



ORIGINAL ARTICLE

Radiofrequency thermocoagulation for the treatment of lower extremity ischemic pain: Comparison of monopolar and bipolar modes

Alt ekstremitenin iskemik ağrı tedavisinde radyofrekans termokoagülasyon: Monopolar ve bipolar modların karşılaştırması

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Summary

Objectives: Radiofrequency thermocoagulation (RFT) has been reported to be used safely to treat ischemic lower extremity pain. The objective of the present study was to evaluate efficiency of RFT for treatment of lower extremity ischemic pain and to compare effectiveness of monopolar RFT and bipolar RFT modes.

Methods: Following ethics committee approval, 30 American Society of Anesthesiologists classification I-III patients with ischemic lower extremity pain aged between 18 and 65 years were recruited. Patients were randomly allocated into 2 groups: MRT group (n=15) received monopolar RFT (80°C) for 2 minutes at L2-3 level, and BRT group (n=15) received bipolar RFT (80°C) for 2 minutes at L2-3 level. Systolic and diastolic blood pressure, heart rate, pain score, and supplemental analgesic requirements were recorded at 24 hours after application and at 7, 30, and 90 days.

Results: Numerical rating scale values in both groups decreased significantly over time and it was found to be significantly lower in BRT group after first and third months ($p<0.05$). Supplemental analgesic requirements were similar with no significant difference between the 2 groups at any point of study period ($p>0.05$). No adverse event or complication related to procedure or treatment was reported.

Conclusion: In patients with ischemic lower extremity pain, both monopolar and bipolar RFT treatment modalities were found to significantly decrease pain levels. However, bipolar mode led to lower pain scores at 30 and 90 days, and longer duration of analgesia than monopolar mode.

Keywords: Radiofrequency thermocoagulation; monopolar; bipolar; ischemic pain; lumbar sympathectomy.

Özet

Amaç: Alt ekstremitenin iskemik ağrı tedavisi için radyofrekans termokoagülasyon'un (RFT) güvenle kullanılabileceği bildirilmiştir. Bu çalışmanın amacı alt ekstremitenin iskemik ağrı tedavisi için RFT'un etkinliğini değerlendirmek ve monopolar ve bipolar RFT modlarını karşılaştırmaktır.

Gereç ve Yöntem: Etik komite kabulünü takiben alt ekstremitede iskemik ağrısı olan, yaşları 18-65 yaş arası, ASA I-III grubu, 30 hasta çalışmaya alındı. Hastalar MRT grubunda (n=15) L₂₋₃ düzeyinden 2 dakika monopolar RFT (80°C), BRT grubunda (n=15) ise L₂₋₃ düzeyinden 2 dakika bipolar RFT (80°C) almak üzere rastgele iki gruba ayrıldı. Sistolik ve diastolik kan basınçları, kalp atım hızı, ağrı skorları (NRS) ve ek analjezik ihtiyaçları hastaneden taburcu edildikten 24 saat ve 7, 30 ve 90. günlerde kaydedildi.

Bulgular: Her iki grupta NRS skorlarının zaman içerisinde önemli derecede azaldığı ve BRT grubunda MRT grubuna göre 30 ve 90. günlerde istatistiksel olarak önemli derecede daha düşük olduğu tespit edildi ($p<0.05$). Bununla birlikte, ek analjezik ihtiyacının iki grupta benzer olduğu ve iki grup arasında çalışma periyotlarında istatistiksel fark oluşturmadığı tespit edildi ($p>0.05$). İşlem veya tedaviye ilişkin yan etki veya komplikasyon bildirilmedi.

Sonuç: Alt ekstremitenin iskemik ağrı tedavisinde hem monopolar hem de bipolar radyofrekans termokoagülasyon tedavi modalitelerinin ağrı düzeylerini önemli derecede azalttığı bulundu. Bununla birlikte, bipolar RFT'un monopolar RFT'a göre 30 ve 90. günlerde daha düşük ağrı skorlarına ve daha uzun analjezi süresine neden olduğu belirlendi.

Anahtar sözcükler: Radyofrekans termokoagülasyon, monopolar, bipolar, iskemik ağrı, lomber sempatotizis.

