

Effect of radiofrequency ablation with chemical neurolysis of lumbar sympathetic ganglion in ischemic limb pain with diabetes mellitus: a randomized control trial

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ABSTRACT

Background: Ischemic limb of peripheral arterial disease with diabetes is a worse comorbid condition affecting the lower limb. The debilitating presentation of ischemic limb include pain, ulceration, impaired ulcer healing which leads to amputation of lower limb. Its treatment includes pharmacological approaches, glycemic control, lumbar sympathectomy, endovascular therapy, revascularization. The minimally interventional treatment strategy includes lumbar sympathectomy by radiofrequency ablation with chemical neurolysis. Our objective is to evaluate the effect of lumbar sympathectomy.

Methods: This randomized clinical trial was conducted at the department of Anesthesiology SICU & Pain Medicine, BIRDEM General Hospital. Before commencement of the study formal ethical clearance and informed consent was taken. Diagnosis of ischemic limb was made on clinical grounds and colour doppler study. Total 52 diabetic patients with ischemic limb were included in this study and randomly divided into two groups (26 patients in each group). Total 26 patients (control group) received conservative treatment (group-A) and 26 patients received radiofrequency ablation with chemical neurolysis of lumbar sympathetic ganglion (group-B). Data obtained were improvement in rest pain (visual analog scale), temperature, capillary refill time, progression of ulcer healing, reduction in dose of drugs, need of debridement or amputation was measured at 0 day, 1st week, 2nd week, 1st month and 3rd month. Following data collection, data were analyzed by the SPSS 24.

Results: Demographic characteristics were similar across the two groups in terms of age, sex, site of the procedure ($p > 0.05$ in all cases). Pain intensity observed in immediately after procedure, 1st, 2nd week, 1st & 3rd month. Improvement in rest pain significantly decreased in group B compared to group A ($p < 0.001$). Mean VAS at 3rd month was 0.7 in group B. Mean capillary refill time decreased in group B to 3.3 sec in comparison to another group ($p < 0.001$). Post treatment increase in skin temperature was significant in group B ($p < 0.001$), mean increase was 1.9°C. Dose of amitriptyline, tramadol, pregabalin and paracetamol significantly decreased in group B compared to group A ($p < 0.001$). Line of demarcation appeared in 80% participants within 3 months in group B and need for post treatment amputation reduced in group B significantly in comparison to group A ($p = 0.008$).

Conclusion: Radiofrequency ablation with chemical neurolysis of lumbar sympathetic ganglion is a potential treatment modality for lower limb ischemia.

Key words: Radiofrequency Ablation, Chemical Neurolysis, Lumbar Sympathetic Ganglion, Ischemic Limb, Diabetes Mellitus, Randomized Controlled Trial.

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INTRODUCTION

Peripheral arterial disease (PAD) of lower extremities is a chronic, occlusive, progressive disease caused by atherosclerosis.¹ It comprises of a wide clinical spectrum of asymptomatic, individuals with exercise limitations and intermittent claudication (IC) at one end and those with critical limb ischaemia at the severe end of the spectrum.² Chronic limb-threatening ischemia (CLTI) is a clinical syndrome defined by the presence of peripheral arterial disease with rest pain, lower limb ulceration or gangrene lasting more than 2 weeks.³

Diabetes as an emerging epidemic has chronic complications. Microvascular which includes neuropathy, nephropathy, and retinopathy, while macrovascular complications consist of cardiovascular disease, stroke, and peripheral arterial disease (PAD). Approximately 30-50% of patients with diabetes developed neuropathic pain.⁴ Patients with diabetic foot ulcers have coexisting PAD of approximately about 50% and suffer from ischemic pain.⁵ Painful diabetic neuropathy and CLTI shows some significant difference.⁶⁻⁸

Chronic ischemic pain is the most common cause of pain in the lower extremities.⁹ Ischemic pain caused by CLTI has a significant neuropathic component.^{10,11} The pathophysiology of ischemic pain still not clear but proposed mechanisms are like hemodynamic abnormalities, oxidative stress and changes in skeletal muscle metabolism.¹² Patients with CLTI also present reduction in arterial perfusion in the affected limb which leads to the accumulation of metabolites, increased acidity in the ischemic tissue and central sensitization.¹³ Chronic ischemic pain in CLTI usually cover from nociceptive pain in patients with intermittent claudication to predominantly neuropathic pain.^{11,14}

