 division) were 3 cases, 2 cases in groups A and B. None of the patients developed blepharoptosis, masticatory atonia, decreased hearing, deafness, blindness, or lethal complications.

3.3. Long-term follow-up

3.3.1. Pain relief. As shown in Fig. 1. At discharge, 100% of patients in both groups A and B had a BNI score of I. In groups A and B, a BNI score of I was found in 81.6% and 92.0% at 1 year, 68.4% and 92.0% at 2 years, and 68.4% and 83.6% at 3 years. A higher proportion of Group B than group A patients had BNI I scores, but the difference was not statistically significant (log rank, $P = 0.128$; Breslow, $P = 0.104$; Tarone-Ware; $P = 0.109$).

During follow-up, 9 (32.1%) and 2 (7.1%) patients of groups A and B, respectively developed recurrence ($P = 0.035$). Five group A and 1 group B patients underwent secondary surgery or other treatments.

Cox regression analysis did not find a significant relationship between postsurgery pain relief and age, pain duration before surgery, or surgery time.

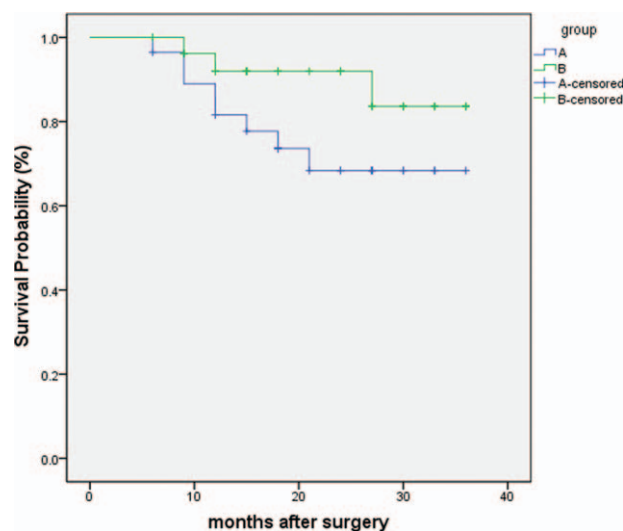


Figure 1. Kaplan-Meier curve indicates the outcomes of pain relief of V1 trigeminal neuralgia treated by continuous radiofrequency thermocoagulation and continuous radiofrequency thermocoagulation plus pulsed radiofrequency.

Table 3
Corneal hypoesthesia.

Group	I	II	III	Recovered time, min
A	17 (60.7)	11 (39.2)	0	11.9±7.5 (4–18)
B	25 (89.3)	3 (10.7)*	0	3.4±2.5 (2–6)*

* $P < 0.05$, compared with group A.

3.3.2. Postprocedural complications. Table 3 shows that at discharge, 14 patients had corneal hypoesthesia (11 and 3 group A and group B patients, respectively; $P < 0.05$). The recovery times of groups A and B patients were 11.9 ± 7.5 (4–18) months and 3.4 ± 2.5 (2–6) months, respectively; ($P < 0.05$).

Facial numbness (mild facial numbness in the distribution region of V2, BNI score II) was observed in 3 (10.7%) and 2 (7.1%) groups A and B patients ($P > 0.05$). The time to recovery from facial numbness was 4.4 ± 1.9 (2–6) months and 3.4 ± 0.8 (2–5) months for groups A and B patients ($P > 0.05$); no severe facial numbness occurred. None of the study patients developed other complications or permanent complications.

3.3.3. HRQoL scores. Table 4 shows that the HRQoL scores of all the study patients were low before the thermalablation procedures and high after the procedures. PCS and MCS gradually decreased over time, at 2 and 3 years, there were statistically significant differences in PCS and MCS between the 2 groups ($P < 0.05$).

4. Discussion

In this study, we observed the effects of PRF on the efficacy of pain relief, recurrence rate, and complications after treatment of V1 ITN by 62°C CRF. Patients undergoing CRF plus PRF had decreased recurrence; reduced complications, including corneal hypoesthesia; and shortened time to recovery compared with patients undergoing CRF only. The HRQoL scores of patients receiving CRF plus PRF were higher than those of patients receiving CRF only.

Temperatures ranging from 60 to 95°C are usually used for TN CRF.^[10,27] But CRF had not been specialized investigated in previous studies for treatment of V1 TN. Most of those studies focused on multiple divisions or divisions that excluded V1 TN.^[28,10,16,18–20] The efficacy and complications of CRF for V1 TN are difficult to deduce from the experience of those studies. In addition, information on temperature used for CRF for V1 TN was not mentioned in some reports.^[29,30] Some study was not standard and unreasonable in design reviewed by Akram et al.^[31] After 90°C CRF for TN of various divisions, including V1, Nie et al.^[9] found facial numbness in 93.3% (28/30) of patients, but

did not report eye complications. So, to reduce or prevent eye complications, we used 62°C CRF for V1 TN.

The application of PRF to the treatment of TN is controversial, mainly because of its poor efficacy for postprocedural pain relief. Chua et al.^[21] reported that at 2, 6, and 12 months after 6 minutes of PRF at 4 Hz and 45 V, the proportions of patients completely free of pain were 73.5%, 61.8%, and 55.9%, respectively. Van Zundert et al.^[13] found excellent efficacy of pain relief in 3 of 5 patients with a 19.2 months follow-up. However, those results were not found in other studies. By contrast, Kim et al.^[18] found that after PRF, every study patient still required use of analgesic drugs, and no patient was completely free of pain. Results of a study by Luo et al.^[16] also suggested that the therapeutic effect of PRF for TN was not ideal.

