

Original Research Article

Clinico-epidemiological study of stasis eczema

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ABSTRACT

Background: This study was done to determine the epidemiological aspects of stasis eczema and the association of various risk factors of the disease in the local population.

Methods: This cross-sectional study was done at a tertiary hospital in southern India over a period of 1 year. Epidemiological and clinical data of stasis dermatitis patients above 20 years of age were recorded. Data was tabulated and analyzed using Microsoft excel software.

Results: Of the study population of 120 prevalence is found to be highest in the age group of 50 to 60 years (42.5%) and males are more commonly affected. Occupation involving prolonged standing or sitting and lack of exercise activity is found to be a significant risk factor. The commonest skin finding in present study is eczema (80%). The most common complication was ulcer which was seen in 12.5% of our patients. Reticular veins are the most common dilated veins seen in our patients. About 70% of patients in present study fall under C4a stage of CEAP classification. About one half of symptomatic patients in present study (53.3%) had no radiological evidence of incompetent veins. Among patients with valvular incompetence, perforator veins were most commonly found to be incompetent (62.5%) followed by involvement of the saphenous venous system (23.2%).

Conclusions: The study confirms the importance of environmental factors in the development of stasis eczema. There is a ten-fold higher prevalence of the disease in men in our population compared to previous studies which invariably reports a female preponderance.

Keywords: Epidemiology, Stasis eczema, Valvular incompetence

INTRODUCTION

Venous eczema, a term that is synonymous with stasis dermatitis and gravitational eczema is a common condition that occurs secondary to venous hypertension. It usually presents to the dermatologist as eczematous lesion around the ankles and lower legs which are the common cutaneous sites which gets affected by chronic ambulatory venous hypertension.¹ In India it commonly affects people of low socio-economic groups which often

forces people to change occupation out of compulsion leading to adversity on the quality of life (QoL) of the individual. Though it is a common condition affecting adolescents to elderly, the etiological aspect of the disease is not completely understood.²

Thus, this study was done to assess the clinico-epidemiological profile and to evaluate the risk factor of patients with stasis eczema in the tertiary care setup of our hospital in Chennai, Tamil Nadu, India.

METHODS

This study was carried out as a cross sectional epidemiologic survey of stasis eczema conducted from July 2015 to July 2016.

All Patients attending dermatology outpatient department having signs and symptoms of stasis eczema between the study period are randomly selected for the study. The sample size is 120. The subjects were interviewed in person. Detailed case history of each patient with reference to the duration and course of the disease, occupation, type of work, exercise activity, BMI, smoking, alcohol consumption, history of thromboembolism, family history, and number of pregnancies were obtained and recorded.

Questions regarding family history of varicose veins were asked pertaining to first-degree relatives and the information obtained were recorded. Leading questions were asked about the nature of their occupation and patients were categorized into three groups.

- Occupation involving prolonged sitting
- Occupation involving prolonged standing, or
- Those who are actively moving.

The first 2 groups were merged for analysing logistic regression. Questions regarding the amount of physical activity are put forth and based on the information obtained patients were divided into 4 categories, and subsequently were combined into 2 categories for logistic regression analysis:

- Those with less than 1 session of exercise (of at least 15-minutes duration) per week or
- At least 1 session per week (of at least 15-minutes duration).

All female patients were questioned about the marital status and the number of pregnancies if any. First trimester abortions and fetal demise were also considered in the number of pregnancies. Patients were quizzed about their life style habits like cigarette smoking and consumption of alcohol and the data were quantitatively recorded in a standardized questionnaire. For logistic regression, they were further categorized into:

- never smoked or less than 1 year of smoking
- smoker (at least one year of smoking).

Alcoholism

- No alcohol consumption ever or < 10 g alcohol per week for less than 1 year
- Consumption of alcohol (>10 g of alcohol per week for at least one year).

10 grams of alcohol is equivalent to one standard beer, 100 ml of wine or a nip of spirits (30 ml). Height, weight

and body mass index were noted. Fasting and post prandial blood sugar, fasting lipid profile, complete haemogram, peripheral smear, liver and renal function tests were done to detect associated disorders and for starting treatment. USG abdomen, venous doppler of the affected limbs were taken according to the needs.

