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# Comparison of long-term efficacy of lumbar sympathetic interventions in peripheral artery disease

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## ABSTRACT

**Objectives:** The aim of this study is comparing the effectiveness of non-surgical interventional methods in peripheral vascular disease.

**Patients and methods:** The results of patients who underwent interventional procedures due to Fontaine stage 2-3 peripheral vascular disease in the algology clinic between June 2016 and December 2023 were evaluated. The numeric rating scale (NRS) scores were recorded before the procedure, at 1st month, 6th month and 12th month follow-ups after the procedure. The developing side effects and complications were evaluated.

**Results:** Thirty-five patients were evaluated in the chemical neurolysis (CN), 32 patients in the radiofrequency thermocoagulation (RFT), 28 patients in the continuous epidural block (CEB), 34 patients in the combined CN and RFT, 38 patients in the combined CN+CEB group. In all groups, NRS scores were significantly lower at 1st and 6th months after the procedure compared to before the procedure ($p<0.001$, $p<0.001$, $p<0.001$, $p<0.001$, $p<0.001$, respectively). In the combined CN+RFT group, NRS scores were significantly lower at 12th month compared to before the procedure. Catheter migration was observed in 2 patients, but no major complications were recorded.

**Conclusion:** Combined CN and RFT treatment applied to the sympathetic chain in peripheral vascular disease is an effective and safe method in long-term follow-up.

**Keywords:** Peripheral arterial ischemia, chemical neurolysis, radiofrequency ablation, continue epidural block.

Ischemic pain is the main symptom of diseases such as peripheral arterial disease and Raynaud phenomenon, which result in inadequate blood flow to the extremities and ischemia.[1] The effective treatment options in critical extremity ischemia are revascularization, bypass, endarterectomy, and endovascular treatments.[2] Surgical sympathectomy is another option for the treatment of ischemic pain and non-healing ulcers.[3] Lumbar sympathectomy is indicated for the treatment of critical extremity ischemia, Buerger disease, thromboembolic events, diabetic ulcers, and diabetic neuropathic pain. Surgical sympathectomy causes too much trauma and tissue damage. Neurolysis of the lumbar sympathetic ganglion is a safe and effective method compared to invasive surgical procedures.[4] Lumbar sympathetic ganglias are located in the paravertebral region from L2 to L5. Lumbar sympathetic ganglia block pruduce vasodilatationby the denervation of sympathetic fibers of the lower extremities. Sympathetic denervation causes increased blood flow and improved circulation. Thermal neurolysis or chemical neurolysis (CN) of the lumbar sympathetic ganglia withh radiofrequency thermocoagulation (RFT) is a safe and effective option.[5] There are reports in the literature onusingg combined methods, but there are very few studies. In this study, we aimedto compareg the effectiveness of the methods we applied in peripheral arterial disease (CN, RFT, continuous epidural block [CEB]) and their combinations.

## PATIENTS AND METHODS

### Ethics, Permission

Our study is a retrospective design based on the collection of data by reviewing the retrospective files. Declaration of Helsinki principles were followed in the study. Approval of the Aydın Adnan Menderes University's Ethics Committee was obtained (approval no: 2024/118,

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date: 10.06.2024). Human ethics and participation approval was obtained from all patients. Written informed consent forms were obtained from all patients.

### Patient Selection

The follow-up data of all patients who underwent CN, RFT and CEB and their combinations to the lumbar sympathetic ganglion due to peripheral arterial disease between May 2016 and December 2023 will be examined.

### Inclusion Criteria

Patients with Peripheral arterial disease who were Fontaine stage 2-3, who were not suitable for revascularization surgery, endovascular treatments or who were unresponsive to endovascular treatments were included in the study.

### Exclusion Criteria

Local infection, pacemaker, mental retardation, coagulopathy, pregnancy, severe liver and kidney dysfunction.

