

## AN OBSERVATIONAL STUDY TO ASSESS THE EFFECT OF XANTINOL NICOTINATE ON CHRONIC LOWER LIMB ISCHEMIA

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### Abstract

**Background:** The aim of the present study was to evaluate the role of Xantinol Nicotinate in chronic lower limb ischemia. **Materials and Methods:** The study of cases of acute and chronic limb ischemia that were admitted in Surgery Department from April 2024 to September 2024 was conducted. 20 patients were included in the study. **Result:** Out of 20 patients, 1 had a claudication distance of 100 meters at presentation, 11 had 101-500 metres, and 8 had >500 metres. Xantinol Nicotinate improves early disease with a p value of 0.001. Maximum individuals were smokers (80%), diabetics (70%), tobacco chewers (15%), hyperlipidemia (10%), and hypertension (25%). After using Xantinol Nicotinate, patients' ABPI improved. **Conclusion:** Most complained of right lower limb involvement. Early childhood claudication distance improved at 3 months. Patients who complained about medical treatment improved clinically.

## INTRODUCTION

Peripheral Vascular Disease (PVD) poses a significant issue regarding therapeutic effectiveness, particularly when surgical options are contraindicated or unfeasible in inoperable instances. Surgical interventions are essential in emergency situations for the preservation of life and limb; nevertheless, the efficacy of pharmacological treatments aimed at enhancing peripheral circulation in managing symptoms of inoperable peripheral vascular disease, in conjunction with conservative approaches, has proven disappointing. Prophylactic techniques using pharmacological agents that inhibit platelet aggregation and promote vasodilation are hypothesized to reduce thromboembolic incidents and slow the course of atherosclerosis, offering a viable method for alleviating PVD symptoms.<sup>[1]</sup> The efficacy of medications in affecting existing arteriosclerotic plaques is uncertain; nonetheless, there is conjecture about their potential to inhibit or slow plaque development and improve overall circulation.<sup>[2]</sup>

In a pilot study, Xanthinolnicotinate benefited a considerable number of patients with peripheral obliterative vascular disease that had been refractory to prior treatments.<sup>[3]</sup> Musil (1973) and others reported favorable outcomes with this preparation.<sup>[4]</sup> The risk factors for atherosclerosis in the lower extremity arteries are identical to those affecting other arterial regions and include advanced age,

male gender, diabetes mellitus, tobacco use, hypertension, and elevated cholesterol levels.<sup>[5]</sup> In another research, multivariate logistic regression analysis was used to identify the risk variables, using PVD as the dependent variable. The duration of diabetes mellitus, serum cholesterol levels, serum creatinine levels, systolic blood pressure, and ischemic heart disease had a favorable correlation with peripheral vascular disease (PVD).<sup>[6]</sup>

The incidence of PAD, both symptomatic and asymptomatic, is higher in males than in women, particularly among younger individuals. At advanced ages, little disparities occur between the genders. Furthermore, the incidence in males is higher for the more severe levels of involvement (Critical ischemia). Age is the primary indicator of PAD risk. The projected prevalence of intermittent claudication among those aged 60 to 65 years is 35%. The frequency among individuals aged 70 to 75 increases to 70%. Research indicates a more pronounced correlation between tobacco use and peripheral artery disease (PAD) compared to its link with ischemic heart disease. Furthermore, heavy smokers not only have an elevated risk for peripheral artery disease (PAD), but they also experience more severe manifestations that lead to catastrophic ischemia.<sup>[7]</sup> The cessation of smoking leads to a decreased risk of PAD; nonetheless, the risk for PAD in ex-smokers is 17 times higher than in non-smokers, while in current smokers, it is 16 times higher. The permeability of both venous

coronary bypass and prosthetic grafts is diminished in people who smoke. Smokers have higher incidence of amputations and death.<sup>[8]</sup>

The objective of this research was to assess the efficacy of Xantinol Nicotinate in chronic lower limb ischemia using Doppler ultrasound, Ankle-Brachial Pressure Index (ABPI), and clinical grading methods.

## MATERIALS AND METHODS

The study of cases of acute and chronic limb ischemia that were admitted in Surgery Department from April 2024 to September 2024 was conducted. 20 patients were included in the study.

### Inclusion criteria

- Individuals with persistent limb ischemia
- Patients of all ages and both sexes

### Exclusion criteria

- Critically sick patients who are unable to understand

- Patients unwilling to cooperate
- Patients with other life-threatening conditions

**Data collection:** The data was collected using a standardized interviewer-administered questionnaire that underwent pilot testing and refinement prior to its use in the study. Information on the patient's background, including age, race/ethnicity, income level, medical history, and current medications and supplements, was documented.