Venous data collection

Patients were asked about venous symptoms like heaviness of legs, pain, edema, pigmentation and ulcer and the information are entered in the standardized questionnaire. Any past history of venous diseases and treatments taken for the same are recorded. Clinical examination of the patient is done initially in the sitting posture and the findings are noted. Patient is then asked to stand and examined for the presence of varicose veins. The venous system which is affected by the varicosity in the individual subject are noted and the subject is further examined for the presence of reticular veins, telangiectasia, ulcers, lipodermatosclerosis, atrophy blanche and other findings. The information collected are recorded for statistical analysis. All the patients in present study are referred to a vascular surgeon and venous doppler ultrasound examination of the limbs was performed and the results are recorded. Subjects were considered to have venous symptoms if they complained of any of these 3 symptoms.

- Pigmentation
- Eczema
- White atrophy (atrophy blanche)
- Induration (lipodermatosclerosis)
- Healed ulcers with scar and
- Active leg ulceration.

The presence of edema involving the pre-tibial or malleolar areas was also recorded. If positive history regarding deep vein thrombosis or superficial thrombophlebitis are found in any of the patients they are referred to a vascular surgeon for detailed evaluation and managed accordingly with anticoagulation therapy as and when required. Varicose veins were defined as dilated, tortuous, superficial subcutaneous veins, either visible or clinically palpable with the patient standing. They were classified as follows.

- Saphenous varicose veins were those involving the saphenous trunks which include the great saphenous vein and the small saphenous veins or the tributaries of the great saphenous vein
- Other subcutaneous varicose veins that did not involve the saphenous veins were classified as non-saphenous varicose veins.

Criteria for classifying the patient as having saphenous varicose veins

If patient had at least 1 varicose vein involving saphenous system in one lower limb or both.

Criteria for classifying the patient as having non-saphenous varicose veins

Patients having non-saphenous varicose veins in either 1 or both lower limbs.

Based on the history and clinical examination noted, the patients in the study were classified according to the International consensus committee protocol which is based on clinical, etiological, anatomical and pathophysiological data (CEAP).

Table 1: Clinical classification.

Clinical classification	
C0	No visible or palpable signs of venous disease
C1	Telangiectasia or reticular veins
C2	Varicose veins
C3	Edema
C4a	Pigmentation and / or eczema
C4b	Lipodermatosclerosis and/or atrophy blanche
C5	Healed venous ulcer
C6	Active venous ulcer
C S	Symptomatic including ache, pain, tightness, skin irritation, heaviness, muscle cramps, and other complaints attributable to venous dysfunction.
CA	Asymptomatic

Table 2: Etiologic classification.

Etiologic classification	
Ec	Congenital
Ep	Primary
Es	Secondary (post-thrombotic)
En	No venous etiology identified

Table 3: Anatomic classification.

Anatomic classification	
As	Superficial vein
Ap	Perforator vein
Ad	Deep vein
An	No venous location identified

Table 4: Pathophysiologic classification.

Pathophysiologic classification	
P r	Reflux
P o	Obstruction
P r,o	Reflux and obstruction
P n	No venous pathophysiology identifiable

Fasting and post prandial blood sugar, fasting lipid profile, Blood haemogram, peripheral smear, liver and renal function tests are done to detect associated disorders and for starting treatment. USG abdomen, venous doppler of the affected limbs are to be taken according to the needs.

Those patients with associated vascular pathology are periodically reviewed by a vascular surgeon and managed accordingly. Patients are advice regarding limb elevation at rest, usage of crepe bandage and are treated with topical and systemic therapy according to needs.

Table 5: The Widmer classification of chronic venous insufficiency.

Classification	Symptom
I	Corona phlebectatica parapatries, mild edema
II	Hyperpigmentation, lipodermatosclerosis, atrophy blanche, edema, eczema
III	Healed or active ulcer

Follow up procedures/visits

Patients are advised to come for review after 1 week. The reports of all the investigations are collected and recorded and classified. Patients are started on appropriate treatment.

