

Article

# EVALUATION OF THE RADIOFREQUENCY ABLATION OF LUMBAR SYMPATHETIC GANGLIA IN LOWER LIMB ISCHEMIC ULCERS IN INDIAN POPULATION

## RADIOFREQUENCY ABLATION AND LOWER LIMB ISCHEMIC ULCERS

### Evaluación de la Ablación por Radiofrecuencia de los Ganglios Simpáticos Lumbares en las Úlceras Isquémicas de las extremidades inferiores en la Población de la India Ablación por Radiofrecuencia y Úlceras Isquémicas de las Extremidades Inferiores

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## ABSTRACT

**Background:** Lumbar sympathectomy through radio ablation is a useful treatment of peripheral ischemia. However, clinical efficacy with respect to lower limb ulcers is not adequately established in the Indian population. The study was conducted to evaluate the role of radiofrequency ablation (RFA) of the lumbar sympathetic ganglia in healing of ischemic ulcers of the lower limb.

**Method:** The prospective study with 63 patients registered in the General surgery department with lower limb ischemic ulcers between December 2017– July2019 were treated with RFA. Patients with cardiopulmonary disease, pregnant, congenital malformation, or skin infection at the site of intervention, or suffering from bleeding disorders, were excluded from the study. Clinical investigation of the wound was performed, and demographic data was collected. Comparative reduction in wound size was assessed through Friedman's ANOVA ( $P<0.001$ ). Difference in pain score, hospital stay, and walking distance were evaluated using Wilcoxon matched pair test ( $P<0.001$ ), Unpaired t-test, and Paired t-test ( $P<0.05$ ).

**Result:** Majority of the patients were male ( $n=40$ ) with a mean age of 60.93 SD14.34 years. Significant reduction in wound size, pain scores and hospital stay were observed post procedure( $P<0.001$ ). Number of RFA sessions was significantly associated with the size of the ulcer and Fontaine's classification 2 and 3 ( $P<0.0001$ ).

**Conclusion:** RFA of lumbar sympathetic ganglia is a potential treatment modality for lower limb ischemic ulcers.

**Keywords:** Isquemic ulcers; Radiofrequency ablation; Sympathetic ganglia; Lower extremity.

## 1. Introduction

Ischemic ulcers, caused due to arterial insufficiency, is common in peripheral artery disease (PAD). (Dormandy, et al., 1999; Fowkes & Gillespie, 2000; Bartus & Margolis, 2004) They are mainly located on the lateral surface of the ankle or distal digits and are excruciating with a characteristic of prolonged healing period.(Manchikanti, 2000; Armstrong & Lipsky, 2004)

Thromboangiitis obliterans or Buerger's disease is a segmental occlusive inflammatory condition of arteries and veins, and its prevalence ranges from 45 to 63% in India among all patients with peripheral arterial disease.(Arkkila, 2006)

An interventional treatment of the ulcers caused by peripheral arterial disease is through interruption of the lumbar sympathetic chain.(Arkkila, 2006) Radiofrequency ablation (RFA), also called rhizotomy, is a non-surgical and minimally invasive interruption modality.(Zhu, et al., 2008; Soloman, et al., 2010; Abramov, 2014) RFA is precise, effective, discrete and offers reproducible results.(Dhaliwal & Mukherjee, 2007) Efficacy of RFA has been previously reported in lung cancer, lower limb ischemia, chronic pain, and venous ulcerations.(Dhaliwal & Mukherjee, 2007; Elshimy, et al., 2014; Mehraj, 2018) Apart from a single centre study to evaluate the efficacy of forward and backward needle for RFA, there is paucity of literature on RFA of lower limb.(Cosman, et al., 1984) Therefore, the aim of the study is to evaluate the efficacy of RFA in lumbar sympathetic blockade in lower limb ischemic ulcers as observed by decreased healing time, pain and length of hospital stay.

## 2. Material and Methods

The prospective, observational study was conducted, among the patients, who were registered with department of General surgery at D.Y. Patil Medical College, Kolhapur, between July 2017–2019. Institutional Ethical Committee approval was taken prior to the study.