The treatment of CLTI in diabetic patients is a topic of discussion in the last few years, and most guidelines referred to general consensus or native experience. Pain management is important to improve quality of life. Patients with CLTI, the main treatment is revascularization by percutaneous transluminal angioplasty or surgical bypass. Due to unfavorable vascular involvement or high surgical risk one-third of patients are not suitable for revascularization.¹⁵⁻¹⁷ Even after surgery, the long-term prognosis is poor. The postoperative restenosis rate is almost 40–60% after 1 year.¹⁸

CLTI patients identified as subjects not treatable by revascularization, medical therapy is mandatory. The current treatment regime includes pharmacological approaches – statins, antiplatelet, anticoagulant,

cilostazole, analgesic, gabapentin, glycemic control.¹⁹ Patients whose pain does not respond medical and physical therapy lumbar sympathectomy has been proposed as an alternative option for the treatment of ischemic pain.¹³

lumbar sympathectomy has a beneficial effect on subjective endpoints, such as relief of rest pain, ulcer healing, prevention of amputation. Lumbar sympathectomy is indicated for the treatment of intermittent claudication or rest pain in legs due to PAD, ischemia of Buerger's disease, chronic regional pain syndrome (CRPS) type I and II, thromboembolic phenomena, diabetic ulcers, diabetic neuropathic pain, acute herpes pain, Paget's disease of bones, hyperhidrosis, chronic pancreatitis and malignant visceral pain.²⁰ Sympathectomy of L₂-L₃ ganglia blocks the sympathetic fibers and produces vasodilatation of the lower extremities.²⁰ Sympathetic denervation increases blood flow, improves the collateral circulation and nutritive value of blood flow, thus decreases the pain.^{21,22}

Radiofrequency ablation is effective minimally invasive treatment approach of lumbar sympathetic ganglion. The unmyelinated nerve fiber C got dissolved and necrotic due to local high temperature. It causes vasodilatation, increases peripheral blood flow, improves symptoms such as numbness induced by nerve injury of lower limbs which gives long term pain relief.^{23,24} Chemical neurolytic lumbar sympathectomy is another method using alcohol or phenol in patients with diabetic lower limb ischemia.²⁴⁻²⁷ There are reports of the use of combined methods by radiofrequency ablation with chemical neurolysis in the literature but very few studies are available.^{20,28,29}

The aim of this study was to evaluate the efficacy of RFA with chemical neurolysis of lumbar sympathetic ganglion superadded with conservative treatment in comparison with conservative treatment alone in patients with ischemic limb pain with diabetes mellitus. The primary outcomes observed were improvement in VAS, temperature of the affected limb, capillary refill time, progress in the wound healing, need of debridement or amputation up to 3 months of proposed treatment.

METHODS

Study setting

This trial was conducted from July 2022 to June 2023 at the department of Anaesthesiology, Surgical ICU & Pain

Medicine, BIRDEM General Hospital, Shahbagh, Dhaka, Bangladesh.

Study design

The study was designed as a prospective, randomized controlled trial.

Study population

After Institutional Review Board (IRB) (No. BIRDEM/IRB/2022/314) approval and informed written consent, a total of 52 surgical OPD and admitted diabetic patients with ischemic limb pain (rest pain), random blood sugar ≥ 10 mmol/L, with nonhealing ulcer, failed conservative treatment, PAD confirmed by color duplex study and refused or failed vascular reconstructive treatment or surgery were included in the study. Patient who refused or had Infection at the intervention site, severe cardiopulmonary disease, bleeding disorder, pregnancy was excluded from the study. All participants were randomly divided into two groups with equal number of participants in each group by lottery. Group A control group (26) received conventional conservative treatment. Group B (26) undergone RFA with CN of lumbar sympathetic ganglion along with conservative treatment. Conservative treatment was given with paracetamol, tramadol, pregabalin, amitriptyline. In group B lumbar sympathectomy was done.