Statistical analysis

The collected data was entered for analysis in Microsoft Excel. This data was exported to statistical package for social sciences software (SPSS) version 22.0. Mean, standard deviations and range were employed to describe continuous variables, while frequency distributions were obtained for dichotomous variables.

The study was approved by the institutional ethics committee and all procedures performed were in accordance with the ethical standards of the institutional ethics committee.

RESULTS

About 86.5% of the affected patients were above 50 years of age. The prevalence is found to be highest in the age group of 50 to 60 years (42.5%). Advancing age is a significant risk factor for the development of the disease.

Table 6: Age distribution.

Age	Number of cases (n=120)	Percentage
20-30	-	-
30-40	-	-
40-50	16	13.3
50-60	51	42.5
60-70	36	30
>70	17	14.2

The prevalence of the disease is common in the male population as about 90.8% of the patients in present study are males. This is a significant finding considering the fact that the previously reported studies in the European

and American literature finds the chronic venous disease to be common in the female gender.

Table 7: Gender distribution.

Sex	Number of cases	Percentage
Male	109	90.8
Female	11	9.2

Occupation involving prolonged standing or sitting and lack of exercise activity is found to be a significant risk factor as more than three fourth of the patients affected by the disease had both the associated risk factors.

Table 8: Risk factor distribution.

Risk Factors	Number	Percentage %
Activity (prolonged sitting/standing)	88	73.3
Exercise (less than once a week)	97	80.8
BMI>25	74	61.7
Smoking	58	48.3
Alcoholism	35	29.2
History of thromboembolic disease	-	-
Family history	14	11.7
Pregnancy	7	5.8

Table 9: Prevalence of skin changes.

Symptoms and signs	Number of cases (N=120)	Percentage
Pain	54	45
Pigmentation	74	61.7
Eczema	96	80
Edema	35	29.2
Induration	27	22.5
Numbness	5	4.7
Claudication	8	6.7
Telangiectasia	11	9.2
Atrophy blanche	6	5

The commonest skin finding seen in the patients in present study is eczema (80%) followed by pigmentation

Table 13: Prevalence of incompetent veins in symptomatic patients.

	Presence of venous symptoms and signs without incompetent veins	%	Presence of venous symptoms and signs with incompetent veins	%
Number of patients	64	53.3	56	46.7

About 70% of patients in present study fall under C4a stage of CEAP classification which implies majority of patients present at the stage of pigmentation with or

(61.7%) and the least common sign and symptom were atrophy blanche (5%) and numbness (4.7 %) respectively.

Table 10: Prevalence of complications.

Complications	Number	Percentage
Ulcer	15	12.5
Discharge	09	7.5
Bleeding	-	-
Cellulitis	11	9.2
Lipodermatosclerosis	10	8.3
Superficial thrombophlebitis	-	-
Deep vein thrombosis	-	-

The most common complication found in our patients was ulcer which was seen in 12.5% of our patients followed by cellulitis which was found in 9.2% patients. Reticular veins are the most common dilated veins seen in our patients. Among the saphenous system of veins varicosities were commonly seen in the great saphenous system.

Table 11: Prevalence of varicose vein.

Varicose veins	Number of patients	Percentage
Great saphenous vein	13	10.8
Small saphenous vein	05	4.2
Reticular veins (<4mm)	26	21.7

Table 12: CEAP classification.

CEAP classification	Number (N=120)	Percentage
C1- Reticular veins (<4 mm)	3	2.5
C2- Varicose veins (>4 mm)	2	1.7
C3- Edema	12	10
C4- Skin changes		
C4a- Hyperpigmentation and /or Eczema	84	70
C4b- Lipodermatosclerosis	4	3.3
C5- Skin changes with healed ulceration	5	4.2
C6- Skin changes with active ulceration	10	8.3

without eczema. Early diagnosis of the disease with appropriate treatment and risk factor modifications are warranted to prevent the disease progression.

