



Original Research Article

EFFECTIVENESS OF CALCIUM DOBESILATE COMPARED TO PLACEBO IN CHRONIC VENOUS INSUFFICIENCY: A COMPARATIVE STUDY

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ABSTRACT

Background: Chronic venous insufficiency (CVI) refers to a condition in which the venous system fails to effectively return blood to the heart in a unidirectional manner, thereby compromising tissue drainage, temperature regulation, and overall hemodynamic balance, irrespective of body position or physical activity. Several randomized controlled trials have demonstrated the therapeutic benefits of calcium dobesilate in managing CVI. The present study aimed to evaluate and compare the efficacy of calcium dobesilate with placebo in patients diagnosed with chronic venous insufficiency.

Materials and Methods: This study was conducted in the Department of Surgery at Muzaffarnagar Medical College, Muzaffarnagar, Uttar Pradesh, India, over a period of two years from March 2020 to March 2022.

Results: A total of 150 participants were included and equally divided into two groups. One group received calcium dobesilate (500 mg) twice daily for 8 weeks, while the other group was administered a placebo. Significant improvement ($P < 0.05$) was observed in symptoms such as pain, leg heaviness, fatigue, tingling, itching, and muscle cramps in the calcium dobesilate group compared to the placebo group. Both patient-reported outcomes and investigator assessments showed better overall improvement in the treatment group.

Conclusion: Calcium dobesilate significantly alleviates symptoms in patients with clinically diagnosed CVI, irrespective of concurrent use of compression stockings.

Keywords: Calcium dobesilate, Chronic venous insufficiency, Venous disorders.

INTRODUCTION

Chronic venous insufficiency (CVI) is a common vascular disorder that causes significant discomfort and can adversely affect daily activities and quality of life. In Western countries, conditions such as varicose veins and chronic venous ulcers are estimated to account for approximately 2–3% of total healthcare expenditure. The prevalence of venous disease is considerable, with reports suggesting that it may affect up to half of the population.^[1,2]

The pathogenesis of CVI involves structural and functional changes in the venous wall along with valvular incompetence. These alterations result in impaired venous return and abnormal hemodynamics in the lower limbs. Elevated venous pressure leads to vein dilation and separation of valve leaflets,

reducing their ability to prevent retrograde blood flow. Consequently, venous stasis develops, which contributes to progressive venous dilation and disturbances in the microcirculation.^[3,4]

The severity and clinical characteristics of venous disease are commonly classified using the CEAP (Clinical, Etiological, Anatomical, and Pathophysiological) system. Clinically, patients with CVI often present with symptoms such as leg pain, heaviness, fatigue, swelling, muscle cramps, paresthesia, and a sensation of restlessness. Physical examination may reveal increased limb circumference and the presence of edema.^[5,6]

Management of CVI primarily focuses on correcting superficial venous reflux through interventions such as conventional vein surgery, endothermal ablation, or foam sclerotherapy, along with the use of

compression stockings. However, adherence to compression therapy is often limited due to difficulty in application and discomfort, particularly among elderly individuals. Additionally, many patients are reluctant to undergo surgical procedures, and recurrence or persistence of symptoms may occur even after intervention.^[7,8]

Pharmacological therapy has been explored as an adjunct or alternative approach for symptom relief and for minimizing skin changes associated with chronic venous hypertension. Calcium dobesilate is a venoactive agent known to improve endothelial function, reduce capillary permeability, and decrease blood viscosity. It is widely used in the management of venous disorders and is also indicated in conditions such as diabetic retinopathy and other microvascular diseases. Its therapeutic effects are attributed to multiple mechanisms, including inhibition of platelet aggregation, reduction of thrombus formation, improvement in red blood cell deformability, and enhancement of lymphatic drainage, thereby contributing to its anti-edematous properties.^[9,10]

The present study aims to evaluate and compare the efficacy of calcium dobesilate with placebo in patients with chronic venous insufficiency.

MATERIALS AND METHODS

This prospective study was conducted in the Department of Surgery at Muzaffarnagar Medical College, Muzaffarnagar, Uttar Pradesh, India, over a period of two years from March 2020 to March 2022. A total of 150 patients presenting to the surgical outpatient department with features suggestive of chronic venous insufficiency (CVI) were enrolled. Patients were evaluated based on risk factors, underlying etiology, clinical presentation, and response to treatment before and after intervention.

Participants were randomly divided into two equal groups:

- Group A: Received calcium dobesilate
- Group B: Received placebo

Inclusion Criteria

Patients diagnosed with chronic venous disease were included. Eligible participants comprised those presenting with telangiectasia or reticular veins, lower limb edema (foot/ankle), varicose veins, skin pigmentation and/or eczema, lipodermatosclerosis, atrophie blanche, healed or active venous ulcers. Individuals aged between 20 and 70 years who provided informed consent were included.

Exclusion Criteria

Patients with clinical features of deep vein thrombosis, those opting for surgical management of

varicose veins or ulcers, individuals below 20 years or above 70 years of age, patients with prior similar episodes, and those unwilling to participate were excluded from the study.

A total of 150 patients were assessed prospectively with respect to demographic profile, risk factors, venous disability score, clinical symptoms, body mass index (BMI), and treatment modality. Group A patients received calcium dobesilate 500 mg twice daily for 8 weeks (n = 75), while Group B received placebo (n = 75).

A detailed clinical history and examination were performed in all cases. Clinical symptoms were graded on a severity scale from 0 to 4 (0 = absent, 1 = mild, 2 = moderate, 3 = severe, 4 = very severe) both before and after treatment. The parameters assessed included pain, itching, fatigue, heaviness, paresthesia, cramps, and limb swelling.