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Introduction

Peripheral arterial disease (PAD) is characterized by an increased risk of vascular ischemic events.^[1] The prevalence of PAD increases with age and the number of vascular risk factors (hypertension, diabetes, smoking, hyperlipidemia and high homocysteine levels).^[2] Traditionally, non-invasive (controlling hypertension and diabetes, pharmacological treatment modalities) and invasive approaches (surgical or endovascular revascularization, with percutaneous balloon angioplasty, and with or without stenting) has been recommended for the treatment of pain in patients with PAD of lower extremities. However, for patients whose pain does not respond to appropriate medical and physical therapy, radiofrequency thermocoagulation (RFT) has been proposed as an alternative treatment option for the treatment of pain in patients with peripheral arterial diseases.^[1] In a pilot study, percutaneous radiofrequency thermal lumbar sympathectomy has been compared to phenol lumbar sympathetic neurolysis for the treatment of complex regional pain syndrome type 1.^[3] In that study, authors have found that both treatment modalities are safe and effective procedures for providing satisfactory pain relief.

The mechanism of action of RFT is to produce tissue destruction and lessen pain by modulating pain transmission.^[4] Additionally it is also speculated that RFT may cause vasorelaxation in vessels when applied for lumbar sympathectomy and thus may reduce pain by producing lumbar sympatholysis.^[4]

RFT is firstly introduced in conventional (monopolar) mode and can be used in different modes. However, the major limitation of the monopolar RFT is its incapability to produce effective tissue destruction, without causing nerve damage.^[5] To overcome the drawback of monopolar RFT, various techniques and modes have been proposed, including multiple probes RFT applied in the form of either simultaneous^[6] or alternative RFT,^[7] and bipolar RFT.^[8-11]

However, to date, as far as we know, there is no published data evaluating the efficiency of RFT for the treatment of lower extremity ischemic pain and compare the effectivity of monopolar RFT and bipolar RFT mode.

In this prospective, double-blind, randomized study, we have evaluated the efficiency of RFT for the treatment of lower extremity ischemic pain and compare the effectivity of monopolar RFT and bipolar RFT mode on pain scores and analgesic consumption. Thus, the primary outcome of this study was considered as pain scores of patients measured by numerical rating scale at 24 hour, and 7, 30 and 90 days after hospital discharge.

Materials and Methods

This prospective, double-blind, randomized study was conducted between 15 March 2013 and 15 September 2013 by Çukurova University, Faculty of Medicine, Department of Anesthesiology. Following faculty ethic committee approval and written patient consent 30 ASA I - II group patients between 18–65 years of age, undergoing lower extremity ischemic pain were included in this study. Exclusion criteria included significant coexisting disease such as cardiopulmonary disease, any contraindication to apply RFT such as local infection or bleeding disorders and long-term opioid use. Patients were instructed on the use of the numerical rating scale (NRS) for pain assessment and interventional procedure preoperatively. All patients were fasted for 8 h preoperatively and no premedication were given.

Before intervention, patients were monitored with pulse oximetry, automated blood pressure cuff and lead II electrocardiogram, and an intravenous access was established. The patients were allocated to one of two groups of 15 each by computer-generated random number assignment.

All procedures were performed in prone position. A pillow was inserted to correct lumbar spinal curve under lower abdomen and brought into a straight line at L₂-L₃ vertebra level. Transverse processes of the vertebra were marked and image of the transverse processes in C-arm fluoroscopy was rotated in oblique direction until image of transverse processes disappeared under the vertebral body. The area was cleaned with antiseptic, povidone iodine. After infiltrating the skin with 2% lidocaine 2 ml, a 15 cm active-curved radiofrequency needle 20 G (NeuroTherm) was introduced to the transverse (spinous) process of L₂-L₃ vertebral bodies under the guidance of a C-arm fluoroscopy. The position of the

needle tip was also confirmed by C-arm fluoroscopy in lateral view. In bipolar mode, the second cannula was inserted at approximately 4–6 mm below of the first needle. Following negative aspiration for blood and cerebrospinal fluid testing, 1 mL of ionic radio-opaque agent was given, which was also checked in the AP and lateral view. The correct placement of the needle/s was confirmed with the image contrast of straight line appearing vertically on the anterior face of corpus vertebra.