A total of 63 patients within 25-70 years of age, suffering from lower limb ischemic ulcers (assessed with the help of Ankle branchial index; data not presented), and consenting to the study were included. Patients with cardiopulmonary disease (as in these patients' condition of vessel walls is compromised by accumulation of plaque, and it can be life threatening if plaque dislodgment occurs), pregnancy, any congenital malformation or skin infection at the site of intervention, or any bleeding disorders, and any venous ulcers due to varicose veins, were excluded from the study. The minimum sample size estimated was 52. Sample size was estimated using formula (Fig 1):

**Figure 1.**

Formula for estimating sample size.  $Z= 1.96$  (value associated with confidence interval of 95%)  $P= 3.5 \%$  (Expected prevalence or proportion),  $D=$  absolute precision = 5% of  $P$ .

$$N = \frac{Z^2 * P * (1 - P)}{d^2}$$

Patients were interviewed to collect demographic data, like gender and age. Clinical examination of wound was conducted, followed by systemic examination. During the clinical examination, wound characteristics were evaluated. Standard systemic investigations were performed (data not presented). Radiological investigations included X-ray, and colour doppler of the affected part were undertaken. Biopsy of the ulcer was undertaken to rule out any malignancy.

Mobile C-arm X-ray device, Epidural Spinal Needles, Sterile gloves, Medications, Contrast, Sterile Drapes, and Betadine Solution, Blood Pressure Cuffs, Cardiac Monitors, Pulse Oximeters, and Skin thermometer.

After the wound area was identified, it was cleaned thoroughly with betadine solution and then covered with sterile draping. The fluoroscope's imaging projector was positioned such that the L2 and L3 vertebrae were easily visualized. Under the guidance of C-arm X- ray device, patients were placed in a prone position. The middle and lower one-third of the L2 vertebra, and the middle and upper one-third of the L3 vertebra were identified to determine the puncture point, and the distance from puncture needle to the front edge of the L2 and L3 vertebra. The needle was aimed towards the anterior aspect of the vertebral bodies of L2 or L3. The needle was placed coaxially to the fluoroscopy beam. Once the trajectory had been confirmed, the c-arm was returned to an anteroposterior view. (Abramov, 2014)

The needle was walked along the vertebral body to ensure correct placement. It was then adjusted so that it was three to five mm dorsal to the most ventral portion of the vertebral body. Once in the correct position, contrast was injected. The needle was inserted at the puncture point and was stopped, when close, to the measurement distance. C- arm x- ray device imaging was performed for a second time to adjust the puncture point to the frontal side of vertebra. After injecting the radiofrequency needle core, the sensory and motor tests were done according to following criteria: (50 Hz, 1.0 V), and (2 Hz, 1.0 V), electrical stimulation, respectively.(Zhu, et al., 2008)

Consequently, 2% lidocaine (1ml) was injected; the lower limbs became warm after 5 min. Continuous radiofrequency thermocoagulation was conducted to gradually increase the temperature; the radio-frequency temperature was 70°, 75°, and 80°C, respectively. Radiofrequency time was 180 s for each temperature, and each site was subjected to radiofrequency thermocoagulation twice. The needle was withdrawn for 5 mm to test the motor and sensory response for a second time.(Soloman, et al., 2010) In addition, the wound was debrided to ensure early recovery of the injured site.

The blood pressure, heart rate, rhythm, and most importantly affected limb temperature, using skin thermometer (pre- and post-block), during lumbar sympathetic block (LSB), was monitored. A rise in temperature indicated that the lumbar sympathetic block was successful. Radiofrequency thermocoagulation lumbar sympathectomy targets unmyelinated nerve fibres (C-axis axons); which in turn dissolves and become necrotic due to high temperature, and in turn maintains a state of vasodilatation in lower extremities, and hence there is an increase in blood flow.

Size of the ulcer was assessed at the beginning of the study and on days 10, 20 and 30 by measuring the wound areas over a transparency sheet. Pain scoring was achieved through VAS (0-no pain; 10-unbearable pain).

### Statistical Analysis

The data was analysed by SPSS 20.00 (Statistical Package for Social Sciences, IBM Inc., Chicago, IL, USA) package program. Continuous data was presented as mean  $\pm$  SD and categorical variables, represented using percentages. Comparative reduction in wound size was assessed through Friedman's ANOVA. Difference in pain score, hospital stay, and walking distance were evaluated using Wilcoxon matched pair test, Unpaired t-test, and Paired t-test.  $P < 0.05$  was considered significant.

