



"AN ANALYTICAL STUDY TO EVALUATE ROLE OF MICRONISED PURIFIED FLAVANOID FRACTION IN MANAGEMENT OF CHRONIC VENOUS INSUFFICIENCY"

General Surgery

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ABSTRACT

Chronic venous insufficiency (CVI) refers to the complete spectrum of manifestations of venous hypertension in the lower limb ranging from varicosities to venous ulcers and in long standing cases, lymphedema. The commonest group of patients with chronic venous insufficiency in present study is 31 to 40 & 51 to 60. Prolonged standing as a part of occupation or lifestyle was seen in most of the patients in present study. All the patients in present study presented with complaint of Dilated veins & Pain in legs. Majority of the patients has GSV involvement & C4a clinical classification of CEAP. All were having primary etiology of CVI and reflux as pathology. All the patients who were included in the study were provided the drug MPFF 500 mg BD for the 7 days and they were advised for not to use any other conservative treatment like compression bandage and various presentations, symptom improvement, complication were noted by follow up of patients at 10th day and at 4th week. On conclusion, MPFF has the ability to stop the progression of symptoms of Chronic venous disease. MPFF is an alternative therapy when surgery is not feasible, not indicated, or when patients are unable to use compression

KEYWORDS

INTRODUCTION-

Chronic venous insufficiency (CVI) refers to the complete spectrum of manifestations of venous hypertension in the lower limb ranging from varicosities to venous ulcers and in long standing cases, lymphedema. The venous system of the dependent limb was the first to bear the burden of posture and blood has to be forced to the heart chamber against gravity. To achieve this aim the human lower limbs adapted themselves to carry out the task by adopting various mechanisms which included division of the column of blood to segments by valves, constant muscular activity especially of the calf muscle to 'pump' the blood in the direction of heart, Intrathoracic negative pressure to 'suck' the blood up, the capillary pressure which 'pushes' the blood forwards and the pressure gradient in the blood vessel. Prevalence: women > men¹ The prevalence of varicose veins increases with age, BMI, height, pregnancy, smoking and occupations that involve prolonged standing. It affects 10–20% of population in the Western world but in India², it is 5%. Varicosity of lower limb develops in a very slow process, asymptomatic and probably harmless and only when the complications of Varicosity like Edema, Ulcer, Skin changes and thrombosis occur, and then the patients present themselves for the relief. Commonly this problem is tackled either by a conservative approach or by surgical interference, both of which have their limitations.

METHODOLOGY-

Study Type: prospective, analytical, observational

Study Site: Department of General Surgery, B.J. Medical college & Civil Hospital Ahmedabad.

Study Duration: JULY 2020 to JANUARY 2023 (30 months)

Sample Size- 50 Patients having chronic venous insufficiency.

Method Of Data Collection –

Patients presenting with signs and symptoms of chronic venous insufficiency in the opd at BJMC, civil hospital Ahmedabad from JULY 2020 to JANUARY 2023, who were diagnosed as having chronic venous insufficiency by history, clinical examination, radiological findings were taken up for the study after explaining the nature of the disease and various modalities of treatment available.

Informed & written consent was taken. All the patients who were included in the study were provided the drug MPFF 500 mg BD for the 7 days and they were advised for not to use any other conservative

treatment like compression bandage and various presentations, symptom improvement, complication were noted by follow up of patients at 10th day and at 4th week

Subject Selection:

Inclusion Criteria-

- All patients with clinical and radiological findings suggestive of chronic venous insufficiency.
- Patients more than 18 years of age.

Exclusion Criteria-

- Patients with superficial and deep vein thrombosis
- Patients with secondary varicose veins.
- Patients below the age of 18 years.
- Patients with diabetes
- Patients with known case of asthma / allergy.
- Pregnant women and breast feeding women.
- Patients operated for varicose veins
- Patients with diagnosis of PVD.
- Patients who do not consent for any interventions if required.

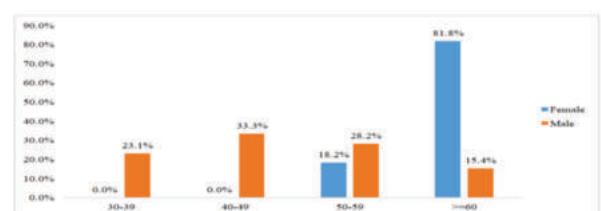
Follow-Up-

consisted of an interview, clinical examination, and color flow duplex scanning. 1st follow up after 10 days of treatment, 2nd follow up after 4 weeks of treatment

Data Analysis –

Data collected from case record form will be entered in a worksheet in a computer and analyzed using the SPSS (master chart). Subsequently, the Fischer's test, Chi-square test for qualitative data, and Student's t-test for quantitative data will be used as tests of significance for appropriate comparison and P < 0.05 will be taken as significance.