Fontaine stage 1 (asymptomatic patients) was excluded from the study because it would present diagnostic difficulties, and Fontaine stage 4 patients were excluded because the effectiveness of interventional procedures in the advanced stage would not be sufficient.

### Patient Evaluation

Patients' demographic and clinical examination findings at admission (gender, age, pain character, neurological examination, Fontaine staging, medications used), NRS scores were recorded.

The patients evaluated for pain intensity with NRS scores (0: No pain; 10: Worst pain).[6]

Patients were staged for peripheral arterial ischemia with Fontaine classification (asymptomatic: Stage I, claudication: Stage II, rest pain: Stage III, ulcers/gangrene, Stage IV).[7]

NRS pain scores, clinical and neurological examination, and developing complication findings will be recorded at the first month follow-up after the procedure. At the end of the 6 and 12 months follow-up, the patients' NRS pain scores were evaluated for developing side effects and complications.

### Procedure

The patient was placed in a sterile operating room and the possible lumbar sympathetic ganglion located at the L2 and L4 levels under fluoroscopy guidance in the prone position. Local anesthesia was provided with 2% lidocaine. For CN, the anterior vertebral body was targeted with a 15 cm long 21 gauge Chiba needle. The needle's depth in the lateral, anterior-posterior position was confirmed with fluoroscopy (Figure 1a, b). After confirmation with radiopaque material, 5 mL of a mixture of 0.25% bupivacaine and 6% phenol was applied for each level. For RFT, the anterior part of the L2 and L4 vertebral body was targeted with a 10x10 mm long 10 mm active tip radiofrequency cannula. The depth of the cannula in the lateral, anterior-posterior position was confirmed with fluoroscopy. The final localization of the cannula was tested with radiopaque material after 50 Hz sensory and 2 Hz motor stimuli. After 5 cc of 0.24% bupivacaine was administered, conventional RFT was performed at 85 degrees and 90 seconds. For CEB, an epidural catheter was inserted and fixed using the paramedian interlaminar approach and loss of resistance method (Figure 1c, d). 100 mg of 2% lidocaine was administered through the epidural catheter 4 times a day for 5 days.

### Statistical Analysis

SPSS 21.0 statistics program was used to analyze the data of the study. Descriptive analyses were studied using number (n), mean, standard deviation, median, minimum, maximum. Parametric properties of continuous variables in independent groups were studied with Student's t-test. Comparing non-parametric properties of continuous variables in independent groups were studied with Mann-Whitney U test. Continuous variables to normal distribution was investigated with Kolmogorov-Smirnov test. Comparing non-parametric properties of continuous variables in dependent groups were studied with Wilcoxon test. Chi-square test was used to show whether there was a difference between categorical variables in the study. P-value was determined as less than 0.05 to indicate statistical significance.

## RESULTS

The clinical and demographic characteristics of the patients are presented in Table 1. Thirty-five patients were evaluated in the CN, 32 patients in the RFT, 28 patients in the CEB, 34 patients in the combined