All patients underwent color Doppler ultrasonography to confirm the diagnosis, assess valvular competence, and exclude deep vein thrombosis. Routine laboratory and urine investigations were performed at baseline and after completion of therapy.

Statistical Analysis

Data were analyzed using Chi-square test, Student's t-test, and Fisher's exact test. A p-value of less than 0.05 was considered statistically significant. Patients were followed for a period of up to six months to assess recurrence or progression of symptoms.

RESULTS

A total of 150 patients were included and equally divided into two groups. The mean age in Group A was 52.23 years, while in Group B it was 53.32 years. The most common risk factor identified was prolonged standing, followed by obesity and pregnancy.

Baseline venous disability scores were comparable between the two groups. Following treatment, patients receiving calcium dobesilate demonstrated significant improvement in symptoms such as pain, venous edema, and varicose veins compared to the placebo group. Additionally, the need for compression therapy was reduced in the treatment group.

Statistically significant improvements ($p < 0.05$) were observed in pain reduction, decrease in venous edema, and reduced dependence on compression therapy in Group A. However, no significant changes were noted in parameters such as skin pigmentation, inflammation, induration, or healing of active ulcers between the two groups.

Table 1: Showing demographic and Venous disability score in studied subjects.

Variables	Group –A	Group –B	P-Value
No. of Patients	75	75	
Male	32	40	0.1
Female	43	35	
Mean Age	52.23	53.32	0.8

Mean BMI	27.43	28.32	0.001*
Venous Disability Score			
Asymptomatic	6	3	0.3
Symptomatic but to Carries out activities without Compressive Therapy	10	12	0.6
Carries out activities without Compressive Therapy	65	72	0.04*
Unable to carry out Activity	10	20	0.04*

*Statistically Significant (p<0.05)

Table 2: Showing comparison of risk factors in studied subjects.

Risk Factor	Group-A	Group-B	p-Value
Prolonged standing	52	39	0.02*
Immobilization	8	12	0.33
Raised intra-abdominal pressure	14	20	0.24
Pregnancy	4	12	0.03*
Chronic constipation	31	50	0.06
Tight clothes	22	43	0.1
Obesity	32	45	0.03*

*Statistically Significant (p<0.05)

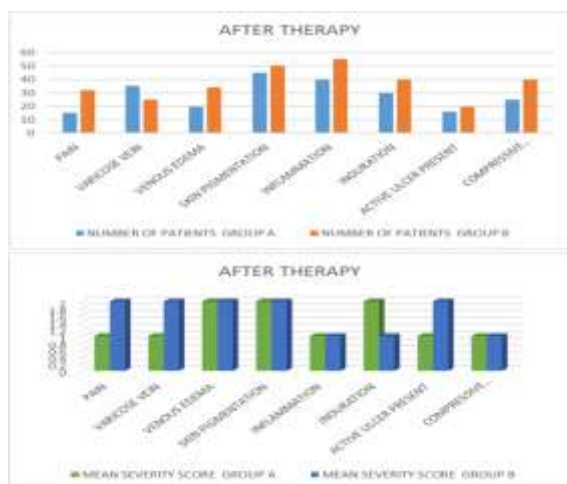
Table 3: Showing Comparison of Use of Calcium dobesilate and Placebo in studied subjects

Variable	Group A (N=75)	Mean Severity Score	Group B (N=75)	Mean Severity Score
Pain	55	2	46	2
Varicose Veins	45	2	50	3
Venous Edema	50	3	44	2
Skin Pigmentation	55	2	59	3
Inflammation	69	2	72	2
Induration	45	2	55	2
Active ulcer present	22	1	27	2
Compressive therapy used	65	3	72	2

Table 4: Showing Comparison of Calcium dobesilate and Placebo in studied subjects

Variable	Group- A (N=75)	Mean Severity Score	Group- B (N=75)	Mean Severity Score	P -Value
Pain	15	1	32	2	0.0002*
Varicose Vein	35	1	25	2	0.005*
Venous Edema	20	2	34	2	0.0002*
Skin Pigmentation	45	2	50	2	0.6
Inflammation	40	1	55	1	0.08
Induration	30	2	40	1	0.5
Active Ulcer Present	16	1	20	2	0.9
Compressive Therapy Used	25	1	40	1	0.017*

*Statistically Significant (p<0.05)



DISCUSSION

Chronic venous insufficiency is a prevalent vascular condition characterized by venous hypertension, leading to lower limb edema, skin changes, and varying degrees of discomfort. If left untreated, it

may progress to complications such as deep vein thrombosis and venous ulceration. Patients commonly present with pain, swelling, discoloration, and cosmetic concerns.^[11]

In the present study, calcium dobesilate demonstrated a significant reduction in symptom severity, particularly in pain, edema, and varicosities, compared to placebo. The observed reduction in symptom scores suggests its effectiveness as a conservative therapeutic option in CVI management. However, its effect on inflammatory changes, pigmentation, and ulcer healing was limited.^[12]

Previous studies have reported similar findings. Clinical trials have shown that calcium dobesilate effectively reduces edema and improves symptoms in patients with CVI. Meta-analyses have also demonstrated its superiority over placebo in alleviating night cramps and discomfort. Some randomized trials comparing other pharmacological agents have shown variable outcomes, highlighting the need for further research.^[13]

The beneficial effects of calcium dobesilate are likely due to its action on microcirculation, including

reduction in capillary permeability, improvement in blood viscosity, inhibition of platelet aggregation, and enhancement of lymphatic drainage.^[14]

CONCLUSION

Calcium dobesilate is an effective pharmacological agent for the symptomatic management of chronic venous insufficiency. It significantly reduces pain, edema, and severity of symptoms and can be considered a primary treatment option, especially in patients who are not suitable candidates for surgical intervention.

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