About one half of patients in present study (53.3%), though had signs and symptoms of chronic venous disease had no radiological evidence of incompetent

veins. This signifies the importance of clinical diagnosis in the early treatment and prevention of progression of the disease.

Table 14: Prevalence of valvular incompetence.

Incompetent venous system	Number of patients' valvular incompetence (N=56)	Percentage
Saphenous venous system	13	23.2
Perforator veins	35	62.5
Both saphenous and perforator incompetence	8	14.2

Among patients with valvular incompetence, perforator veins were most commonly found to be incompetent (62.5%) followed by involvement of the saphenous venous system (23.2%). Only 14.2% of them had involvement of both perforator and the saphenous venous system.

DISCUSSION

Chronic venous insufficiency (CVI) of the lower extremities is the principle cause of stasis eczema and the other cutaneous changes and ulceration that is associated with the disease. Varicose veins are so common in the general population that it accounts for about 75% of all chronic leg ulcers. At least 1 % of general population get affected by venous ulcers during their lifetime and it causes considerable morbidity to the patient with the quality of life getting affected considerably. Besides chronic venous disease is difficult to cure which further compounds the problem.³ A number of risk factors play a significant role in the development of chronic venous disease. These include

Age

Stasis eczema is a disease of middle age and the elderly. The disease usually presents in the fifth decade of life with an increasing prevalence as the age advances.⁴

Sex

Higher prevalence is seen in women which is probably related to pregnancy. Female to male ratio is estimated to be 3:1.

Trauma

Mechanical trauma or fracture that involve the legs can damage the venous valves inadvertently leading to the development of chronic venous disease. Any history or current evidence of deep vein thrombosis can damage the deep venous system which could affect the normal venous drainage system leading to the development of venous hypertension and its sequelae. Superficial

thrombophlebitis damages the superficial venous system which could lead to ambulatory venous hypertension.

Hereditary

Abnormalities in the FOXC2 gene, Factor V mutation and Congenital absence of valves in the superficial venous system has been suggested as a risk factor.

Genetic conditions like Klippel-Trenaunay syndrome, Ehlers-Danlos syndrome and cerebral autosomal dominant arteriopathy with subcortical infarcts and leukoencephalopathy (CADASIL) has been reported to be associated with stasis eczema.⁵

Occupation and life style factors

Any occupation involving prolonged standing or sitting and sedentary life style with lack of physical activity are recognised risk factors. Western diet, straining during micturition, western style toilets have also been suggested with equivocal evidence.

Pregnancy

Hormonal factors are implicated as a cause in pregnancy. Varicose veins are usually seen in the first trimester of pregnancy and are believed to be due to the effect of progesterone on venous dilatation and valvular insufficiency.

Smoking, diabetes and atherosclerosis

Disturbance in the microcirculation is critical to the development of chronic venous disease (CVD). The endothelium plays an important role in regulating the vascular tone and is a key player in achieving haemostasis after an injury. All factors that can damage the vascular endothelium like infection, injury immune mediated diseases, genetic predisposition, diabetes mellitus, environmental factors, smoking, and atherosclerosis leads to a compromise in the microcirculation.

Miscellaneous

Mutations in Prothrombin gene, antithrombin deficiency, antiphospholipid antibody syndrome, deficiency of protein C and S and elevated homocysteine levels in blood are also implicated.⁶

Various theories like fibrin cuff theory, stasis theory and inflammatory trap theory have been put forth to explain chronic venous insufficiency. Dysregulation of pro-inflammatory cytokines and various growth factors like tumor necrosis factor (TNF) -alpha, TGF-beta and matrix metalloproteinases lead to the development of chronic ulcers.⁶

The age wise distribution of chronic venous disease of lower limbs in present study is shown in Table 6. As stated earlier, the incidence of chronic venous disease is common after the fifth decade of life. In a cross-sectional study conducted in the French population to assess the risk factors, prevalence and clinical pattern of chronic venous disease, the prevalence was found to increase with the advancing age with the highest prevalence reported in patients above 80 years of age.⁷

