

Prevalence of Vasculitis among Chronic Venous Insufficiency Patients Attending a Tertiary Care Centre, Tamil Nadu, India: A Descriptive Observational Study

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ABSTRACT

Introduction: Chronic Venous Insufficiency (CVI) is a relatively common condition seen worldwide and also in the Indian population. Vasculitis is a heterogenous group of disorders that affects and destroys blood vessels by inflammation. While both are separate disease entities, the presence of vasculitis in patients who present with CVI often goes unnoticed, thereby complicating the treatment of varicose veins.

Aim: To determine the clinical profile and prevalence of vasculitis among patients with CVI attending a tertiary care hospital in Tamil Nadu, India.

Materials and Methods: This descriptive observational study was carried out in the Department of General Surgery among 162 patients (out of which 130 were selected based on inclusion criteria) with CVI attending tertiary care centre in Tamil Nadu, India, from February 2018 to January 2019. Patients with an active or healed ulcer on the long and short saphenous vein of lower limbs were included in the study. They were studied to assess the prevalence of vasculitis among them and the implications it had on the overall morbidity of the patient and

their treatment outcome. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency, and proportion for categorical variables.

Results: The mean age of the study population was 45.52 years. Out of 130 patients, 33.08% and 23.85% of the study population were diagnosed with Type 2 Diabetes Mellitus (T2DM) and systemic hypertension, respectively. Only 3 (2.3%) participants had vasculitis and all of them were smokers and had a painful ulcer, fever, elevated C-Reactive Protein (CRP), elevated Erythrocyte Sedimentation Rate (ESR), and elevated total leukocyte count levels. Two (66.7%) of them had an active ulcer at the time of presentation, against 1 (33.3%) who had a healing ulcer. All patients were cured by Bisgaard's regimen+steroids/no steroids+surgery.

Conclusion: The prevalence of vasculitis was 2.3%. This study confirms that patients suffering from CVI may be at a marginal risk of having co-existing vasculitis which may complicate the clinical picture and result in postoperative complications if left unchecked.

Keywords: Diabetes mellitus, Edge-wedge biopsy, Hypertension, Smoking, Venous ulcer

INTRODUCTION

The CVI is a relatively common condition seen worldwide and also in the Indian population. The most common manifestations of chronic venous disease are dilated cutaneous veins, such as telangiectasis and reticular veins, and varicose veins [1]. It was observed in the hospital that routinely majority of the patients presented to the general surgical clinic after the development of severe complications or due to chronic pain and seldom reported asymptotically for a routine check-up.

The more serious consequences of CVI such as venous ulcers have an estimated prevalence of 4.5% (prevalence was reported per 1000 individuals per year) of the adult population in India, 1-3% in United States of America (USA) and around 3% in United Kingdom (UK) [2,3]. In a study conducted in Mangalore, India in 2016 [4] it was seen that the common symptoms at the time of presentation were ulceration 98 (57.6%) followed by pain in the legs 96 (56.5%). 12.3% of the study population was found to have non healing ulcers. Ulceration was seen significantly more among women ($p < 0.027$) and housewives ($p < 0.004$) [5]. The disease course of venous ulcers is generally poor with delayed healing and recurrent ulceration being common [6]. More than 50% of venous ulcers require prolonged therapy lasting >1 year [7]. The socio-economic impact of venous ulceration is dramatic, resulting in an impaired ability to engage in social and occupational activities, thus reducing the quality of life and imposing financial constraints. A study from India showed

venous ulcers to be one of the major causes of chronic no healing ulcers [8].

A vasculitis is a heterogeneous group of disorders that destroy blood vessels by inflammation and necrosis of blood vessel walls. Both arteries and veins are affected [9]. It can range from being a rather benign condition to being a life-threatening entity with multiorgan involvement. The aetiology of vasculitis is unknown but is generally considered to involve a complex interaction between an environmental trigger factor (e.g. drugs, infection, chemicals, ultraviolet light, smoking) and a genetically predisposed host [10]. In India, vasculitis is underdiagnosed and under-reported and its role in patients with chronic venous ulcers is yet to be fully understood [11,12].

Established risk factors contributing to vasculitis among chronic insufficiency patients across the globe include older age, women, pregnancy, family history of vasculitis, obesity, and occupations associated with orthostasis [13]. However, there are not many studies available that elaborate on the various contributory factors that may lead to this disease combination.

Hence, this study aimed to determine the clinical profile and prevalence of vasculitis among patients with CVI attending a tertiary care hospital in India to determine symptoms, clinical signs, and combination of co-morbidities heighten the clinician's suspicion of possible underlying vasculitis.

