

ORIGINAL RESEARCH

PAIN MANAGEMENT

Comparison of the efficacy of radiofrequency ablation at 60°C, 65°C and 70°C for managing trigeminal neuralgia

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ABSTRACT

Introduction: The observed efficacy of radiofrequency ablation (RFA) in patients with trigeminal neuralgia (TN) ranged from 42.2% to 97.2% at 2 to 15 years' follow-up. The temperature used varied from 60°C to 95°C, with nonsignificant differences for durations of 2 min or more. Here we compare the analgesic efficacy of 60°C, 65°C and 70°C for a single 90-sec duration.

Methodology: The study was conducted in 100 patients (57 females, 43 males), at Dr Kariadi Hospital Semarang, using the Leeds Assessment of Neuropathic Symptoms and Signs Scale (LANSS) in patients with trigeminal neuralgia. They were divided into control and three RFA groups, e.g., 60°C, 65°C, and 70°C. Carbamazepine 100-200 mg every 8-12 hours and vitamin B12 50 µg every 12 hours, were administered in the control group. While RFA was applied in three RFA groups by placing the electrode needle as close to the target branch(es) at prescribed temperatures for 90 sec duration. Follow-up was done pre-intervention, at 2 weeks, 3 months and 6 months.

Results: All one hundred patients included showed significant improvement in pain ($P < 0.001$). The RFA groups showed significant improvement compared to the control group ($P < 0.05$). Comparison by RFA 60°C group was not significant ($P = 0.083$) at 3- and 6-months follow-up, but it was significant in RFA 65°C group ($P < 0.001$). Comparison between RFA 60°C and RFA 65°C groups was not significant.

Conclusions: RFA 60°C has similar efficacy results to 65°C or 70°C in the treatment of trigeminal neuralgia patients and may cause less tissue damage. Needle placement to the nearest affected branch(es) was more important than temperature of RFA procedures.

Abbreviations: TN: trigeminal neuralgia, SCA: superior cerebellar artery, MVD: microvascular decompression, RTC: radiofrequency thermocoagulation, RFA: radiofrequency ablation, EMF: electromagnetic field, PRF: pulsed radiofrequency, NRS: numerical rating scale, GABA: gamma-aminobutyric acid

Keywords: trigeminal neuralgia; radiofrequency ablation: electrode placement: temperature: neuropathic pain; LANSS

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1. INTRODUCTION

The prevalence of trigeminal neuralgia (TN) or tic douloureux ranges from 6-8% in France and the United Kingdom to 21.8% in Indonesia, based on data from

13 hospitals. The prevalence rate is 0.16-0.3% in Europe, 0.3-0.4% in Asia and 12.6-27.0 per 100,000 people per year worldwide.¹⁻³ The pathophysiology is unclear but is most commonly caused by vascular

compression (80%),⁴⁻⁶ of which 75% is caused by the superior cerebellar artery (SCA) and 25% by the small arteries.^{3,5} Surgical treatment as microvascular decompression (MVD) is still considered effective for classic trigeminal neuralgia due to vascular compression (basilar artery), with improvements ranging from 61% to 80% over 4-5 years. Stereotactic surgery using radioactive waves requires careful consideration. Therefore, other treatments such as radiofrequency thermocoagulation or ablation (RTC or RFA), glycerol injection or balloon implantation may be alternative options. These are known as non-surgical interventions.⁷

Radiofrequency treatment is based on an electromagnetic field (EMF) produced by the generator to block pain impulses.^{8,9} There are two methods of pain interruption, namely: pulsed and ablation set-up. Radiofrequency ablation (RFA) is more effective than pulsed radiofrequency (PRF) in treating trigeminal neuralgia. However, it may have a higher risk of complications than PRF. The temperature setting varies from 60°C to 95°C,⁸ and there is no evidence that the high temperatures (80°C) have better results than the low temperatures (60°C to 75°C).¹⁰ The trigeminal nucleus, called the gasserian ganglion, is a therapeutic target for neuroablation. The usual procedure is to perform 2 to 3 cycles of ablation and temperature increase. However, if the electrode needle is placed according to the local nerve lesion, 1 cycle of 90 sec duration has given good results. The 60°C temperature showed an effective numerical rating scale (NRS) improvement ranging from 33.3% to 85.7% at 6 months, even though only one 90-sec cycle was performed.¹¹ Approximately 76% of trigeminal neuralgia patients are pain free without analgesics, 5% can reduce the dose, and 15% remain on high doses.⁹ Study results of a 42°C PRF procedure in 4 to 5 cycles of 2 min each, followed by RFA at 60°C to 68°C for 180 to 270 sec, observed good results.^{8,12} The use of RFA showed efficacy for up to 3 to 10 years, with more than 75% pain-free or reduced analgesic therapy. At 2 years, 97.2% of patients were pain free, 57.7% at 5 years, 52% at 11 years and 42.2% at 15 years.⁸