## 3. Results

Total 63 participants, male predominance was observed in the study (n=40). The mean age of the study participants was 60.93 SD 14.34 years. On admission, patients were suffering from the complaint for 30 days (n=21), followed by suffering from the complaint for 60 & 90 days (n=12), respectively. In most of the cases mode size of the ulcer was  $>5 \times 5$  cm (n= 39), with equal distribution of foot side affected, with the ability to walk 100-200 m (n=33), with a pain score between 5-8 (n=58) (Table I).

**Table I:**  
Demographic distribution of the participants

Variable	n (%)
<b>Gender</b>	
Male	40 (63.49)
Female	23 (36.51)
<b>Duration of complaint (days)</b>	
15	7 (11.11)
30	21 (33.33)
60	12 (19.05)
90	12 (19.05)
120	7 (11.11)
150	2 (3.17)
180	2 (3.17)
<b>Foot affected</b>	
Left foot	30 (47.62)
Right foot	33 (52.38)
<b>Size of the ulcer (cm)</b>	
$<5 \times 5$	24 (38.10)
$>5 \times 5$	39 (61.90)

Variable	n (%)
<b>Pre-procedure walking distance (m)</b>	
<100	27 (42.86)
100-200	33 (52.38)
>200	3 (4.76)
<b>Pre-procedure pain score</b>	
0-5	5 (7.94)
5-8	58 (92.06)

Grading of the ulcer by Fontaine’s classification demonstrated grade 1 (n=19), grade 2 (n=24), and grade 3 (n=20).

The size of the ulcer influenced the number of radiofrequency ablation sessions received: mean sizes (cm) of 31.44, 58.9, and 100 received 1,2, and 3 sessions, respectively. Mean ulcer size in grading 1 was 22.63 with C.I range being 21.35-23.92, grading 2 was 33.54 with C.I range being 31.99-35.37, and grading 3 was 59.47 with C.I range being 51.94-60.21. Significant association was observed with Grading 2 (P=0.026), Grading 3 (P=1.35 e<sup>-05</sup>) and ulcer size as tested using multiple linear regression. Other demographic variables such as age and gender were not associated with ulcer size.

**Figure 2.**

Wound healing at different time intervals and Reduction in wound size



Continuous significant improvement in healing of ischemic ulcers was noticed, as observed by wound closure (P<0.001) and reduced size (P<0.0001) (Figure 2, Table II). Post 30 days, complete, partial and no improvement was observed in 28, 22 and 4 cases, respectively.

**Table II:**

Wound size at different time intervals

Time Interval	Wound size (cm <sup>2</sup> )	
	Mean ± SD	P value <sup>¥</sup>
Admission time	35.19±23.0210	-
Day 10	23.61±20.349	<0.001*
Day 20	10.81±14.924.	<0.001*
Day 30	4.52±10.368	<0.001*

¥ANOVA, \*Significant

Mean pain score reduced from 7.08 to 0.86 post procedure at 5% level of significance using Wilcoxon’s paired t-test (P<0.001). Mean walking distance significantly improved from 107.2±46 m

to >250 m ( $P < 0.001$ ). Average hospital stay was significantly reduced from 55.8 days (from previously available patient data of hospital stay) to 19.2 days, ( $P < 0.0001$ ).

#### 4. Discussion:

Radio frequency ablation technique, though having its beginnings in neurosurgery with the work of Sweet and Cosman, has today found far wider application in peripheral pain therapy, chronic wounds or/ ischaemia etc.(Cosman, et al., 1984; Mehraj, 2018) This study focused on evaluating the efficacy of radiofrequency ablation for lumbar sympathetic blockade in healing of lower limb ulcers. And also, it is one of the first kind of a report to assess the efficacy of the RFA in lumbar sympathetic blockade in lower limb ischemic ulcers in an Indian population.