MATERIALS AND METHODS

This was a descriptive observational study conducted among CVI patients attending Shri Sathya Sai Medical College and Research Institute, Ammapettai, Tamil Nadu, India, from February 2018 to January 2019. After obtaining clearance from the Institutional Ethics Committee (IEC) (IEC No. 2017/374), an informed written consent was obtained from each subject before the start of the study. Confidentiality was maintained throughout.

Sample size calculation: Sample size estimation was done based on the average number of cases of CVI seen in the general surgery Outpatient Department (OPD) in a year. A total of 162 consecutive patients diagnosed with CVI attending the OPD were recruited out of which 130 were selected based on inclusion criteria.

Inclusion criteria: Only patients with an active, healed or recurrent ulcer of the lower limb with other clinical features of varicose veins such as reticular veins, dilated veins of the lower limb, oedema of the lower limb, skin changes such as eczema, hyperpigmentation, and lipodermatosclerosis [14], were included in the study. Patients only with a primary aetiology (p), wherein no secondary causes for varicose veins such as intravenous luminal obstruction like a thrombus or extra venous extrinsic compression due to a tumour could be identified were included in the study. Patients with both superficial (s) and perforator (p) incompetence were included. Patients where only reflux (r) pathology was found were included in the study.

An active ulcer is defined as the presence of breach of the epithelium or skin and is classified as under category C6 of the CEAP (Clinical-Etiology-Anatomy-Pathophysiology) classification for chronic venous insufficiency [15,16]. Healed ulcers were concluded on the basis of history of the disease of the patient and previous treatment history upon presentation to outpatient department.

Exclusion criteria: Patients with recurrent varicose veins following previous surgery, underlying osteomyelitis, immunocompromised, previous coronary artery disease, features of multiorgan dysfunction syndrome, and patients who got discharged from the hospital during their treatment but against medical advice before completion of the treatment were excluded from the study. Immunocompromised individuals were excluded because in those individuals the immune response is already poor and the desired immune response to inflammatory venous disorders may be inadequate thereby affecting the results. In cardiac patients, the long saphenous vein is needed for future potential bypass surgery and hence was excluded from the study. Patients with known vasculitis and those already treated for the same were also excluded since the steroids used to treat them could potentially affect the results of the ongoing study by providing false-negative results.

Study Procedure

A detailed history was taken and a diagnosis was made based on the clinical features of varicose veins and the results of the blood investigations and tissue biopsy reports. Varicose veins are classified into six classes based on clinical presentation [17]. In this study, only classes 5 and 6 (healed, active and recurrent ulcers respectively) were taken into account.

Varicose vein patients with an active or recurrent ulcer were first treated conservatively by following Bisgaard's regimen which comprised of daily dressing, elastic-crepe bandage application, lower limb elevation, and evaluation of the venous system using Doppler scan [18]. All routine blood investigations were sent and a biopsy of the ulcer edge was also sent for histopathology. Once the ulcer started improving, patients who had normal blood parameters and histopathology reports underwent Trendelenburg operation with the stripping of veins for varicose veins, and the vein was also sent for histopathology. Varicose vein patients with a healed ulcer were directly taken up for surgery provided their blood parameters were normal. Varicose vein patients with features suggestive of vasculitis

were treated for vasculitis and upon improvement were later taken up for varicose vein surgery.

Outcome measures: Patients were diagnosed to have vasculitis based on certain diagnostic criteria such as the presence of elevated CRP (above 3 mg/L), elevated ESR, fever (above 100°F), elevated total counts (above 11000/mm), and based on biopsy from active or recurrent ulcers and of the vein [19].

Other co-morbidities like T2DM (known history of diabetes mellitus and those diagnosed following admission based on increased fasting and postprandial blood sugar) were checked for and recorded. Respiratory diseases were ruled out based on history and after doing a chest X-ray. A history of smoking was also recorded to see if there was any association with vasculitis. Patients once diagnosed with vasculitis among the study population were then treated for vasculitis before proceeding with surgery and the impact of this problem on the morbidity of the patient was also studied.

Participants with values above 7% of glycosylated haemoglobin were considered diabetic and for hypertension those diagnosed following admission based on elevated blood pressure readings, i.e., above 140/90 mm of Hg for people of age <80 and above 150/90 mm of Hg for people of age >80 during three consecutive early morning readings [20].

STATISTICAL ANALYSIS

Clinical and pathological indicators were considered as primary explanatory variables. Vasculitis was considered the primary outcome variable. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency, and proportion for categorical variables. Age and duration of hospital stay were presented as mean and standard deviation. Gender, clinical and laboratory parameters, co-morbidities etc. were presented as frequency and proportions. The coGuide version V.1.0 was used for statistical analysis [21].