In present study, more than 85 percent of the patients were above 50 years of age which shows age is a significant factor in the development of the disease. 42.5 % of these patients were in the age group of fifty to sixty years who are still a part of the working population in the Indian community which adds to the socio-economic burden of the family and the society as a whole. The clustering of cases between the age group of 50 to 60 years of age may be partly due to under reporting of the cases below 50 years of age probably because of milder symptoms and lesser patient attendance to the hospital beyond 60 years of age because of increasing morbidity associated with the disease in advancing age groups. None of the patients in our cross-sectional study were below 40 years of age with the youngest patient being 43 years old and the oldest being 78 years old.

The gender distribution of patients in present study are shown in Table 7. Chronic venous disease has been widely attributed in the literature to be favouring the female gender. In the study conducted in France mentioned above there was a threefold higher prevalence of non-saphenous varicose veins in the female gender in comparison to male gender. In many other studies conducted to assess the sex related difference in prevalence it was found that a higher female-male ratio existed, with the exception of the Basle Study III and the Edinburgh Vein Study, in which a male preponderance was found.⁸

However, in our society the disease appears to be prevalent in the male population in a grossly higher proportion compared to the female gender. The male to female ratio in present study was approximately 10: 1. This could be attributed to a number of socio-cultural

factors including occupation involving prolonged sitting or standing, smoking, alcoholism, trauma which are more prevalent among men in our society. Although pregnancy and hormonal influences are recognised risk factors for the development of chronic venous disease in women, they seem less relevant in our community which may point to some unrecognised socio-cultural differences in the Indian population compared to the western population.

A large-scale study comparing the prevalence of chronic venous disease in the rural and urban women in India might throw some light on the socio-cultural influences affecting the disease in women. Furthermore, selection biases or reporting biases can occur in studies that are based on subject self-evaluation or in studies in which sampling is drawn from clinical practice.

The distribution of risk factors among the study group is shown in Table 8. Among the various risk factors associated with the disease about 73 % of the patients had an occupation which involved prolonged standing or sitting of which majority of them belonged to semi-skilled and unskilled occupation. The most common occupation encountered were industrial workers and shopkeepers which together contributed to 28 percent of the risk group.

The implication of this finding would be in convincing the affected individual for a change of occupation which is more disease friendly, an important intervention in altering the progression of the disease which in many cases was practically impossible as the patients encountered were ill equipped for an alternative occupation. Such patients are candidates for venous surgery which involves removing the underlying functional defect which help in lessening the economic and psychosocial burden of the affected patient.

In the studies reported in the literature, lack of exercise was found to be an independent risk factor for the development of varicose veins in men. This is consistent with our understanding of the positive influence of the calf muscle pump function on the venous system thereby preventing the development of varicose veins. The potential benefit of exercise lies in the fact that using the calf muscle pump leads to reduction in the ambulatory venous pressure.⁹ However, the evidence regarding daily activity and exercise levels must be cautiously interpreted because the data collected depend primarily on patient reporting and are thus prone to recall bias.

The significance of smoking, alcoholism, and pregnancy in chronic venous disease could not be made out from present study as we did not have a control group and smokers and alcoholics comprised only about 48.3 % and 29.2 % respectively. Not surprisingly 68% of patients who presented with active or healed venous ulcers were smokers. Smoking is a significant factor which may retard any attempt at halting the disease process as it

affects the wound healing due to its interaction with the collagen synthesis and matrix metalloproteinase activity. Pregnancy was not found to be a significant factor in present study as the disease itself is found to be drastically less common among women in our community. However, pregnancy was found to be a strong risk factor in various European studies where the disease has a high female preponderance.⁷ These differences in prevalence however were mainly in relation to first and second pregnancies.¹⁰

It is not surprising that 61.7% of the patients in the study had BMI > 25 (overweight) of which 18% had BMI exceeding 30 (obese) considering the relatively higher BMI values of Asian population compared to the western population. However, considering the fact that only present weight was measured and the body weight is subject to changes with age and time it could be said that the influence of overweight on development of varicose veins could not be analysed with certainty. In the study conducted by capentier et al, overweight was not found to be a significant factor for the development of the disease. However, height was found to be a significant risk factor in both men and women.⁷ Height is directly related to venous pressure in the standing position and hence this association might have some physiological significance. This makes it difficult to assess the influence of BMI on chronic venous disease as body mass depends on the relation of weight to height.