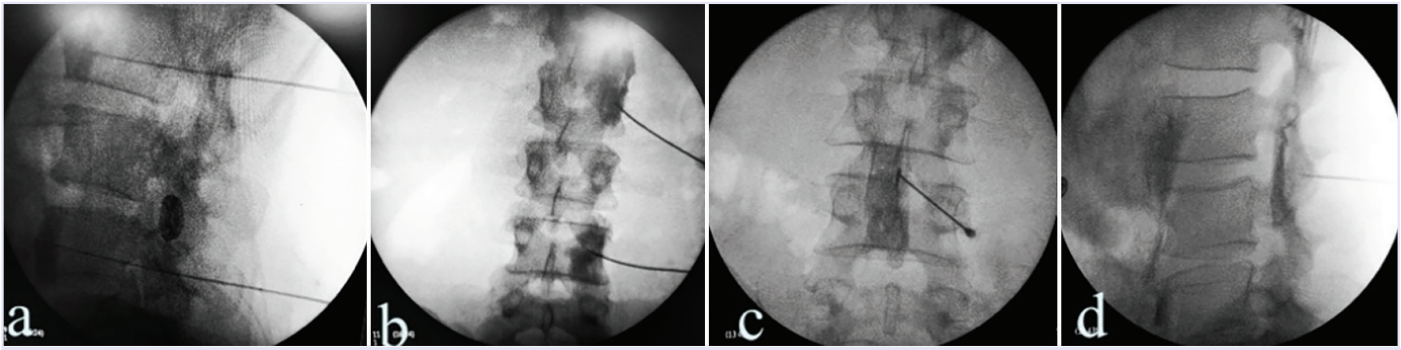


**Figure 1.** a) Fluoroscopic demonstration of opaque spread in the lateral plane of the needle/cannula placed anterior to the L2 and L4 vertebrae; b) Fluoroscopic demonstration of opaque spread in the anterior-posterior plane of the needle/cannula placed anterior to the L2 and L4 vertebrae; c) Image of epidural catheter placement with the interlaminar method using the paramedian approach from the L3 level and demonstration of contrast medium spread; d) Demonstration of contrast medium spread in the anterior vertebrae and posterior epidural space in combined CEB and CN application.
*CEB: Continuous epidural block; CN: Chemical neurolysis.*

CN+RFT, 38 patients in the combined CN+CEB group. In all groups, NRS scores were significantly lower at 1st month and 6th month after the procedure compared to before the procedure (p<0.001, p<0.001, p<0.001, p<0.001, p<0.001, respectively) (Table 2).

NRS scores were significantly lower at 12th month in the combined (CN+RFT) group compared to before the procedure (Table 2). Catheter migration was observed in 2 patients, and no major complication was recorded.

**Table 1.** Comparison of demographic and clinical characteristics of the groups

| | | CN | RFT | CEB | CN+RFT | CN+CEB | p |
|---|---|---|---|---|---|---|---|
| **Gender** (n) | **Female** | 8 | 10 | 11 | 10 | 12 | 0.06 |
| | **Male** | 27 | 22 | 17 | 24 | 26 | |
| **Age** (mean ± SD) | | 58.3±5.6 | 56.7±3.3 | 51.8±9.6 | 62.2±7.2 | 59.8±4.5 | 0.21* |
| **Symptom duration** (year) | | 4.8±2.2 | 6.3±1.5 | 7.2±1.4 | 5.4±2.3 | 6.5±3.1 | 0.07 |
| **Fontaine stage** (n) | **2** | 17 | 14 | 15 | 19 | 20 | 0.2 |
| | **3** | 18 | 18 | 13 | 15 | 18 | |
| **NRS 0** (mean ± SD) | | 7.1±0.9 | 8.3±0.4 | 7.9±1.6 | 8.4±0.7 | 8.2±1.3 | 0.3** |
| **Drugs** (n) | **Gabapentinoid** | 14 | 13 | 11 | 10 | 17 | 0.1 |
| | **SNRI** | 3 | 2 | 6 | 8 | 5 | |
| | **Opioid** | 10 | 10 | 12 | 9 | 11 | |
| | **TCA** | 10 | 7 | 11 | 7 | 10 | |
| | **Anticonvulsant** | 7 | 4 | 4 | 6 | 4 | |

*: Parametric test; **: Non-parametric test; SD: Standard deviation; SNRI: Serotonin-neuradrenaline reuptake inhibitor; TCA: Tricyclic antidepressants; NRS: Numeric rating scale; CEB: Continuous epidural block; CN: Chemical neurolysis; RFT: Radiofrequency thermocoagulation.