Data collection

Participants were kept nil by mouth period of 6-8 hours. Intravenous access was done. Monitoring for the vitals like pulse, NIBP, ECG, SPO2 started. We followed the single needle technique of LSGB at L₃ vertebral level in prone position. Under fluoroscopy RF needles was placed at the anterolateral border of L₃ vertebra. After negative aspiration test 1ml of non ionic contrast and its spread noted under fluoroscopy. Sensory and motor testing attempted with the active RF electrode by stimulation with 50 HZ & 2 Hz with 0.5 V and 2 V respectively. The injection of test dose 2ml of 1% lignocaine was given. Rise of temperature of 1-2°C within 2-3 minutes in the affected limb measured to confirm the block effect. RF ablation with 3 lesions at L₃ level was done with 80°C for 60 sec. The final step was to inject 10 ml of 95% alcohol in a single rapid shot. Post block sensory and motor functions were checked after each block. Pre and post block VAS, temperature, capillary refill time, progression of ulcer healing/ appearance of line of demarcation, reduction in drug dose is followed up on 0 day, 1st week, 2nd week, 1st month & 3rd month. Temperature was measured in popliteal fossa to avoid the interference with

external environment temperature with temperature prob. Data entry and analysis was done using SPSS for windows version 24.0. A 'p' value less than 0.05 was considered significant. Chi-square test and unpaired t test was done to measure the level of significance.

RESULTS

Most of the participants from both groups belonged to the 60-70 years of age group. There was a male predominance in study population is observed in this study. There was no significant difference in site of ischemia in both group (p value- 0.815).

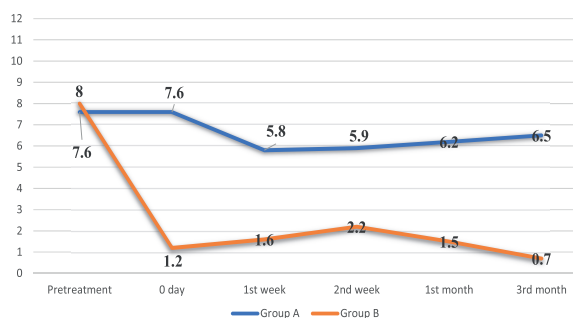


Figure 1. Pain intensity (VAS) on different follow-up (n=52).

The pain intensity (VAS) was 7.6 and 8 in group A & B respectively before intervention. There was no significant difference ($p > 0.005$). But post treatment follow up on 0 day, 1st week, 2nd week, 1st month, 3rd month shows significant reduction of VAS in group B compared to Group A. There was a slight rise of mean VAS (2.2) in 2nd week but gradually it decreased. 3rd months follow up showed highest reduction of mean VAS (0.7).

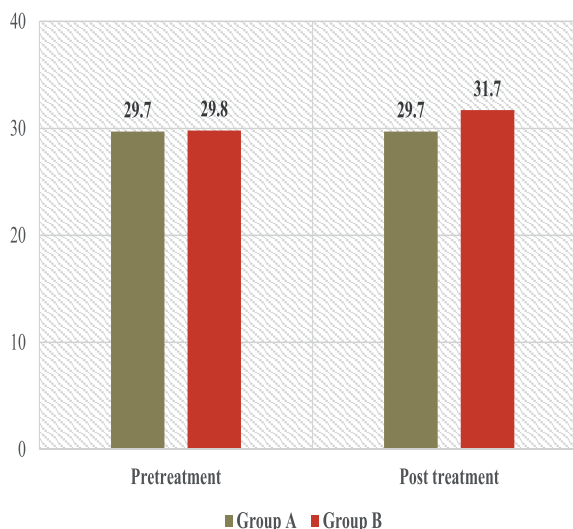


Figure 2. Temperature(°C) follow-up on 0 day

Pretreatment skin temperature in both groups showed no significant difference. But post treatment immediately after intervention temperature in group B significantly increases. Mean increase was 1.9°C in group B.