**Statistical analysis:** Collected data was analyzed using SPSS version 22. p-value and confidence interval were kept at 5% and 95%.

## RESULTS

Out of 20 patients, 1 subject had claudication distance of 100 metres at the time of presentation, 11 subjects had claudication distance of between 101-500 metres, 8 subjects had claudication distance of >500 metres.

**Table 1: Claudication distance at the time of presentation.**

Claudication Distance In Presentation (Metres)	No.	Percentage
Upto100	1	5
101-500	11	55
>500	8	40
Total	20	100

**Table 2: Analysis of claudication distance at presentation and after 3 months**

Claudication distance	Upto100m	101-500	>500 m
Atpresentation	1	11	8
After3months	0	3	17
Pvalue	2.24	1.442	0.001

The Xantinol Nicotinate is beneficial and shows positive effect in early stages of disease with a significant p value of 0.001.

**Table 3: Analysis of Risk factor in study population.**

Risk factor	Frequency	Percentage
Diabetes	14	70
Smoker	16	80
Tobaccochewing	3	15
Hyperlipidemia	2	10
Hypertension(SBP>140,DBP>90mmofHg)	5	25

Maximum subjects were smokers (80%), diabetes (70%), Tobacco chewing (15%), Hyperlipidemia (10%) andHypertension (25%).

**Table 4: Comparison ABI of left and right limb in study population at presentation and after 3 months.**

ABI	Left	Right	Left	Right
Mild(0.89-0.7)	2	3	3	11
Moderate(0.69-0.4)	3	7	1	2
Severe(0.4)	3	2	1	2

There was positive change in the ABPI of patients after taking Xantinol Nicotinate.

## DISCUSSION

Chronic limb ischemia is a kind of peripheral artery disease characterized by diminished blood flow to the extremities. Peripheral vascular disease (PVD), often referred to as peripheral artery disease (PAD), peripheral artery occlusive disease, and peripheral obliterative arteriopathy, is characterized by the constriction of arteries except those that feed the

heart or brain.<sup>[9]</sup> It is an almost pandemic disorder that may result in limb loss or even mortality. Peripheral vascular disease (PVD) presents as reduced tissue perfusion, exacerbated abruptly by pre-existing atherosclerosis and the presence of either emboli or thrombi. Atherosclerosis is the principal cause of peripheral vascular disease (PVD). The PVD is clinically critical for two primary reasons: first, individuals with PAD may encounter several complications, including

claudication, ischemic rest discomfort, ischemic ulcerations, recurrent hospitalizations, revascularizations, and limb loss. These result in diminished quality of life and elevated rates of depression.<sup>[10]</sup> Secondly, individuals with peripheral artery disease (PAD) have an elevated risk of myocardial infarction (MI), stroke, cardiovascular mortality, and an increased overall mortality rate in comparison to those without PAD.<sup>[11]</sup> Peripheral artery disease (PAD) affects 12%-14% of the general population, with prevalence rising with age, impacting up to 20% of those over 75 years old.<sup>[12]</sup> Among 20 patients, 1 individual had a claudication distance of 100 meters at presentation, 11 individuals had a claudication distance ranging from 101 to 500 meters, and 8 individuals had a claudication distance above 500 meters. Xanthinol Nicotinate is advantageous and has a good impact in the first stages of the illness, with a significant p-value of 0.001. The majority of respondents were smokers (80%), followed by those with diabetes (70%), tobacco chewers (15%), those with hyperlipidemia (10%), and those with hypertension (25%). Patients exhibited a favorable alteration in ABPI after the administration of Xanthinol Nicotinate. Xanthinol nicotinate has shown promise in a pilot study, being beneficial in a significant proportion of patients unresponsive to previous therapies for peripheral obliterative vascular disease.<sup>[13]</sup> Recent studies have demonstrated promising outcomes with this preparation,<sup>[14,15]</sup> indicating its potential as a significant therapeutic agent for tackling the problems associated with inoperable instances of PVD. The study offers significant insights into the immediate effects and side effects of Xanthinol nicotinate; nevertheless, more research with prolonged follow-up is necessary to clarify the long-term results, possible problems, and enduring advantages of this medication. Recent evidence underscores the need of evaluating individual patient profiles and customizing treatment techniques to enhance therapeutic results in the management of peripheral vascular disease.<sup>[15-17]</sup>

## CONCLUSION

The majority of patients reported experiencing involvement in their right lower leg. In the early stages of life, the research demonstrates that there is an improvement in claudication distance after three months of treatment. In the population of the study that was complaining about the medical treatment, there was a noticeable improvement in clinical outcomes.

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