Mean age of the patients were  $60.93 \pm 14.34$  years. Similar finding was seen in a study conducted by Tamura K et al.(Tamura, et al., 2019) It can be attributed to associated comorbid conditions in elderly population that may contribute to the development of the ulcers.(Labropoulos, 2009)

Male preponderance was seen in the present study. In contrast to findings of the study done by Tamura K et al.(Tamura, et al., 2019) The difference seen can be attributed to geographical variation of non-communicable disease and the associated lifestyle factors such as smoking.(Morimoto, et al., 2010; Statista Research Department, 2020)

After RFA of lumbar sympathetic ganglia, ischemic ulcers of lower limb showed significant reduction in the wound size ( $P < 0.001$ ). Similar finding was seen in previous literature.(Cosman, et al., 1984) It can be explained by the fact that radio frequency waves acts on connective tissue and in turn breaks the collagen triple-helix junctions.(Luebke et al., 2008; Gloviczki et al., 2011; Madrid et al., 2012)

The complete closure of the wound was observed on the 30th day. Similar observation was seen in a study done by Destegül et al.(Destegül et al., 2017) It point towards the efficacy of radiofrequency ablation in lower limb ischemia.

Mean pain score reduced post procedure, ( $P < 0.001$ ). Similar finding was seen in the previous study. (Madrid et al., 2012) It can be attributed to LSG excision or ablation can block the pain stimulus conducting to central nervous system through nerve fibres and can also relieve vascular spasm in lower extremities.(Destegül et al., 2017)

The average hospital stay was significantly reduced, and mean walking distance increased, post procedure, ( $P < 0.0001$ ). It points towards better quality of life in the patients suffering from lower limb ischemic ulcers.(Madrid et al., 2012)

However, further multi-centric studies in a larger sample size with long term follow up is required to conclude the efficacy of RFA on lower limb ischemic ulcers. Further limitation of the study can be aetiology of ischaemic ulcers were not assessed, and as diabetes patients were not excluded it can act as a confounding factor.

#### 5. Conclusion

RFA of lumbar sympathetic ganglia is an effective treatment modality for lower limb ischemic ulcers, as it leads to faster wound healing and better pain management.

## 6. Funding:

None

## 7. Conflicts of interest/Competing interests:

None to declare.

## 8. Ethics approval:

Institutional ethical clearance from D.Y. Patil Medical College Kolhapur (DMCK/112/2017, 27/12/2017)

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## RESUMEN

Antecedentes: La simpatectomía lumbar a través de la ablación por radiofrecuencia es un tratamiento útil de la isquemia periférica. Sin embargo, la eficacia clínica con respecto a las úlceras en las extremidades inferiores no está adecuadamente establecida en la población india. El estudio se llevó a cabo para evaluar el papel de la ablación por radiofrecuencia (RFA) de los ganglios simpáticos lumbares en la curación de las úlceras isquémicas de la extremidad inferior.



**Método:** El estudio prospectivo con 63 pacientes registrados en el departamento de cirugía general con úlceras isquémicas de las extremidades inferiores entre diciembre de 2017 y julio de 2019 fueron tratados con RFA. Los pacientes con enfermedad cardiopulmonar, malformación embarazada, congénita o infección de la piel en el lugar de la intervención, o que sufren de trastornos hemorrágicos, fueron excluidos del estudio. Se realizó una investigación clínica de la herida y se recopilaron datos demográficos. La reducción comparativa en el tamaño de la herida se evaluó a través del ANOVA de Friedman ( $P<0.001$ ).

**Resultado:** La diferencia en la puntuación del dolor, la estancia en el hospital y la distancia a pie se evaluaron mediante la prueba de par coincidente de Wilcoxon ( $P<0.001$ ), la prueba t no emparejada y la prueba t emparejada ( $P<0.05$ ). La mayoría de los pacientes eran varones (n-40) con una edad media de 60,93 SD14,34 años. Se observó una reducción significativa en el tamaño de la herida, las puntuaciones de dolor y la estancia hospitalaria ( $P<0.001$ ). El número de sesiones de RFA se asoció significativamente con el tamaño de la úlcera y las clasificaciones 2 y 3 de Fontaine ( $P<0.0001$ ).

**Conclusión:** LA RFA de los ganglios simpáticos lumbares puede constituir una opción terapéutica para las úlceras isquémicas de las extremidades inferiores.

**Palabras Clave:** Úlceras Isquémicas; Ablación por Radiofrecuencia; Ganglio simpatico; Extremidad Inferior.

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