Following confirmation of correct placement of the needle, radiofrequency stimulation was done at 50 Hz to identify proximity to motor (2 V) or sensory (0.5 V) nerves, respectively. No motor (fasciculation) or sensory (paresthesia) block was observed. Radiofrequency lesioning was applied in monopolar mode for 2 min at a temperature of 80°C in group MRT and in bipolar mode for 2 min with 4–6 mm intervals of two electrodes at a temperature of 80°C in group BRT. Ten milliliter of 0.25% bupivacaine was injected at each level after radiofrequency lesioning in both groups. No additional analgesic was administered unless requested by the patients.

Systolic and diastolic blood pressures and heart rate variables were regularly monitored at preoperatively and during the procedure. All patients were observed routinely at postanesthesia care unit (PACU) for 4–6 hours postoperatively and discharged from PACU on the day of intervention when they met the discharge criteria. The discharge criteria for home were stable vital signs, awake and alert patient, no pain and other side effects. Patients were prescribed supplement analgesia with per orally (po) naproxen sodium 550 mg twice a day and allowed to take whenever they needed.

Pain scores were evaluated preoperatively and at 24 hour, and 7, 30 and 90 days after hospital discharge. Pain was assessed using a numerical rating scale (NRS) ranging from 0 (no pain) to 10 (worst pain imaginable).

Demographic data (Gender, age, weight, height and patients' education) were recorded by an observer blinded to the treatment group. Pain scores, systolic and diastolic blood pressures (SBP, DBP) and heart rate (HR) were recorded by an investigator blinded to the patient group, at preoperatively, 24 hour, and

7, 30 and 90 days after hospital discharge. Supplement analgesic consumptions were questioned and recorded. All patients were also assessed in terms of adverse effects and complications.

Patients were readmitted to hospital for general assessments and data collection (Hemodynamic variables, pain scores and supplement analgesic requirement) at 24 hour, 7, 30 and 90 days after hospital discharge.

Statistical analysis

The data were analyzed by using SPSS 20.0. Categorical measurements were summarized as number and percentage; continuous measurements were summarized as average and standard deviation. For the comparison of categorical variables, Chi-square test or Fisher exact test statistics were used. Distributions were controlled in continuously comparing the measurements between the groups. Eligibility of variables to normal distribution were examined visually (histograms and probability plots) and analytically (Kolmogorov-Smirnov/Shapiro-Wilk tests). Student T Test was used for the comparison of normally distributed parameters and Mann-Whitney-U test for the parameters which were not normally distributed. As normal distribution conditions could not be achieved in the comparison of repeated measurements such as NRS values, statistical significance of the change over time was carried out using the Friedman test for these parameters. The changes in the rate of additional analgesic requirements between the initial and subsequent tracking were evaluated by using Cochran Q test. The level of statistical significance (p value) was taken as 0.05 in all tests.

Results

All patients completed the study protocol, $n=15$ in each group. The demographic variables (Gender, age, weight, height and patients' education) of patients are shown in Table 1. There were no significant differences between groups in demographic variables. SpO_2 values remained within the normal range during the intervention in both groups. SBP, DBP and HR values remained within the normal range throughout the study period. There were no statistically significant differences in hemodynamic variables between two groups (Table 2).

Mean NRS scores significantly decreased over time.

Table 1. Demographic variables of the patients

	Group MRT (n=15)			Group BRT (n=15)			p
	n	%	Mean±SD	n	%	Mean±SD	
Gender	9	60		9	60		p>0.05
Male	6	40		6	40		p>0.05
Female							
Age			49.2±9.2			51.2±12.1	p>0.05
Height			171±6.9			168.4±5.3	p>0.05
Weight			73.5±9.1			71.4±12.5	p>0.05
Education							
Primary school	–	–		4	26.6		p>0.05
Secondary school	6	40.0		4	26.6		p>0.05
High school	6	40		5	33.3		p>0.05
University	1	6.6		1	6.6		p>0.05

MRT: Monopolar Radiofrequency Thermocoagulation; BRT: Bipolar Radiofrequency Thermocoagulation; SD: Standard deviation.

