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CHRONIC VENOUS INSUFFICIENCY: A STUDY OF CLINICAL PRESENTATION AT A RURAL HOSPITAL AND ITS MANAGEMENT IN INTERVENTIONAL RADIOLOGY CLINIC.

Radiology

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ABSTRACT

Background:
Chronic Venous Insufficiency (CVI) is a disease having varying clinical presentation from relatively early subclinical disease to overt chronic nonhealing venous leg ulcers. The etiopathogenesis of CVI is relatively complex owing to different risk factors and variable patient characteristics. Many a times the underlying disease is masked with insidious and slow progression of disease and its manifestations. CVI in rural population of India has its own importance in its diagnosis and management, as rural population in our country has longstanding disease with late presentations in contrast to urban areas where people are more concerned with early skin changes. With advances in technology, popularity with minimally invasive procedures and availability of Interventional Radiology Clinic (IRC) it is becoming possible to treat these patients by minimally invasive IR procedures.

Aims and Objectives:
To study the demographic characteristics, risk factors, clinical features and management outcomes after interventional radiology procedures in patients with chronic venous insufficiency.

Materials and Methods:
This was a prospective study of patients with chronic venous insufficiency conducted in department of interventional radiology of a medical institute situated in a rural area. The patients were included on the basis of a predefined inclusion and exclusion criteria and were evaluated for demographic and disease characteristics. A detailed history was taken in all the patients. Appropriate Imaging was done and patients were classified using CEAP classification. Patients were treated by Ablation, sclerotherapy or combination of these two. Following treatment patients were followed up for any complications. The data was tabulated and analyzed using Minitab Version 17.

Results:
Out of 72 studied cases of chronic venous insufficiency there were 47 (65.27%) males and 25 (34.72%) females with a M:F ratio of 1:0.53. The most common affected age group was found to be 41-50 years (27.77%) followed by 51-60 years (25%) and 31-40 years (22.22%). Majority of the patients (84.27%) belonged to rural areas while urban population consisted of only 15.27%. The common risk factors associated with CVI were found to be prolonged standing which was present in 33 (45.84%) patients. The other risk factors found were predisposing physical traits (38.9%), occupational (36.2%), visible-varicose veins (34.72 %). Most of the patients belonged to C6 (28/72) class and presented with active ulcers. Only 4 cases were managed conservatively. Ablation and sclerotherapy both was done in 58 patients while only sclerotherapy was done only in 1 patient. All the patients had excellent outcome and there were no complications in any patient during follow up except in 1 patient who was found to have progressed from Class 3 to Class 5.

Conclusion:
Management of chronic venous insufficiency by interventional radiological procedures is found to have excellent outcome with minimal complication rates.

KEYWORDS

Chronic venous insufficiency, Endo Venous Laser Ablation, Sclerotheraphy, Outcome.

Introduction:
Chronic venous insufficiency (CVI) commonly affects the elderly population and lower limbs are predominantly involved. The prevalence ranges from 9 % in males and 7 % in females[1]. Given the fact that many of the patients having venous insufficiency may not show any symptoms in early stages of the disease it is more likely that the symptomatic patients seeking medical attention will be a minority of the total affected population (Iceberg phenomenon). It won't be an overstatement to say that it is one of the most underrated and under-detected disease[2]. Another important hindrance in studying the demographics of CVI is lack of a standard definition. The incidence of chronic venous insufficiency is more in individuals with prolonged standing, occupation related, family history of chronic venous insufficiency and higher BMI or tall stature. The assessment of CVI can be done by various imaging techniques including ultrasound with colour Doppler and pulse Doppler imaging and MRI angiography[3]. Among the many assessment tools developed for assessment of chronic venous insufficiency the descriptive clinical, etiological, anatomical, and pathophysiological findings (CEAP classification) was found to be the most appropriate for the purpose not only of diagnosis but also classification of CVI[4]. The spectrum of signs and symptoms related to CVI ranges from asymptomatic patients to more serious consequences including but not limited to non-healing ulcers, infected wounds and slow healing[5]. The socioeconomic impact of these non-healing ulcers and wounds is immense and may result in significant morbidity in affected individuals. The patients may also present with dilated lower limb veins, pedal edema, pain and cutaneous changes in the leg[6]. The common symptoms include discomfort and heaviness or aching legs after prolonged standing. The symptoms characteristically reduce after rest or elevation of legs[7].