**Table 2.** Comparison of pre-procedure NRS scores with post-procedure scores at 1, 6, 12 months

| | | NRS 0 | NRS 1 | NRS 6 | NRS 12 | p |
|---|---|---|---|---|---|---|
| **CN** | **Mean** | 7.8 | 3.5 | 4 | 7.2 | **<0.001**[1,2] |
| | **SD** | 0.8 | 1.3 | 1.5 | 0.9 | |
| | **Median** | 8 | 3 | 4 | 8 | |
| | **Minimum** | 6 | 2 | 1 | 5 | |
| | **Maximum** | 9 | 8 | 8 | 8 | |
| **RFT** | **Mean** | 8 | 3.7 | 3.3 | 7.7 | **<0.001**[1,2] |
| | **SD** | 1.1 | 1.9 | 1.3 | 1.3 | |
| | **Median** | 8 | 3.8 | 3.1 | 7 | |
| | **Minimum** | 6 | 1 | 1 | 6 | |
| | **Maximum** | 10 | 8 | 7 | 8 | |
| **CEB** | **Mean** | 7.6 | 3.6 | 4.3 | 7.5 | **<0.001**[1,2] |
| | **SD** | 0.8 | 1.2 | 1.5 | 0.9 | |
| | **Median** | 8 | 3 | 4 | 7 | |
| | **Minimum** | 7 | 2 | 1 | 6 | |
| | **Maximum** | 9 | 8 | 8 | 8 | |
| **CN+RFT** | **Mean** | 8 | 3.7 | 3.3 | 3.8 | **<0.001**[1,2,3] |
| | **SD** | 1.2 | 1.9 | 1.1 | 1.8 | |
| | **Median** | 7 | 4 | 3 | 4 | |
| | **Minimum** | 6 | 2 | 1 | 1 | |
| | **Maximum** | 10 | 9 | 6 | 8 | |
| **CN+CEB** | **Mean** | 8.3 | 3.2 | 3.6 | 7.2 | **<0.001**[1,2] |
| | **SD** | 1.1 | 1.7 | 1.2 | 1.1 | |
| | **Median** | 8 | 4 | 3 | 4 | |
| | **Minimum** | 6 | 2 | 2 | 1 | |
| | **Maximum** | 10 | 8 | 6 | 8 | |

[1]: There is a statistically significant difference between NRS 0 and NRS 1st month; [2]: There is a statistically significant difference between NRS 0 and NRS 6 months; [3]: There is a statistically significant difference between NRS 0 and NRS 12 months; SD: Standard deviation; NRS: Numeric rating scale; CEB: Continuous epidural block; CN: Chemical neurolysis; RFT: Radiofrequency thermocoagulation.

## DISCUSSION

Peripheral artery disease is an important health problem that results in disability due to the increasing frequency of amputations. Early diagnosis of patients, especially in the early-mid stage, and treatment directed at the pathogenesis of the disease can be protective against amputation. For this purpose, applying chemical thermal denervation to the sympathetic chains as a minimally invasive method will increase extremity blood circulation with peripheral vasodilator activity. In this direction, there are many studies investigating the effectiveness of methods such as CN, RFT, and CEB applied to the sympathetic chain.[8-12]

RFT is a known method of effectiveness. However, the number and location of the lumbar sympathetic ganglia vary greatly. This may cause the degree of ablation to be insufficient for nerve ablation by being affected by temperature and location.[13]

Sympathetic nerve resection is achieved by damaging the lumbar sympathetic nerve through CN. Blood vessels dilate, peripheral vascular resistance decreases, collateral circulation increases, and skin and muscle blood perfusion in the lower extremities increases.[14] However, the duration of neurolysis effects is relatively short and symptoms usually recur within 3-6 months. CEB; it is a repeatable and effective analgesic method applied by continuously blocking the somatic and sympathetic nerve fibers located in the epidural. Its effectiveness depends on the duration of blockade and is evident in the short-term. In the long-term, its effectiveness decreases due to common reasons such as catheter migration and can be limited to a chronic persistent pain syndrome such as ischemic pain alone.