Table 2. Hemodynamic variables in MRT and BRT groups

	24 hour Mean±SD	7 th days Mean±SD	30 th days Mean±SD	90 th days Mean±SD
SBP				
Group MRT	129.9±9.3	132.1±10.3	130.5±9.7	128.8±8.2
Group BRT	122.6±32	130.4±7.8	128.2±8.0	129.8±8.1
DBP				
Group MRT	74±6.5	77.6±5.5	78±7.4	75.7±6.8
Group BRT	72.2±6.3	74.7±5.5	74.2±5.8	75.2±6.5
HR				
Group MRT	76.3±5.9	77.2±5.4	76.3±5.8	75.8±5.1
Group BRT	73.8±4.5	73.8±6.9	76.2±5.1	75.4±5.6

MRT: Monopolar Radiofrequency Thermocoagulation; BRT: Bipolar Radiofrequency Thermocoagulation; SD: Standard deviation; SBP: Systolic blood pressures; DBP: Diastolic blood pressures; HR: Heart rate.

Table 3. Mean NRS scores in MRT and BRT groups

NRS Scores	Group MRT Mean±SD	Group BRT Mean±SD	p
Preoperative	7.6±0.8	7.5±0.6	0.541
24 hour	5.7±1.3	6.4±1.4	0.130
7 th days	4.5±1.2	4.4±1.5	0.705
30 th days	4.4±1.9	2.6±0.9*	0.003
90 th days	5.0±2.3	3.2±1.0*	0.035

NRS: Numerical rating scale; MRT: Monopolar Radiofrequency Thermocoagulation; BRT: Bipolar Radiofrequency Thermocoagulation. *p<0.05 statistically significant, compared with group MRT.

Although NRS scores was significantly lower in both groups at each study period than preoperative scores (p<0.001), there was no significant difference

in pain scores between BRT and MRT groups at 24 hours and 7 days (p>0.05). However, it was significantly lower at the 30 and 90 days in BRT group than in MRT group (p<0.003, p<0.035) (Table 3).

Number of patients requiring supplement analgesic also decreased over time. However there was no significant difference in analgesic requirement between two groups at each study period (p>0.05) (Table 4). No major complication or side effect related with procedure was reported and mostly (hypotension, nausea) were minor and resolved spontaneously.

Discussion

The main object of the present study was to evaluate

Table 4. Number of patients requiring supplement analgesic in MRT and BRT groups

	24 hour	7 th days	30 th days	90 th days
Number of patients requiring supplement analgesic				
Group MRT				
Group BRT				
p	>0.05	0.715	0.598	0.245

MRT: Monopolar Radiofrequency Thermocoagulation; BRT: Bipolar Radiofrequency Thermocoagulation ; Data are presented as number.

the efficiency of RFT for the treatment of lower extremity ischemic pain and compare the effectivity of monopolar RFT and bipolar RFT mode. We found that both RFT mode is effectively reduce pain scores in patients with lower extremity ischemic pain. However, bipolar mod led to lower pain scores at the 30 and 90 days and longer duration of analgesia than monopolar mode.

When applied for sympatholysis, RFT may reduce pain by producing lumbar sympathectomy.^[4] Kang and Umeda reported that lumbar sympathetic ganglia is most frequently found at the level of the upper third of the third lumbar vertebra, at the level of the lower third of the second lumbar vertebra and at the L₂₋₃ interspace on both the right and left sides.^[12,13] In the present study, the needles were introduced through the L₂₋₃ intervertebral space under the guidance of C-arm fluoroscopy to make selective nerve destruction (lumbar sympatholysis) (evaluated by the stimulation of sensory and motor nerves).

Radiofrequency lumbar sympatholysis has been proposed to have effective treatment option in patients with hyperhidrosis of lower limbs, sympathetically maintained pain, and vascular diseases.^[14] For example, in the treatment of Raynaud's disease, bipolar RF thermocoagulation within 7 mm intervals of the two electrodes has been used to produce sympatholysis.^[12] In that case, sequential bipolar radiofrequency lumbar sympathectomy provided a long duration of symptom relief. In our study, in fact, both RFT modes provided effective analgesia in patients with lower extremity ischemic pain. However, BRT offered more beneficial effect in reducing pain scores in long time period than MRT because of the lower NRS scores after the first and third months.