Management of these patients may consist of frequent elevation of legs, compression stockings, Bandages with a high static stiffness index, Ablation and sclerotherapy[8]. The choice of treatment may depend upon severity of the disease and general condition of the patients. The role of interventional radiologists can't be overemphasized as far as management of patients with CVI is concerned. It is a well-known fact that minimally invasive interventional radiology procedures for management of chronic venous insufficiency are associated with decrease morbidity and excellent outcomes even in patients having co-morbid conditions[9]. Availability of such facilities to interventional radiological procedures and scarcity of such expert personnel, especially in rural areas, is the main reason behind underutilization of these procedures. Although in many developing countries traditionally surgical methods were in vogue, with advances in ablation technology and popularity of

minimally invasive methods, successful application of interventional radiology in management of CVI is possible in today's era and gaining ground day by day[10]. Ours is one such medical institute located in rural area but having all the facilities for various interventional radiology procedures. We therefore are in unique position to provide the minimally invasive IR procedures for the management of cases with chronic venous insufficiency.We conducted this prospective study to evaluate patients referred to our IRC with respect to patient characteristics, clinical features, imaging studies and management of patients with chronic venous insufficiency.

Materials And Methods:

This was a prospective study conducted in department of interventional radiology of a medical institute situated in a rural area. The study consisted of patients of CVI referred to our department for evaluation and further management. The patients were included on the basis of a predefined inclusion and exclusion criteria and were evaluated for demographic and disease characteristics (age, sex, urban or rural, occupation, pre-existing conditions, Clinical characteristics of CVI and ultrasound colour-Doppler evaluation). A detailed history was taken in all the patients. Special emphasis was given to find out, on the basis of history, possibility of systemic diseases (hypertension and diabetes), diabetic ulcer & peripheral neuropathy, past history of road traffic accident/fracture - related limb swelling and immobilization or history of DVT. Occupation of all the patients was also enquired into with a view to find out whether any patient had occupation associated (demanding prolonged standing) with increased incidence of peripheral chronic venous insufficiency (e.g. nurses, saloon professionals, traffic police,labourers etc).

Patients were investigated and complete blood count, blood sugar levels, PT/INR, infective Viral Markers (HIV, HCV and HBsAg), blood pressure estimations and Doppler ultrasound was done in all cases along with previous history of medical management, compressive dressings and wound care (class C 5/6) was noted.The patients were classified on the basis of clinical evaluation and stage of the disease was determined (C1 to C6) on the basis of CEAP (Comprehensive Classification System for Chronic Venous Disorders) classification[4].

Table 1: CEAP "Clinical" classification system of chronic venous disorders

CEAP classification of chronic venous disorders	Clinical classification
C0	No visible or palpable signs of venous disease
C1	Telangiectasias or reticular veins
C2	Varicose veins
C3	Edema
C4a	Pigmentation or eczema
C4b	Lipodermatosclerosis or atrophie blanche
C5	Healed venous ulcer
C6	Active venous ulcer

Presence of venous ulcers and its characteristics like number of lesions (single, multiple), size, site, presence of infection, and relation of ulcer to major superficial veins (Great or Small saphenous veins) or presence of varicosities were noted. All patients underwent color doppler of leg vessels to rule out Peripheral vascular disease, Deep Vein Thrombosis, Deep vein reflux and to evaluate cause of Chronic venous insufficiency in terms of reflux at Saphenofemoral junction, intrinsic reflux, perforator incompetence, reflux in superficial veins and involved anatomy in terms of major superficial Veins and perforators of lower limb as per CEAP classification. Further the presence of venous anomalies and chronic DVT (recanalized, partially treated or undiagnosed), deep vein reflux and other causes like AV fistula or underlying PVD was also confirmed or ruled out in all the patients.

Patients initially received counselling about their disease process and management as well as about IR procedure techniques (Laser Ablation, Sclerotheraphy). In uncomplicated cases Conservative and medical management (weight management, life style changes, calf strengthening exercise, compressive stockings, pharmacological medicines like micronized purified flavonoid fraction[7] , Vitamin E and diosmin[15]) was advised. In patients in whom the disease was severe and those who didn't respond to pharmacological or conservative management, either Endo Venous Laser Ablation (EVLA) therapy alone or sclerotheraphy or combinations of these two were done depending upon the severity of the disease.