In our study pretreatment capillary refill time was 5.4 sec in group A, 6 sec in group B. Post treatment immediately after intervention capillary refill time decreased significantly in group B ($p<0.001$). Mean time was 3.3 sec in group B.

Post treatment progression of ulcer healing was significant in group B from 2nd week of follow up ($p<0.001$). Line of demarcation appeared from 1st month (Figure 5). At 3rd month 80.76 % (21) cases had line of demarcation in group B (Figure 5). On other hand 12.1% (3) cases had line of demarcation in group A (Figure 4).

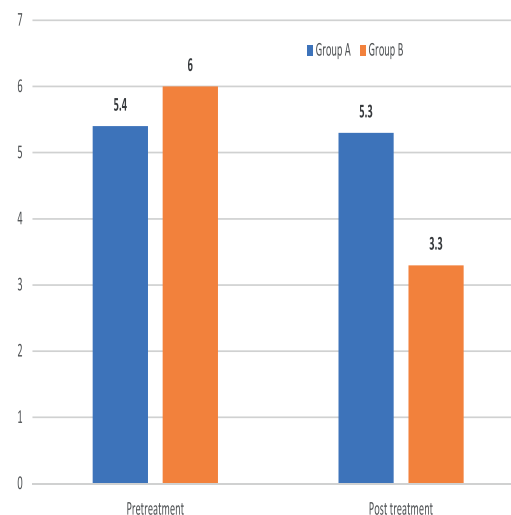


Figure 3. Mean Capillary refill time(sec) follow up on 0 day

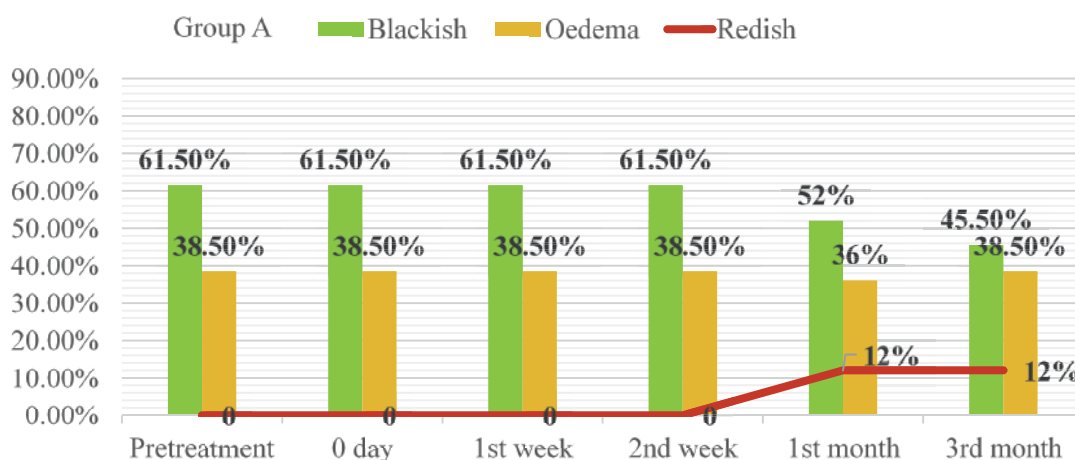


Figure 4. Progression of ulcer healing on different follow up (Group A)