Zhao et al.^[19] recently reported that PRF reduced the complications and shortened the recovery time after CRF for V2 and/or V3 TN. In agreement with that report, we found that PRF after CRF for V1 TN led to decreased recurrence and shortened recovery time for corneal hypoesthesia. The PRF parameters used in our study were based on those used in the previous studies,^[13,21] and the PRF voltage and electrical field intensity were optimized based on the study results of Luo et al.^[22] Our results showed that at discharge from the hospital, all the study patients felt satisfactory about pain relief. During follow up, more group B patients than group A patients had BNI I scores at 1, 2, and 3 years after surgery, but the differences were not significant. These findings are consistent with the results of CRF plus PRF for V2 and/or V3 TN.^[19] We did not find an enhancement in pain relief after CRF plus PRF, perhaps because of the small sample size (28 cases in each group). We plan to perform an ongoing study with more patients.

The recurrence rate of the patients in group B was 7.1%, lower than 32.1% in group A, which indicates that PRF can decrease the recurrence rate after CRF. The higher recurrence rate for the patients in group A might be accounted for by the lower temperature used. As reported previously, the recurrence rate of V1 TN was 22%^[27] (65–70°C CRF for V1 TN) or 36%^[32] after CRF for mixed TN, which is similar to the rate of our study (32.1%) but lower than the 46%^[33] to 65%^[34] in other studies. After CT-guided CRF for mixed TN,^[34] found recurrence rates of 46%, 60%, and 65% at 1, 2, and 3 years, respectively. In our 3 years follow-up, the recurrence rate was only 7.1% after CRF plus PRF, far lower than the rate after CRF only.

The following factors might account for that PRF decrease recurrence rate after CRF: inhibit the signal transduction of unmyelinated C nerve fibers^[35]; reduce abnormal neurotransmitter transmission in demyelinated trigeminal nerve fibers^[36]; change the electrical field intensity in the local environment, which modulates the expression of the pain-regulating *C-fos* gene^[37] and activating transcription factor 3^[38]; and change the

Table 4
Comparison of SF-36 scores between the groups.

SF-36	Group	Presurgery	Postsurgery	1 y	2 y	3 y
PCS	A	37.6±7.2	72.1±16.5**	63.3±12.3**	49.6±9.4**	43.1±11.1
	B	37.8±7.5	72.6±17.4**	70.4±14.3**	66.8±11.2 ^Δ **	65.2±13.6 ^Δ **
MCS	A	38.7±8.6	75.2±18.3**	67.7±15.3**	53.8±10.8**	47.3±8.0
	B	39.4±8.9	75.6±17.4**	70.2±15.5**	67.3±9.3 ^Δ **	63.5±10.2 ^Δ **

MCS=mental component summary, PCS=physical component summary, SF-36=Short Form-36 questionnaire.

^Δ $P < 0.05$, compared with A group.** $P < 0.05$, compared with presurgery.

cellular structures involved in the transmission of pain information.^[39] However, these mechanisms need confirmation in additional studies.

To the best of our knowledge, there have not been any published reports on complications occurring after PRF for neuropathic pain.^[40] Therefore, all the complications found in our study were considered to be associated with CRF. Corneal hypoesthesia was the major complication; the incidence rate and recovery time of corneal hypoesthesia were significantly lower in the group B patients than that in group A patients. The results indicate that PRF decreases the incidence and shortens the recovery time of corneal hypoesthesia after CRF. The incidence of corneal hypoesthesia after CRF alone in this study is consistent with the 31.4% of a previous study on CRF for TN^[41] but lower than the 60% (12/20) reported in another study.^[19] However, these previous studies all investigated CRF used for TN of multiple divisions, and none of them focused on CRF for V1 TN only.

Mild facial numbness was found in the V2 distribution region of all patients, but none of the patients developed severe facial numbness. The incidence of facial numbness was lower in both of our study groups than reported in previous studies (34.8%–100%).^[8,27,42,43] The lower incidence might be accounted for by the lower temperature (62°C) used for CRF in our study. The incidence of complications after CRF is directly correlated with the temperature of CRF.^[19] No serious complications, including masticatory atonia, dry eye, or blindness occurred in our study.

There was a high proportion of patients with CSF return, the incidence was higher than for other studies (8% to 17.6%).^[29,44] The difference might be accounted for by the technique used to perform CRF for V1 TN. The puncture needle must be delivered as deeply as possible after arriving at the trigeminal ganglion via the foramen ovale, in order to test V1. In addition, the need to deliver the puncture needle deeply resulted in more patients developing an intracranial hypotension headache.

We evaluated the HRQoL of patients using a widely recognized SF-36 scale.^[45,46] Lam et al^[26] carefully observed the average status of Chinese patients. In this study, we calculated PCS and MCS according to their method. Our follow-up results showed that the postprocedural survival status of V1 TN patients was accurately assessed by SF-36. Before the CRF procedure, the study patients had severe pain, which was reflected as low PCS and MCS; the pain was resolved after the procedure, and SF-36 scores were markedly increased. At 2 and 3 years, the PCS and MCS of patients receiving CRF plus PRF were significantly higher than those of the patients receiving CRF only. These findings indicate that the patients undergoing CRF plus PRF had higher HRQoL and satisfaction.

Our study has some limitations. Neither PRF only group nor CRF group at a higher temperature was set. The relevant reasons are described below: PRF has poor efficacy for TN and thus its use for TN is controversial; no CRF group at a higher temperature was set to prevent serious eye complications.

5. Conclusions

We used CRF plus PRF to treat V1 ITN, and the results suggest that PRF can decrease the recurrence rate of TN, decrease the incidence rate and shorten the recovery time of corneal hypoesthesia, and lead to increased HRQoL scores after CRF. Therefore, we recommend the clinical use of CRF plus PRF for treating V1 TN.

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