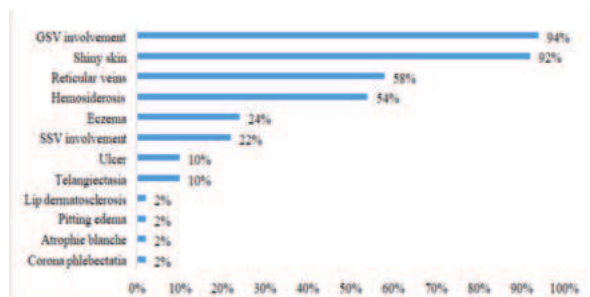
RESULTS



Age group and gender wise distribution of the study participants



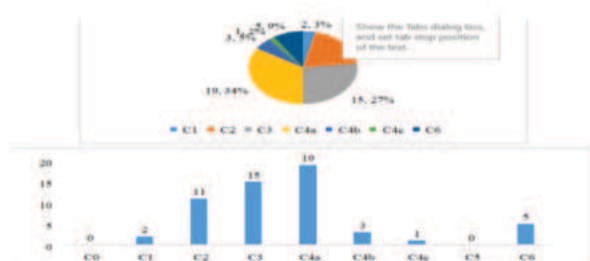
Symptomatic presentation of the study participants



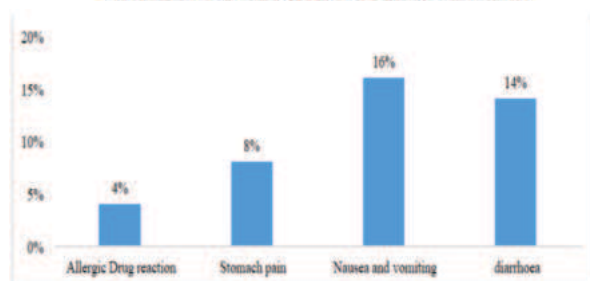
Examination finding of the patients



Doppler study finding of the patients



Distribution of patients according to Clinical classification



Post treatment development of Side effect among study participants

DISCUSSION

Age group and gender wise distribution of the study participants

11 were female and 39 were male patients. 15 patient is more than equal to 60 years. where 9 patients were between 30-39 years of age, 13 patients were between 40-49 years of age and 13 patients were between 50-59 years of age. There is a much significant difference among patients gender and age distribution. In most of the standard literature like bailey&love and sabiston textbook of surgery it is mentioned that varicose vein is predominantly seen in females.³ According to Indian literature by Mishra et al incidence of varicose veins is more in male.⁴

This could be attributed to illiteracy amongst Indian female and traditionally females do not seek medical attention and present to the hospital.

Symptomatic presentation of the study participants shows,

pre-procedure dilated veins seen among all patients among them only 15 had persist symptom on week 4. Pain in legs pre-procedure complained by 42(84%) patients which decrease to 15 patients at week 4. Night cramps pre-procedure in 28(56%) patients which is seen only in 4 patients at week 4. Leg discomfort in 26(52%) patients, Darkening of skin (ankle) in 24(48%) patients, Oedema in 23(46%) patients, Leg heaviness in 21(42%) patients, Extremity fatigue in 19(38%) patients, Itching in 11(22%) patients and Ulcer in 5(10%) patients. At week 4 follow up symptoms decrease for all other complains. In a study by Kompally et al⁵ pain in the leg was present in 70% of the patients, leg heaviness was present in 75% of the patients, itching was present in 35% of the patients, cramp was present in 50% of the patients, oedema was present in 15% of the patients, pigmentation was present in 25% of the patients, ulcer was present in 30% of the patients.

Examination finding of the patients:

majority of the patients shows GSV involvement which is seen in 47(94%) patients. Followed by disorder of Shiny skin in 46(92%) patients, other disorders are also present like Reticular veins in 29(58%), Hemosiderosis in 27(54%), Eczema in 12(24%), SSV involvement in 11(22%), Telangiectasia in 5(10%), Ulcer in 5(10%), Corona in 1(2%), phlebectasia in 1(2%), Atrophie blanche in 1(2%), Pitting edema in 1(2%) Lipodermatosclerosis in 1(2%). In a study by Mishra et al,⁵ 17% of the patient had involvement of short saphenous vein. And 60% of the patient had involvement of great saphenous vein.⁵⁸

Distribution of patients according to CEAP Clinical classification

shows majorities of the patients were included In C4a were 19(38%), In C3 there were 15(30%) patients, In C2 there were 11 (22%) patients, In C4b there were 3(6%) patients, In C6 there were 5 (10%), In C1 there were 2(4%) patients In C4c there were 1(2%) patients and none of the patients shows C0 and C5 involvement. In a study by Mishra et al, out of 60 patients 20 were in CEAP C2 (33%), 15 cases in CEAP C3 (25%) and 15 cases in CEAP C4 (25%) and 10 cases in C5(16%).⁴

Post treatment development of Side effect among study participants:

out of total patients who were given MPFF, 16% of the patients had shown side effects as nausea and vomiting, and 14% had diarrhoea, 8% had stomach ache and 2% had allergic drug reaction. In several human studies, the adverse effects reported (mainly GI disorders) did not differ from adverse effects reported with placebo. The incidence of adverse effects did not vary with age, concomitant diseases (hypertension, atherosclerosis, diabetes mellitus, neurological or psychiatric disease), or daily treatment for 1 year. There was no interaction with other drugs.

CONCLUSION

Chronic venous insufficiency is a fairly common clinical entity. The number of cases reporting to the hospital is much less than the real incidence; because in absence of troublesome symptoms, patients do not seek treatment in our country. The widespread availability and accuracy of color flow duplex scanning made it possible to combine the two modalities identify perforator veins that are not visible or accurately isolated by external examination. On the basis of this study finding, MPFF has the ability to stop the progression of symptoms of Chronic venous disease. MPFF eases symptoms, lessens edema and skin changes, and aids in the recovery of leg ulcers. Furthermore, MPFF enhances quality of life of patients by relieving symptoms. It can be used at all stages of CEAP (C0s and C1- C6). MPFF is an alternative therapy when surgery is not feasible, not indicated, or when patients are unable to use compression & it is also cost-effective & affordable. In some patients, It causes nausea, diarrhoea, stomach ache as side effects but it doesn't make them noncompliant.

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