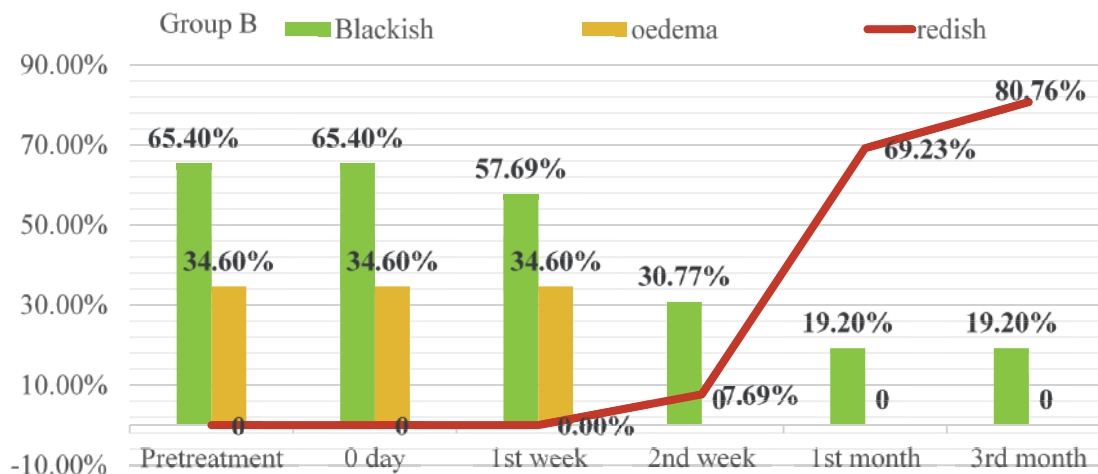


Figure 5. Progression of ulcer healing on different follow up (Group B)