RESULTS

In this study, a total of 130 patients who were diagnosed with varicose veins were enrolled. Among these patients, all of them either had active or recurrent ulcers at presentation itself, or had a recent history of an ulcer which had just healed. The mean age of the study population was 45.52±9.47 years, ranging between 25-67 years. Out of 130 patients, 100 (76.92%) participants were men and remaining 30 (23.08%) were women.

Out of 130 participants, only 3 (2.3%) participants were diagnosed with vasculitis. The mean duration of hospital stay was 16.72±7.05 days and it ranged between 1-40 days. Among the people with co-morbidities, 40 (30.77%) were T2DM and 30 (23.08%) patients were hypertensive. Ulcer was located on greater saphenous vein in all 130 participants and 36 (27.70%) participants had ulcer on both greater and small saphenous vein. Out of 130, 14.62% had increased total leukocyte count, 13.85% had fever, 8.46% had anaemia and 4.62% had increased eosinophil count. Three (2.31%) participants showed ulcer and vein biopsy positive for vasculitis. The majority of the 97.69% participants had undergone Bisgaard's regimen+surgery and 3 (2.31%) participants underwent Bisgaard's regimen+steroids+surgery and all of the participants were cured [Table/Fig-1].

Out of 130 patients diagnosed with varicose veins, only three patients (2.3%) were confirmed to have vasculitis based on the biopsy report of the vein. Among those three patients, all of them were men, smokers and had a painful ulcer, fever, elevated CRP, elevated ESR, and elevated TLC levels [Table/Fig-2]. Two of the three patients had an active ulcer (66.7%) while one patient had a healing ulcer (33.3%).

Once the ulcers healed, all the three patients were taken up for surgery and all of them were cured. The mean time for ulcer healing

Various parameters	Summary (mean±SD/n (%))
Age (Mean±SD) (years)	45.52±9.47 (ranged 25 to 67)
Gender	
Men	100 (76.92)
Women	30 (23.08)
Duration of hospital stay (days)	Mean 16.72±7.05 (ranged 1 to 40)
Respiratory disorder	0
Location of ulcer	
Great saphenous vein	130 (100)
Small saphenous vein	36 (27.70)
Clinical stage	
5	93 (71.54)
6	37 (28.46)
Aetiology (p)	130 (100)
Anatomical stage (s+ p)	130 (100)
Pathological stage (R)	130 (100)
Laboratory investigations	
C-Reactive protein	3 (2.31)
Erythrocyte sedimentation rate	3 (2.31)
Anaemia	11 (8.46)
Total leukocyte count	19 (14.62)
Absolute eosinophil count	6 (4.62)
Biopsy showing vasculitis	
Ulcer biopsy showing vasculitis	3 (2.31)
Vein biopsy showing vasculitis	3 (2.31)
Treatment	
Bisgaard's regimen+Steroids+Surgery	3 (2.31)
Bisgaard's regimen+Surgery	127 (97.69)
Outcome	
Cured	130 (100)

[Table/Fig-1]: Summary of various parameters (N=130).

*A total of 130 subjects were included in the final analysis; Aetiology perforator (P); Anatomical stage- Superficial+reflux (S+R); Pathological stage- R-reflux

was 16.72±7.05 days. They were given 40 mg of methylprednisolone per day for four weeks and then tapered to 10 mg per day for two weeks.

Clinical and pathological indicators	Vasculitis		
	Yes (N=3)	No (N=127)	Total (N=130)
Smoking status			
Smokers	3 (100%)	54 (42.52%)	57 (43.85%)
Non smokers	0	73 (57.48%)	73 (56.15%)
Small saphenous vein pathology (SSV)			
Yes	0	36 (28.35%)	36 (27.69%)
No	3 (100%)	91 (71.65%)	94 (72.31%)
Painful ulcer			
Yes	3 (100%)	2 (1.57%)	5 (3.85%)
No	0	125 (98.43%)	125 (96.15%)
Co-morbidities			
Diabetes	3 (100%)	40 (30.77%)	43 (33.08%)
Hypertension	1 (33.33%)	30 (23.08%)	31 (23.85%)
Fever			
Yes	3 (100%)	15 (11.81%)	18 (13.85%)
No	0	112 (88.19%)	112 (86.15%)
C-Reactive protein			
Elevated	3 (100%)	0	3 (2.31%)
Normal	0	127 (100%)	127 (97.69%)

ESR			
Elevated	3 (100%)	0	3 (2.31%)
Normal	0	127 (100%)	127 (97.69%)
Total leukocyte count			
Elevated	3 (100%)	16 (12.6%)	19 (14.62%)
Normal	0	111 (87.4%)	111 (85.38%)

[Table/Fig-2]: Comparison of clinical and pathological indicators with vasculitis (N=130).