None of the patients in present study had a prior history of thromboembolic disease or any history of venous surgery in the past. However, in the European study by capentier et al, history of thromboembolism though less common was found to be a significant risk factor.⁷

About 11.7% of the study group had a family history of chronic venous disease, all of them were first degree relatives with no hereditary disease running in the family. This may not be a significant finding considering the high prevalence of stasis syndrome in the general population although family history of the disease in the first-degree relatives is a strong risk factor reported in the previous studies.⁷

The prevalence of skin changes in the study group is shown in Table 9. Pigmentation and eczema were found in 61.7% and 80% of patients respectively. Most patients presented to the dermatology clinic at the stage of pigmentation and eczema as 70 % of patients in the study group fall under C4a stage of CEAP classification which is shown in Table 12. The prevalence of trophic changes in the skin was found in the same range as previously reported in the European population, particularly for leg ulcers and their strong relation with age. However, the prevalence of telangiectasia and atrophy blanche were found to be less in present study. Overall the presence of venous symptoms was high in present study, with a significantly high disproportion between women and men.

Lipodermatosclerosis, venous ulcer and cellulitis were the common complications encountered as listed in Table 10. Advancing age was reported to be a strong factor for the development of complications which was also noted in present study. Lipodermatosclerosis was found in 10 patients with or without venous ulceration out of which 4 patients (3.3%) came under C4 b stage of CEAP classification. In the study group 4.2% patients had skin changes with active ulcer while 8.3 % had skin changes with healed ulcer and were classified under C5 and C6 stages respectively. The total number of patients presenting in the C1 and C2 stages of the disease were less which can be attributed to the lack of skin changes in the early stages of the disease.

All the patients in the study group were referred to the vascular surgeon for Venous Doppler study of which 46.7 % of them were found to have incompetent veins either in the saphenous venous system or the perforator veins. Out of them, 62.5 % had perforator vein incompetence while 23.2% had involvement of saphenous venous system and 14.2% had both perforator and saphenous venous incompetence. The data is shown in Table 14. It becomes important to distinguish between saphenous and nonsaphenous varicose veins because saphenous varicose veins have stronger association with cutaneous trophic changes compared to non-saphenous varicose veins. However, in present study perforator incompetence was found to be more common than the incompetence of saphenous venous system as could be inferred from the data mentioned above.

Thus, it is clear that stasis eczema is a disease of the venous system influenced by physical, occupation, environmental and life style factors.

CONCLUSION

This cross-sectional study conducted in the Indian population has found a significant association between the various risk factors and the chronic venous disease. Of note advancing age along with occupation involving prolonged standing or sitting is found to be very common in the affected patients in our community. The study confirms the importance of environmental factors in the development of the varicose veins and stasis eczema with occupation, lack of exercise, smoking and alcohol all playing a significant role. The major highlight of present study is the difference in the gender prevalence where there is a ten-fold higher prevalence of the disease in men in our population compared to previous studies which invariably reports a female preponderance.

A wide range of presentation of the disease was noticed in the study with the majority of patients reporting to the hospital after the onset of skin changes notably pigmentation and eczema. As many patients with chronic venous insufficiency are referred late, when the tissue changes of lipodermatosclerosis and chronic venous ulcer has already set in, it becomes difficult to cure the disease

and any intervention becomes frequently unsuccessful. The long-term goal would be to identify the high-risk patients at an early stage and appropriate preventive measures be initiated to prevent disease complications. Future research must be directed towards identifying the additional risk factors for chronic venous disease and stasis eczema and predictors for venous ulcer, with effective preventive measures for both.

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