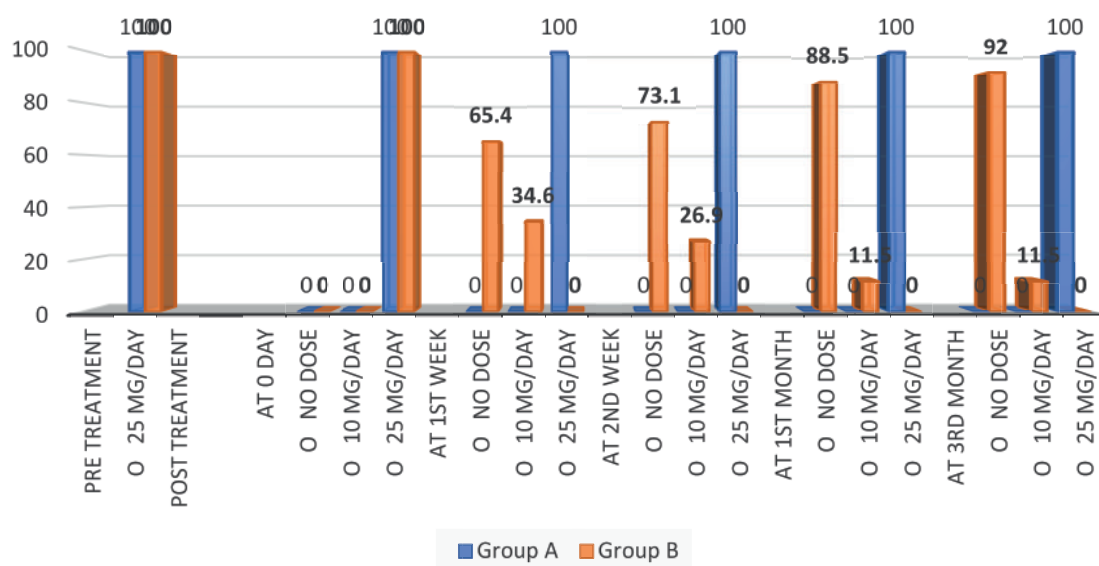


Figure 6. Dose of Amitriptyline on different follow

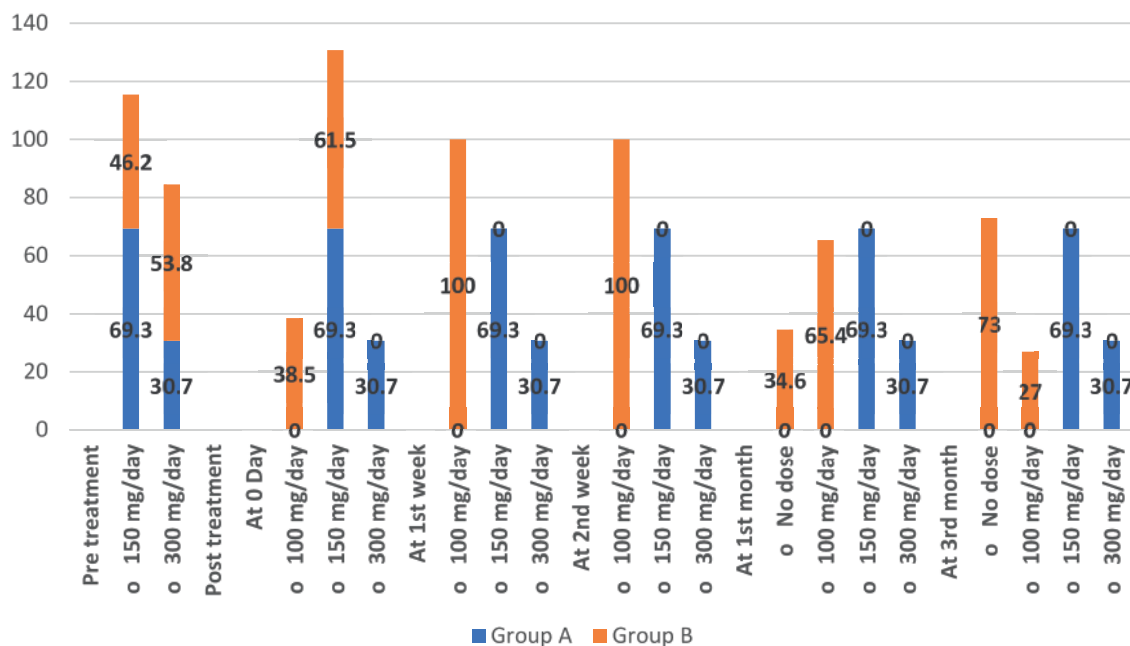


Figure 7. Dose of Pregabalin on different follow up

Dose of amitriptyline decreased in group B from 1st week to 3rd month gradually in comparison to group A. At 3rd month 92% cases were medication free where 100% in group A were having 25 mg of amitriptyline.

Dose of pregabalin decreased from 0 day to 3rd month in group B than group A ($p < 0.001$). At 3rd month 73% participants were on no medication and 27% were having

100mg/day but in group A 30.7% were having 300 mg/day and 69.3% were having 150mg/day pregabalin.

Dose of tramadol decreased from 0 day to 3rd month in group B than group A ($P < 0.001$). At 3rd month 76% participants were on no medication and 24% were having 100mg/day but in group A 80.8% were having 150 mg/day and 19.2% were having 100mg/day.