While research has compared the efficacy of RFA procedures using different temperatures, a cycle of

less than 2 min has not been found recently. Therefore, we compared the effectiveness of the RFA procedure by adjusting the temperature at 60°C, 65°C and 70°C at a cycle of less than 2 min.

2. METHODOLOGY

This study was conducted at Dr Kariadi Hospital Semarang from July 2021 to July 2022, where subjects were selected based on outpatients and inpatients after Ethical Clearance approval: No. 856/EC/KEPK-RSDK/2021. Neuropathic pain was measured using the Leeds Assessment of Neuropathic Symptoms and Sign Scale (LANSS). It is widely used and has a sensitivity in the range of 82% to 91% and a specificity of about 80% to 94%.¹³ Subjects were recruited consecutively and divided into four groups, e.g., control (analgesic) group, and RFA 60°C group, RFA 65°C group and RFA 70°C group. In the control group, carbamazepine 100-200 mg/8-12 hours and vitamin B12 50 µg/12 hours were prescribed as neurotrophic drugs. Pain was assessed at pre-intervention, then at 2 weeks, 3 months and 6 months.

The RFA procedure was performed in the operating theatre of Dr Kariadi Hospital, Semarang, under fluoroscopic guidance. All patients were started with 0.9% NaCl infusion, pulse oximetry and vital signs monitoring without sedation. With the patient supine on the operating table, under aseptic conditions, procedures were performed by needle insertion 2 cm lateral to the orbicularis oris. A 15-20° oblique and 135° caudal view of the foramen ovale (FO) could be obtained. Injection of 2-3 mL of 2% lidocaine local anesthetic followed by insertion of a 22-G, 10 cm RF needle with a 5 mm needle tip capable of transmitting electromagnetic waves (Cosman TIC-C5 electrode) towards the FO. A lateral view of the needle direction to the posterior clivus was observed and the 3 mm needle tip was passed through the foramen ovale. Sensory (50 Hz, 1 ms) and motor (2 Hz, 0.1 ms) stimulation ensured that the motor component was safe from the ablation process. A 0.5 mL dilution of 5 mg dexamethasone and 2% lidocaine was injected at the time of ablation.¹⁴ After the procedure, subjects were monitored for vital signs, swallowing reflexes, motor and sensory function and postoperative corneal reflexes.

Table 1: Demographic data of the participants

Variables		Groups			
		Control	60° C	65° C	70° C
Gender	Female	15	15	14	13
	Male	10	10	11	12
Age (yr)	< 55	13	12	12	12
	> 55	12	13	13	13
Duration of illness	< 6 months	20	17	16	14
	> 6 months	5	8	9	11

3. RESULTS

One hundred trigeminal neuralgia patients attending Dr Kariadi Hospital, Semarang, were willing to participate in this study. Fifty-seven were female and 43 were male; 49 subjects were younger than 55 years and

Table 2: Descriptive and normality of LANSS score among group (Friedmann test)