Although these methods are effective when applied alone, they are short-term. The effectiveness of combination treatments has not been sufficiently investigated. In our study, we examined 167 patients who underwent fluoroscopy-guided interventions due to peripheral artery disease in 5 groups to evaluate the results. We compared the effectiveness of combined interventional treatments and single applications. We found that pain scores were significantly lower in the combined CN+RFT group compared to the other groups at the 12$^{th}$ month follow-up. Ding et al.,[15] who conducted a study with 90 diabetic peripheral artery patients with a similar design to our study, found combined RFT and CN treatment under CT guidance to be effective and safe compared to single applications at the 1-year follow-up. They found the total remission period to be significantly higher in the combined treatment. This study also found combination interventional treatments to be more effective in the long-term follow-up with similar results to our study. In our study, we performed a more comprehensive examination by including CEB application in single and combined treatments. In addition, we provided less ionizing radiation exposure compared to CT by performing the interventions under fluoroscopy. We did not record any major complications during fluoroscopy-guided interventions.

In another study, Sun et al.[16] showed that CT-guided alcohol neurolysis followed by continuous lumbar sympathetic blockade in 60 patients with refractory diabetic neuropathy provided greater benefit than sympathetic alcohol neurolysis alone in the treatment of painful diabetic neuropathy at 6-month follow-up. This study was providing clinical evidence that pain in diabetic neuropathy may be and the analgesic effects of continuous blocks were long-lasting, In this study, it was concluded that diabetic neuropathic pain is a sympathetically mediated. It is emphasized that the analgesic effects of continuous sympathetic blocks combined with CN are long-lasting.

In a case of erythromelalgia in which combined therapy was offered, the positive results of the combination of lumbar sympathetic blockade and CEB were emphasized.[17]

The role of the sympathetic nervous system in the pain of primary erythermelalgia is unclear. Several theories have been proposed, including vasoconstriction. Epidural blockade is not always effective treatment. In patients who do not respond to epidural blockade may respond to sympathetic blockade. Lumbar sympathetic ganglion block is thought to reduce pain by increasing blood flow to the extremities and by blocking C and Aδ fibers in dorsal root and sympathetic ganglion neurons. Therefore, it has been assumed that the combination of CEB with lumbar sympathetic ganglion block is an effective treatment option for permenant erythromelalgia.

Although CN, RFT and CEB methods provide short-term pain control when applied alone in sympathetic or ischemic pain, we believe that combination treatments are effective in long-term pain relief. Current studies in interventional pain treatments highlight the importance of combining several effective methods to achieve long-term pain control. In this study, we combined both epidural and peripheral ganglion blocks to provide more effective and long-lasting sympathetic blockade. We also chose to combine both known destruction methods: Neurolysis and ablation. We believe that combining these interventional techniques will yield more effective results by targeting multiple pathophysiological mechanisms without creating safety vulnerabilities.

We believe that our study will contribute to the literature by emphasizing the effectiveness of combined methods. However, the limitation of our study is that it is a retrospective design. Prospective studies will shed light on our current findings. Homogeneity and inadequate within-group pain assessment analyses are another limitations of the study. The use of clinical scoring systems in evaluating results is among the recurring production limitations.

In conclusion, the combined application of methods such as RFT, CN and CEB, which are known to be effective in ischemic pain, is more effective in long-term pain relief. Combined interventional procedures are both effective and safe when performed under fluoroscopic guidance under optimum conditions with appropriate patient selection.

### Ethics

**Ethics Committee Approval:** Approval of the Aydın Adnan Menderes University's Ethics Committee was obtained (approval no: 2024/118, date: 10.06.2024).

**Informed Consent:** Written informed consent forms were obtained from all patients.

### Footnotes

### Authorship Contributions

Surgical and Medical Practices: E.E.; Concept: E.E., D.E.; Design: E.E., D.E.; Data Collection or Processing: E.E., D.E.; Analysis or Interpretation: E.E., D.E.; Literature Search: D.E.; Writing: E.E.

**Conflict of Interest:** No conflict of interest was declared by the authors.

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