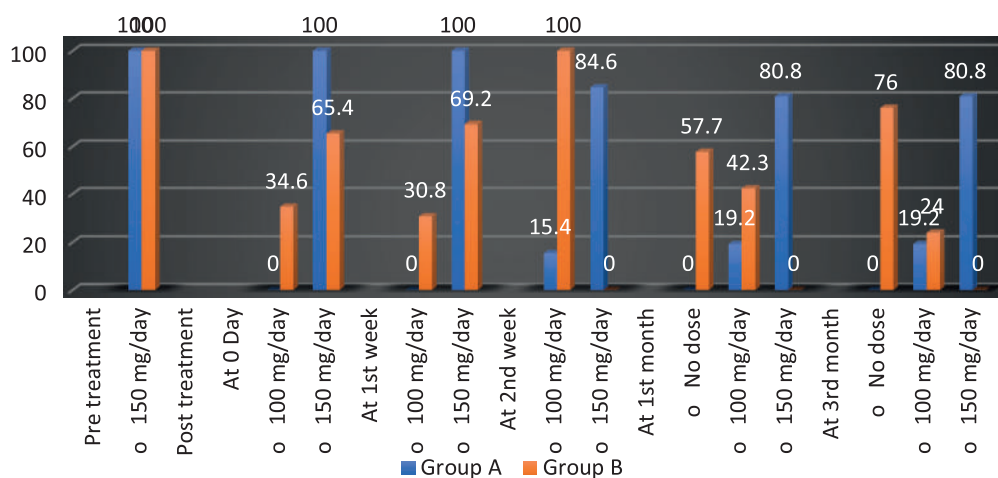


Figure 8. Dose of Tramadol on different follow up

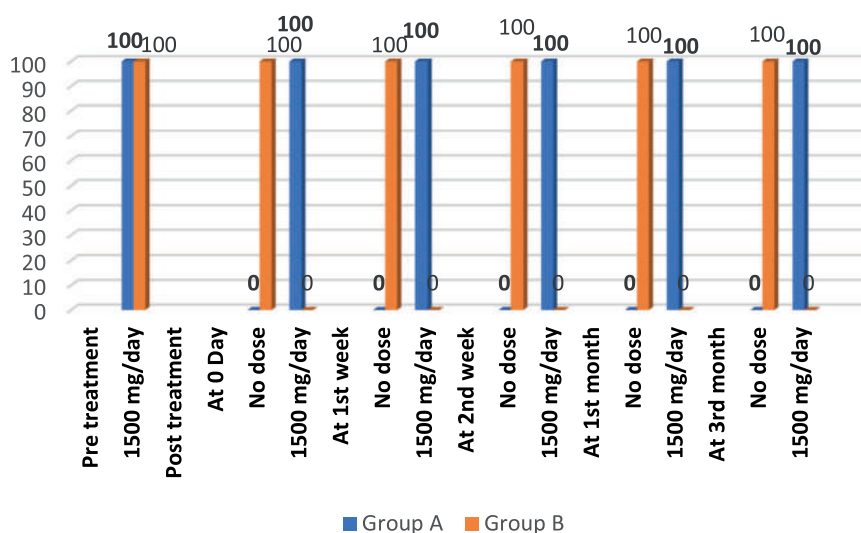


Figure 9. Dose of Paracetamol on different follow up

Paracetamol was stopped from 0 day in group B. But in group A at 3rd month 100% participants were having the medication.

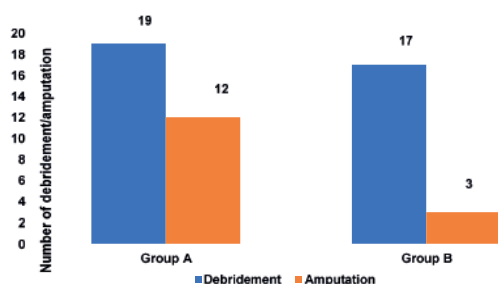


Figure 10. Number of post treatment debridement/ amputation

Post treatment follow up showed significant reduction in amputation in group B compared to group A ($p=0.008$). In group B 3 participants and in group A 12 participants needed amputation. There was no significant reduction in debridement.

DISCUSSION

Lumbar sympathectomy does not eliminate the atherosclerosis in the vessels. This only release the spasm of the main and peripheral arteries and stimulates angiogenesis which increases blood supply to the tissues of the extremities, reduces ischemia and pain. They are in a state of spasm under the influence of stimuli from the occluding vessels.³⁰

The pressure gradient above and below the occluded part increases which contribute to the development of collateral circulation and further reduces the overall peripheral resistance. It causes prolong vasodilation & reduces pain syndrome. This process is more effective in early stage. The positive effect of sympathectomy is less pronounced in the decompensated stages of the disease but it does not lose its therapeutic effect.³¹

The duration of the chemical neurolysis is relatively short, and the symptoms recur within 3–6 months.³² Location of lumbar sympathetic ganglia vary with absent division of sympathetic stem and communicating branches which causes incomplete nerve ablation. The effect of simple radiofrequency ablation of LSG is often not stable.³³

Recently combined RFA with chemical neurolysis of lumbar sympathetic ganglion is studied in PAD and diabetic patients which shows significant advantage over only RFA or chemical neurolysis.

Demographic profile in our study, we found that most of the cases in our study was from 60–70 years of age range. Male predominance was observed in our study. 17 cases had left sided lesion, 26 had right sided and 9 had bilateral limb lesion.