Groups	Period	Mean \pm SD	Median (min – max)	ρ^{L}	ρ^{Y}
Analgesics (Control Group)	Before	19.72 \pm 2.51	19 (16 – 24)	0.003	< 0.001
	Week 2	12.1 \pm 2.64	13 (8 – 15)	0.001	
	Month 3	3.40 \pm 2.35	2 (2 – 10)	0.000	
	Month 6	3.56 \pm 2.9	3 (0 – 10)	0.028	
60° C Group	Before	21.12 \pm 2.24	20 (19 – 24)	0.000	0.000
	Week 2	8 \pm 1.18	8 (7 – 10)	0.000	
	Month 3	0.6 \pm 1.66	0 (0 – 5)	0.000	
	Month 6	0	0	0.000	
65° C Group	Before	21.56 \pm 2.23	20 (19 – 24)	<0.001	< 0.001
	Week 2	8.4 \pm 1.85	8 (5 – 13)	0.001	
	Month 3	1.24 \pm 2.1	0 (0 – 5)	0.000	
	Month 6	0	0	0.000	
70° C v	Before	21,4 \pm 2,25	20 (19 – 24)	<0,001	< 0.001
	Week 2	8,4 \pm 1,85	8 (5 – 13)	< 0,001	
	Month 3	2.44 \pm 2.18	3 (0 - 5)	< 0,001	
	Month 6	0.36 \pm 0.81	0 (0 - 3)	< 0,001	

Note : ^L Shapiro-Wilk, Normal ($p > 0.05$) ^Y Friedmann (significant $P < 0.05$)

51 were older than 55 years. A total of 57 subjects had pain for less than 6 months and 43 subjects for more than 6 months (Table 1).

Significant changes in neuropathic pain improvement ($P < 0.001$) were observed at baseline, week 2 and month 3 (Table 2). There was a significant improvement in neuropathic pain in the RFA 65°C group ($P < 0.001$). The significant changes in neuropathic pain improvement ($P < 0.001$) were observed before the intervention, at week 2 and at month 3 in the 60°C group (Table 3) and in the 65°C group (Table 5).

Comparison of neuropathic pain improvement showed no significant changes from month 3 to month 6 in the 60°C group ($P = 0.083$) (Table 3). These results are also similar to those of the RFA 70°C group, which showed a significant improvement in the pre-post changes at week 2, months 3 and 6 ($P < 0.001$). Of course, the analgesic (Control) group also showed a significant improvement in the pre-post changes at week 2, month 3 and month 6 ($P < 0.001$). At week 2 of the follow-up, there was no significant improvement between 60° C, 65° C and 70° C groups. Significance was shown at month 3 when comparing 60° C vs 70° C and 65° C vs. 70° C groups ($P < 0.05$), but not for 60° C vs 65° C.

Significant differences ($P < 0.05$) were observed between 60° C vs 70° C and 65° C vs. 70° C at month 6, whereas 60° C vs 65° C was not significant ($P = 1.000$).

4. DISCUSSION

Carbamazepine 100–200 mg showed improvement throughout the follow-up period in the control group, as this is the first-line analgesic treatment for NT. It is a sodium channel blocker, which can reduce nerve excitability or stabilise nerve membrane hyperexcitability. It also reduces the propagation of synaptic impulses and/or inhibits excitatory bursts of recurrent nerve fibres.¹⁵ It causes potentiation of gamma-aminobutyric acid (GABA) receptors, so pain may improve with most doses in the range of 200-800 mg/8-12 hours.¹⁶

Pain improvement in the 60°C, 65°C and 70°C groups showed significant differences compared with the analgesic group. The 60°C group had no significant difference in pain improvement compared to follow-up at months 3 and 6, whereas the 65°C and 70°C groups had significant improvement at month 6. All subjects in the RFA groups had no significant difference in pain improvement at week 2 after RFA procedures. At month 6, there was no significant difference in pain improvement between the 60°C and 65°C groups. This means that the 60°C temperature set for RFA may have a similar effectiveness in improving pain to the 65°C of neuroablation by RFA in NT patients. This means that by setting a lower temperature of 60°C in the RF machine, it may be a better option for neuroablation in the treatment of NT. And it promises a better improvement in pain with minimal or no side effects.