1- Ablation therapy (ENDO VENOUS LASER THERAPHY-EVLA 1470 nm)

After preliminary investigations & Clinician's opinion (Referring Physician or surgeon and consultant Interventional Radiologist) patients were selected for ablation therapy. Under all aseptic precautions Great saphenous vein (GSV) was accessed under ultrasound guidance after infiltration of local anesthetic agent using 18G single wall puncture needle and utilizing Seldinger technique. Guide wire followed by sheath placement was done and guide wire (hydrophilic 0.35 Terumo) was then exchanged with Laser fiber after check contrast venogram, under fluoroscopy, to rule out deep vein reflux, Position from Sapheno-Femoral Junction (SFJ) was confirmed (at least 2 to 3 cm away from SFJ) followed by perivenular infiltration of anesthetic agent and laser ablation was done in sequential segments from proximal to distal (in some cases with technical issues antegrade ablations were done with due precautions). Hemostasis was achieved. Any other vein which was found to be affected was dealt similarly. GSV Ablation was done in all C5/C6 cases. GSV, SSV or a large perforator were ablated if ulcer was found in that distribution in same setting; similarly large ulcer with adjacent/underlying perforator (pathological perforator) was ablated. For perforator ablation, similarly coaxial direct Ultrasound guided 18G needle accesses was taken at or just below the fascia-plane level.

2. Sclerotherapy alone. (With 2% setrol foam).

Under all aseptic precautions with ultrasound and fluoroscopy Cath lab guidance superficial varicosities accesses taken using scalp-vein set and check venogram was done to delineate course and connections of venous anatomy. Potential perforators as well as deep system communications were evaluated and potential flow of sclerosant was delineated and "foam" sclerosant was injected in pulsed manner under smart mask in Cath lab or utilizing injection and other end aspiration technique under ultrasound guidance and/or cathlab.

3. Ablation along-with sclerotherapy

In some cases, combination of the two procedures was needed.

Following the procedure, the patients were managed by IV or oral antibiotics and ulcer-wound care utilizing special dressings depending on soakage and presence of infection[7]; and local injections (in few selected C6 cases) of platelet rich plasma [7] (PRP) if very large ulcers or to aid for rapid ulcer healing . Post procedure on day 3 or day 5 review color Doppler was done to rule out complication like deep vein thrombosis and to evaluate for residual disease if any in terms of perforators, additional veins and to evaluate success of ablation. Patients were also evaluated clinically for presence of any minor complications like puncture/accesses site skin burns or infection and also for ulcer healing. Further management for residual disease at follow-up, compressive stockings and calf strengthening exercises were also advised.

Inclusion Criteria:

- Patients presenting with Venous ulcers, varicose veins or chronic venous insufficiency who were symptomatic and were referred to our department for imaging and further management.
- Those who gave informed consent.
- Age more than 18 years.

Exclusion Criteria

- Those Who refused consent.
- Age less than 18 years.
- Pregnancy.
- Acute DVT, D-dimer positive.
- Peripheral Vascular Disease (PVD).
- Uncorrected coagulation disorders, contrast allergy.
- Known case of previous deep vein thrombosis, deep vein reflux, Individuals with congenital absence of valves in deep system. (relative exclusion criteria for: EVLA, but conservative or if

deemed necessary local sclerotheraphy / local pathological perforator ablation and appropriate wound care management done and are included in study cases.)

Results:

In this prospective study of 72 patients of peripheral chronic venous insufficiency who were referred to interventional radiology department for further evaluation and management there were 47 males and 25 females with an M: F ratio of 1:0.53.

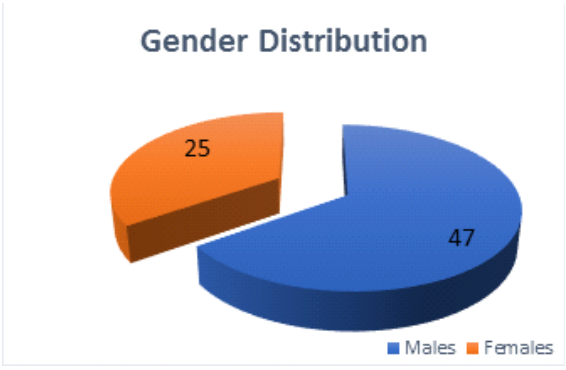

Figure 1: Gender Distribution of the studied Cases.

The analysis of the affected patients age showed that the minimum and maximum age was found to be 18 years and 80 years respectively. The most common age group affected was found to be between the age group of 41-50 years (27.77%), followed by 51-60 years (25%), 31-40 years (22.22%), 61-70 years (11.11%), 18-30 years (9.72%) and more than 70 years (4.16%).

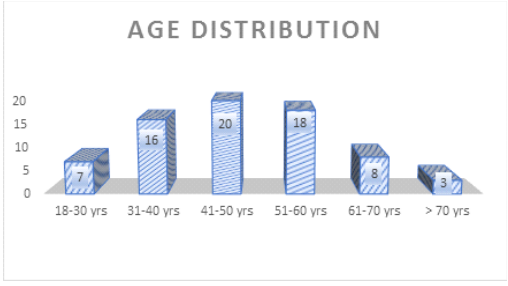

Figure 2: Age distribution of the studied cases.