Haynsworth and Noe compared the efficiency of RF thermocoagulation with chemical nerve destruction for the production of lumbar sympathectomy. They reported that percutaneous sympathectomy using RF thermocoagulation have a longer duration of analgesia and lower incidence of post-operative neuralgia, as compared to chemical nerve destruction.^[15]

Radiofrequency thermocoagulation impairs or destroys the nerves by creating heat to targeted nerve tissues and results in a disruption of the transmission of nerve function.^[4] Conventional (monopolar) and bipolar RFT are the two basic types of radiofrequency thermocoagulation. Both of these methods have been shown to eliminate or reduce the chronic pain by disrupting pain signal transmission from specific nerves.^[4]

In the RFT treatment, semi-intact, a lesion in nerves is targeted from the tip of the RFT device, which disrupts the pain signal but not to cause necrosis in nerves. However, the lesion should also be large enough to produce long duration of analgesia. In the literature, in some cases, conventional monopolar RFT has been reported to fail to produce effective tissue destruction and lead to deafferentation pain during and after the application. Especially, in two studies, analysing the size of the thermal lesion created by RF under sonographic guidance, authors have stated that, there is a real need to increase the dimension of thermocoagulation using a single probe application.^[5,16]

To increase radiofrequency-induced coagulation, several investigators have proposed to use of bipolar radiofrequency thermocoagulation technique. Bipolar RFT may produce more predictable and larger lesions than monopolar RFT.^[17-19] In bipolar mode, there is a high and constant electric field gradient between the two electrodes.^[20] Anfinson et al. compared the lesion size of bipolar and monopolar RFT techniques on porcine right atrium and reported greater lesion length in bipolar mode than unipolar mode.^[19] Similarly, Pino et al. noted that bipolar RF created the largest lesion in performing thermocoagulation at 90°C for 120–150 seconds with 4–6 mm intervals of two electrodes.^[21] Derby and Lee reported that bipolar electrodes produce greater thermocoagulation and better coagulation

on a larger area than that of monopolar electrodes.^[22] In our study, radiofrequency lesioning was created at a temperature of 80°C for 120 seconds in both groups. Bipolar RFT provided better pain scores at the 30 and 90 days, suggesting this technique produced greater thermocoagulation area than conventional monopolar RFT.

Our findings are in accordance with other studies which also reported that bipolar radiofrequency thermocoagulation may create larger lesions than monopolar radiofrequency thermocoagulation using a bipolar RF-system with the two electrodes.^[17-19] An explanation for this result may be that in bipolar RF modes, the first electrode is thermally shielded by the second electrode so that heat is trapped between the two probes and higher temperatures are achieved. This effect may produce higher temperatures and increase the dimension of thermocoagulation.^[18]

Wound healing and analgesia follows tissue destruction so we hypothesized that effective tissue destruction would result in lower pain scores and longer duration of analgesia. Thus, in the present study, better pain scores at the 30 and 90 days in bipolar RFT group implies bipolar RFT produced more effective tissue destruction, than monopolar RFT.

In an experimental study, Bruners et al. investigated the differences between bipolar and monopolar radiofrequency (RF)-ablation devices regarding the shape and volume of the induced coagulation zone. They reported that if probes with 20 and 30 mm active tip length were used, the bipolar system creates more spherical lesion. In final, they concluded that the proper combination of RF-system and electrode length allows to individually adapting the shape and volume of the generated coagulation necrosis to the target lesion.^[23] In the present study, we used a 15 cm active-curved radiofrequency needle (NeuroTherm) in both groups. Better pain scores at the 30 and 90 days and longer duration of analgesia in bipolar RFT group suggesting larger volume of coagulation was achieved with bipolar RFT mode.

RFT can cause rare but serious complications such as abscess, cranial nerve palsies, blindness, meningitis and carotid-cavernous fistula.^[24] In our study,

no major complication or side effect was noticed. Minor side effects (hypotension, nausea) resolved spontaneously.

There are two limitations of this study. The first; the sample size was not large enough to demonstrate a power as the study was conducted between 15 March 2013 and 15 September 2013. Another limitation was that recruited patients were not staged as to the level of claudication. Classification of the patients could be beneficial to provide the heterogeneity of the groups.

In conclusion; both RF thermocoagulation technique (monopolar and bipolar) is effectively and safely used for the patients with lower extremity ischemic pain which need a long-term sympatholysis. However, bipolar RFT mod led to lower pain scores at the 30 and 90 days and longer duration of analgesia than monopolar mode, suggesting bipolar technique produced better thermocoagulation effect than conventional monopolar RFT. Further and large series of clinical studies are needed to confirm this relationship.

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