Table 3: The comparison of LANSS score improvement Before, at Week 2, Month 3 and 6 among groups (Wilcoxon-signed Ranks Test)

Groups	Period	Follow-Up	P-value
Analgesics (Control) Group	Before	Week 2	0.001*
		Month 3	< 0.001*
		Month 6	< 0.001*
	Week 2	Month 3	< 0.001*
		Month 6	< 0.001*
	Month 3	Month 6	< 0.001*
60° C Group	Before	Week2	< 0.001*
		Month 3	< 0.001*
		Month 6	< 0.001*
	Week 2	Month 3	< 0.001*
		Month 6	< 0.001*
	Month 3	Month 6	0.083
65° C Group	Before	Week 2	< 0.001*
		Month 3	< 0.001*
		Month 6	< 0.001*
	Week 2	Month 3	< 0.001*
		Month 6	< 0.001*
	Month 3	Month 6	< 0.001*
70° C Group	Before	Week 2	< 0.001*
		Month 3	< 0.001*
		Month 6	< 0.001*
	Week 2	Month 3	< 0.001*
		Month 6	< 0.001*
	Month 2	Month 8	< 0.001*

Note : * Significant (P < 0.05)

Thus, it may not be necessary to use repetition or three cycles by increasing the temperature set for neuroablative purposes in NT patients.¹⁷

Recently, the pulsed RF method by choosing 42°C, 4 to 5 cycles for 2 min each cycle¹⁸; then followed by RFA 60°C to 68°C for 180 to 270 sec effectively reduces pain.¹² RFA may cause a higher risk of complications than PRF, so lower temperatures (68°C–70°C) for neuroablation purposes¹⁹ Temperature preference of 55°C to 85°C is widely used as the therapeutic effects may be long term. Temperatures above 65°C tend to damage A δ and nociceptive nerve fibres C.

Persistent facial hypesthesia was found in patients who received RFA above 80°C, by setting 75°C facial hypesthesia showed improvement and a temperature of 70°C with no findings of facial hypesthesia. The 70°C, 75°C and above 89°C RFA settings tend to cause facial hypesthesia in 70%, 55.4% and 75.6% of cases respectively. However, this may improve after 31.4 \pm 14.9 weeks or 7 to 14 months²⁰ RFA with a

temperature setting of 50°C to 55°C for 4 to 6 min causes irreversible nerve damage. Above 60°C to 100°C, coagulation of cellular proteins and changes in mitochondrial and cytosolic enzymes may be increased. Thus, the coagulated area gradually develops into necrotic tissue and then into dead cells.^{9, 21-23}

Temperature regulation is an important factor affecting efficacy, with 66°C to 80°C providing effective results for RFA. While PRF procedures are in the range of 45°C to 50°C, especially for elderly patients.⁹ When performing RFA procedures, always ensure that the placement of the needle electrode corresponds to the nearest site of the affected branch(es), based on the immediate response to sensory stimulation. Tissue damage around the gasserian ganglion tends to be related to the technique of the procedure, as most trigeminal nerve compressions are located a few millimetres at the entrance to the foramen ovale or adjacent to the pons. Approximately 80-90% of compression lesions are

caused by adjacent vessels through abnormal arterial or venous loops²⁴ Although previously RFA applied in ranges between 90-sec and 180-sec and graded heating from 55°C to 75°C at 5°C may minimise side effects,²⁴ such injuries to adjacent structures require caution and care in electrode needle placement due to the risk of surrounding vascular penetration or inadvertent injury to the gasserian nerves.

5. LIMITATIONS

The study did not analyze patients' comorbidities, such as blood pressure, anxiety or psychological states, which could influence pain perception. And the follow-up period could be up to 12-24 months.

6. CONCLUSIONS

The prescription of analgesics showed a significant improvement as with RFA at different temperatures, but long-term therapy needs to pay attention to the side effects. There was no significant difference in neuropathic pain improvement with RFA 60°C when compared to 65°C or 70°C at week 2, or with 70°C at month 6. It means that 60°C brings good improvement in neuropathic pain for trigeminal neuralgia patients, even though in 90-sec duration and single cycle of RFA set up. Studies have shown that cycle duration of 120-sec or more is not the only guideline that leads to better results. Our study results can be considered a guideline for the management of radiofrequency neuroablation in patients with trigeminal neuralgia. The use of a single 90-sec cycle set at 60°C can provide effective improvement of neuropathic pain without side effects.

7. Data availability

The numerical data generated during this research is available with the authors.

8. Acknowledgement

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9. Conflict of interest

The authors declare that there was no conflict of interest involved.

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11. Authors' contribution

TB: Conceived the concept, track and monitor changes in pain intensity during outpatient visits before and after radiofrequency ablation surgery.

AH: analysed aspects of the patients' neuroanatomy and

DP: statistical analysis

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