*No statistical test was applied-due to 0 subjects in the cell

DISCUSSION

This study was carried out to understand if there was any relation between vasculitis and CVI. CVI is a relatively common problem that is encountered in the general surgical clinics of South-East Asia; [4] however, there have been no definitive studies conducted to find out the relation between vasculitis and CVI. According to the author's knowledge, this was the first study of its kind to be conducted in this region.

The incidence of primary vasculitis disorders seen on average at a rheumatology clinic in India was 0.38% and 0.44% as reported in two studies [22,23]. An incidence of around 0.79% was reported by the self-experience of an author in a study [24]. Vasculitis is a serious complication of rheumatoid arthritis [25]. Among the patients who were diagnosed with vasculitis, all three of them were men. This was in contrast with the epidemiological study [24], where there was no sex predilection. In comparison, the aetiological study [26], showed a predominance with men, and a clinical study [4], showed a women's predominance. In present study, we saw that the incidence of CVI was more prevalent among patients above the age of 45 years. It is thought that the incidence of ulceration is rising as a result of an ageing population and increased risk factors for atherosclerotic occlusion such as smoking, obesity, and diabetes. In the course of a lifetime, almost 10% of the population will develop a chronic wound with a wound-related mortality rate of 2.5% [27].

Among the 130 patients, 43 (33.08%) were type 2 diabetic and 31 (23.85%) patients were hypertensive. This finding was similar to a dual case-control study by Scott TE et al., which confirmed a relationship between vasculitis and systemic diseases such as diabetes mellitus and hypertension [7]. All of the patients diagnosed with vasculitis were smokers; however, it was also noted that among the 130 patients studied, 57 of them were smokers against 73 who were non smokers. A smoking and rheumatology study by Struthers GR et al., [28], and an aetiological study by Kumar S et al., [29], suggested that there was a significant relationship between smoking and vasculitis. The difference from the norm observed in present study when compared to other papers may be because among the 57 smokers only three had developed vasculitis. Among the 130 patients studied, only 36 (27.69%) of them had involvement of the short saphenous system. Among the three with vasculitis, none of them had short saphenous vein involvement. This is contradictory to a cross-sectional population study [30] which confirmed that 40% of all ulcerated legs showed potentially surgically curable circulatory disturbances.

All the patients with vasculitis presented with painful ulcers. Among the 130 patients studied, only five had painful ulcers. These painful ulcers were also present in the worldwide relief study by Jantet G [31]. All patients with vasculitis also presented with fever.

In ulcers due to vasculitis which is a systemic disease patient usually complains of fever, weight loss, fatigue, joint pain, rash and is associated with an increase in acute phase reactants like ESR and CRP. Positive serological tests for Anti-neutrophil cytoplasmic antibodies (ANCA), Antinuclear Antibody (ANA) etc., are usually present. The skin surrounding the vasculitic ulcer was noted to be normal before the onset of the ulcer and also after the ulcer develops. This makes an important clue to diagnosis differentiating

it from venous ulcers [32]. Bacterial colonisation and secondary infection play a significant role in delayed wound healing with *Staphylococcus aureus* being the most common pathogen [33]. A biopsy from the edge of the ulcer helps in cases with definite histopathological features, such as pyoderma gangrenosum and cutaneous small-vessel vasculitis was confirmed by an aetiological study [25]. In this study, vasculitis was confirmed only by performing an edge-wedge biopsy. Elastic crepe bandages are the most important form of treatment for venous ulcer patients [34]. All the patients in this study were subjected to local dressings and Bisgaard's line of management.

Limitation(s)

The small sample size and lack of follow-up were the limitations of the study. Further long-term multicentric studies must be conducted to confirm the prevalence and the role of various risk factors in CVI in the Indian population.

CONCLUSION(S)

The prevalence of vasculitis was found to be 2.3% in this study. Two of the three patients had an active ulcer (66.7%) while one patient had a healing ulcer (33.3%). The presence of painful ulcers of the lower limb with a history of fever and upon investigation, elevated levels of CRP, ESR rate, increased total counts, and eosinophil counts should raise flags and the surgeon should consider evaluating for vasculitis in addition to the workup for varicose veins. If vasculitis is diagnosed, surgical treatment for varicose veins should be deferred till appropriate treatment for vasculitis is completed first. In this study, authors have used methylprednisolone 40 mg per day for four weeks followed by 10 mg per day for two weeks which helped in the resolution of the vasculitis ulcer. The patient was taken up for surgery two weeks after completion of the course of steroids and recovered fully.

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