The majority of the patients belonged to rural areas (84.72%) while only 11 patients (15.27%) belonged to urban areas.

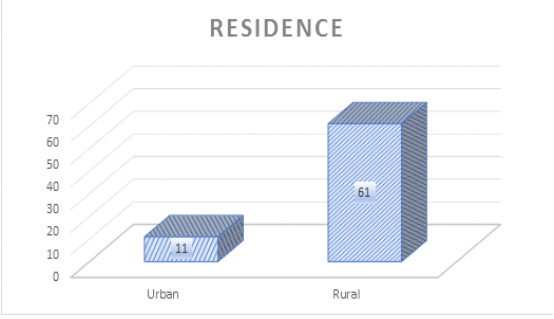

Figure 3: Urban Vs Rural Population in the studied cases.

The analysis of risk factors for chronic venous insufficiency showed that all the patients had some or the other form of risk factor present. Some patients had multiple risk factors for chronic venous insufficiency. The most common risk factor was found to be prolonged standing which was present in 33 (45.84%) patients. The other risk factors found in studied cases were predisposing physical traits (28 cases), heavy weight lifting (27.8 %), occupational (26 patients), visible-varicose veins (34.72 %), family history of varicose veins (8.34 %) and superficial thrombo-phlebitis (11.2%).

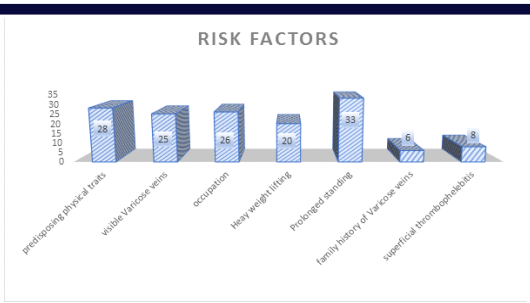

Figure 4: Risk factors for chronic venous insufficiency in studied cases.

The analysis of the patients on the basis of CEAP classification showed that the majority of patients belonged to class C6 (28/72) i.e. presence of active venous ulcers followed by patients belonging to class C5 (Healed venous ulcer), C4 (Pigmentation, eczema or Lipodermatosclerosis), C3 (Edema) and C2 (only Varicose Veins). There was no patient belonging to class C1.

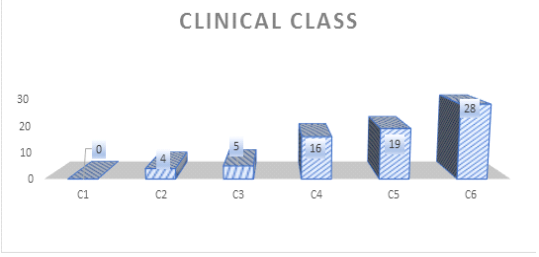

Figure 5: Clinical(C) Class in the studied cases according to CEAP.

Out of 72 cases only 4 cases were managed conservatively while remaining patients required some or the other form of intervention in the form of either the ablation or sclerotherapy or both. Only ablation was done in 9 patients while ablation and sclerotherapy both was done in 58 patients. Only sclerotherapy was done in 1 patient.

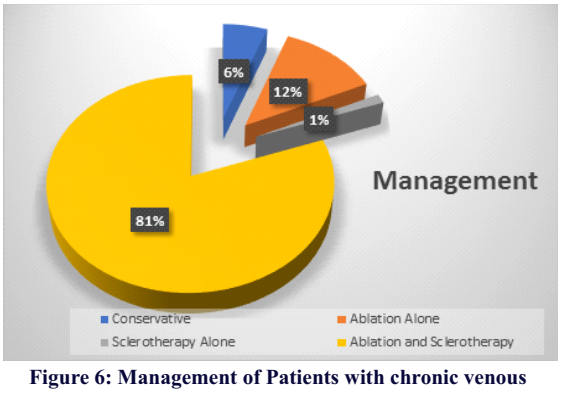

Figure 6: Management of Patients with chronic venous insufficiency.

Patients were followed up for 6 months post-operatively. All the patients had excellent outcome and there were no complications in any patient during follow up except in 1 patient who was found to have progressed from Class 3 to Class 5. His follow-up revealed that he had an episode of superficial thrombo-phlebitis post sclerotheraphy and ablation.

Discussion:

In this study of study of 72 patients with peripheral chronic venous insufficiency, males were found to be affected predominantly with an M: F ratio of 1:0.53. Many studies have reported that men are predominantly affected, there are no definite reasons known for such a gender difference. Moreover, there are some other studies which have found CVI to be more common in females[11].