In the following study pretreatment VAS score was almost similar in both groups. But post block VAS significantly lower in group B at all of the post-block evaluation times when compared to the group A. Another observation found from the study, that there was a slight increase in the mean VAS in 2nd week (mean 2.2) and gradual decrease after that in group B. At 3rd month mean VAS significantly decreased in Group B (mean 0.7) compared to group A (mean 6.5). Similar type of observations also found in study by Kulkarni where mean VAS was significantly decrease in follow up over 6 month period in patients with peripheral vascular disease.²⁰ A study by Ding also shows reduce VAS score in a follow up over 1 year in painful diabetic peripheral neuropathic patient receiving combined radiofrequency ablation with chemical neurolytic lumbar sympathectomy.²⁸

In current study baseline temperature of the affected limb before treatment was mean 29.7°C in Group A, 29.8°C in Group B. Immediately after LSGB there was significant rise in temperature of the affected limb in group B (mean

rise 1.9°C) when compared with group A. This finding is similar to the study of Kulkarni in which mean rise of temperature was 1.6°C at 1st week and at six months of follow up the mean temp. 2.76° C in combined group of RFA & CN.²⁰

In our study pretreatment capillary refill time in both group is almost similar. Post treatment value in group B significantly decrease. This finding matches with study by Sun et al where post lumbar sympathectomy improvement in capillary refill time observed.³⁴

Pretreatment non healing ulcer progression in the following study shows blackening of skin of the limb 16(61.5%), 17(65.4%) & oedema in 10(38.5%), 9(34.6%) cases in group A & B respectively. Post treatment improvement was significant in group B from 2nd week in compared to group A. Appearance of line of demarcation in group B is significant. 21 participants had appearance of line of demarcation in 3rd month in group B and only 3 participants in group A. Studies by Sapkal & Kulkarni also showed improvement in blackening of skin, oedema and healing of ischemic ulcer in treatment group of combined RFA with chemical neurolysis.^{20,35}

Another important follow up in our research was significant reduction in the dose of the drug which were Amitriptyline, Pregabalin, Tramadol, Paracetamol in group B compared to group A. Paracetamol was omitted in group B from 0 day. At the end of 3rd month only 2 cases in group B and all the patients of A are on Amitriptyline medication. At the end of 3rd month only 27% were having pregabalin 100 mg and 73% were medication free in group B. In other hand in group A 30.7% having 300 mg/day and 69.3% having 150 mg/day of pregabalin. Conservative treatment dose was started from 300 mg/day. Dose of Tramadol decrease significantly from 0 day to 3rd month in group B compared to group A. 76% cases didn't need any tramadol and 26% need 100 mg/day in Group B following 3rd month. In group A 80.8% cases needed 150mg/day drug at the end of 3rd month. A study by Wu et al. also found post procedural reduction in the dose of tramadol.³⁶

We observed in our study that post treatment amputation markedly decrease in Group B than group A. Amputation was done in 12 cases in group A and 3 cases in group B. But there was no significant change in debridement. Debridement was needed in 19 cases in

group A and 17 cases in group B. Study by kulkarni also showed decrease in post block surgical intervention.²⁰

Incidence of immediate and late complications post block is minimal in group B. Immediate complications occurred like urinary retention in 1 case who had bilateral lumbar sympathectomy. Patient was managed with catheterization & resolved within 24 hours. 4 patient's complaints of burning sensation which also treated with medication and resolved.

Our overall study showed significant improvement in VAS, temperature, capillary refill time, progression in ulcer healing & reduction in dose of the drug in lumbar sympathectomy group which is better than other previous study in terms of decrease in VAS, progress in ulcer healing and reduction in amputation.²⁰ It illustrates that RFA with chemical neurolysis of lumbar sympathetic ganglion along with conservative treatment is supportive & effective treatment in patients with ischemic limb with diabetes mellitus.

Limitations

Our study had some limitations. This study was a single center study & sample size was small. Multiple center and larger sample would have helped us delineate further advantages of combined lumbar sympathectomy in ischemic pain of diabetic patient.

Conclusion

Radiofrequency ablation with chemical neurolysis of the lumbar sympathetic ganglion along with conservative treatment is minimally invasive safe procedure for ischemic limb pain in diabetic patient. It significantly alleviates the symptoms and improves the patient's degree of satisfaction. More detailed and long duration study need to be further investigated.

Authors' contribution: All authors contributed by designed the analysis, collecting data, analysis tools & writing assistance

Conflicts of interest: Nothing to declare.

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