C. J. Evans et al in their prospective study of 1566 subjects aged between 18-64 years selected randomly from age-sex registers of various hospitals found that the age adjusted prevalence of trunk

varices was 40% in men and 32% in women (p < or = 0.01). They moreover found that the age adjusted prevalence of CVI was 9% in men and 7% in women (p < or = 0.05). The authors found that approximately one third of men and women aged 18-64 years had trunk varices. In contrast to this there are some other studied which have reported chronic venous insufficiency to be more common in women than in men[12]. Al Shammeri O et al conducted a cross sectional study to assess the prevalence of CVI among patients. The authors found that Among the 226 screened patients, 138 (61.1%) were diagnosed as having CVI (69% female and 45% male, p<0.001). Compared to the baseline, both the clinical and venous scores for CVI at the follow-up were significantly lower among patients using compression stockings. The authors concluded that compression stocking is an effective treatment of CVI in uncomplicated cases. This study reported higher prevalence of CVI in women (69%) as compared to men (45%)[13].

As the age advances there is an increase in incidence of chronic venous insufficiency. In our study the most common age group affected was found to be 41-50 years followed by 51-60 years. Chiesa R in a study of 5,187 subjects (4,457 women [mean age, 54 years] and 730 men [mean age, 61 years]), found that the mean age for both and women is above 50 and men were affected at a relatively older age as compared to women[14]. Similarly, Maksimović ZV et al in their study of 80 patients found that chronic venous insufficiency was more common in females than in males. The authors further found the mean age of studied cases to be 52.3 +/- 10.5[15].

Majority of our patients belonged to rural areas (84.72 %) and only a minority of patients (15.27%) came from urban areas. This may have to do with the fact that our interventional radiology center is situated in rural area. Rabe E et al conducted a study of 1350 men, 1722 women to find out he prevalence of venous disorders in urban and rural populations, the frequency of its signs and symptoms, and the risk factors. The authors found that the prevalence of a positive Stemmer's sign II and III was markedly higher in the urban population (2.4%) compared with the rural population (0.7%) and increased with the clinical stages of chronic venous diseases according to the CEAP-classification[16].

The risk factors associated with chronic venous insufficiency in our study include long standing hours, heavy weight lifting, occupational, predisposing physical traits (like higher BMI or tall stature), visible varicose veins and superficial thrombo-phlebitis. Michael H. Criqui et al in their population-based study of chronic venous insufficiency found that moderate venous disease was independently related to age, a family history of venous disease, previous hernia surgery, and normotension in both sexes. Their study found that in men, occupation as a laborer, cigarette smoking, and normotension were independently associated with severe venous disease, while in women additional significant and independent predictors were hours standing, history of leg injury, number of deliveries, and cardiovascular disease[17].

The clinical class of the affected patients were determined by Comprehensive Classification System for Chronic Venous Disorders (CEAP). This classification system takes into account presence of reticular or varicose veins, pedal edema, pigmentation, eczema, Lipodermatosclerosis or athrophie blanche, healed venous ulcer or active venous ulcer and can be used as a guide to the management of patients with CVI[18]. Kistner RL et al conducted a prospective study of 102 extremities in 70 consecutive patients with CVD. The purpose of the study was to test classification of chronic venous disease (CVD)--based on clinical, etiologic, anatomic, and pathophysiologic data (the CEAP system). The authors concluded that Use of the CEAP classification with diagnoses determined by objective testing accurately identifies categories of CVD. The objective data provides a clear description of the abnormalities in each case and may be used for analyses of meaningful relationships between categories of CVD. The authors recommended that adoption of this objective method of classifying CVD will facilitate inter-institutional studies[19].

The management of chronic venous insufficiency consists of either conservative or surgical treatment ; with minimally invasive endovascular interventions now being standard of treatment over conventional surgery. Best suitable treatment protocol is based upon severity (class) of the disease, general condition of the patients and whether venous insufficiency is complicated or uncomplicated. Various interventions used for CVI include sclerotherapy, Ablation or a combination of these two methods. If properly managed patients undergoing these interventional radiology procedures have an excellent outcome with negligible complication rates[20].

Conclusion: Chronic venous insufficiency is a common condition in middle-age & elderly population. Most of the individuals remain asymptomatic in initial phases of the disease and may present only at an advanced stage of the disease with overt signs and symptoms especially the rural population. Interventional radiology procedures are found to have excellent outcome with minimal complication rates in individuals with chronic venous insufficiency.

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