

Original Research Article

Case-control research on the impact of body mass index (BMI) on the occurrence of ulcers in venous disease patients

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Abstract: Background: To identify and address the factors which lead to ulceration in patients with chronic venous disease is essential to prevent progression of disease. Obesity is one such controversial factor. The aim of our study was to assess the influence of body mass index on the development of ulceration in patients with venous disease. We also analysed other risk factors that might lead to progression of disease to ulceration.

Aim and objectives: The aim of this study is to evaluate the impact of Body Mass Index on the occurrence of ulceration in venous disease patients.

Methods: This prospective case-control study was carried out at ASRAM Medical College, Eluru, AP in the general surgery department. Every patient who participated in the trial had a venous duplex that was documented as having venous insufficiency. A comparison of 130 cases with venous ulcers that were either active or healed and 130 controls without ulcers was conducted. A survey was given out to examine the variables affecting the likelihood of acquiring an ulcer. The clinical class of venous illness was identified after a clinical evaluation of the patients. Using standardised equipment, the patient's height, weight, and body mass index(BMI) were measured.

Results: The study's sample's mean BMI was 29.04 pounds. 260 individuals were enrolled, and 38.8% of them were obese and another 38.8% were overweight. Inactive or healed ulcers were present in 45.5% of the obese patients. Patients with recurrent ulcers made up 77.8% of the population and were either overweight or obese. However, there was no statistically significant difference when comparing the body mass index between the cases and controls. A strong connection between ulceration in venous disease and older age, male gender, deep vein thrombosis, and prolonged durations of standing was discovered by multivariate analysis.

Conclusion: According to our study, there is no connection between body mass index and ulceration in venous disease patients. Venous ulceration is linked to advanced age, male gender, deep vein thrombosis, and periods of extended standing. However, the researchers did take into account the likelihood that overweight individuals may have a different pathophysiology of venous illness, and as a result, they concluded that venous duplex alone might not be a sufficient diagnostic tool for selecting obese patients for subsequent trials. In order to establish obesity as a risk factor for ulcers, we suggest that additional research be conducted in this area and that obese individuals in the control group be monitored to see if they experience ulcers in the future.

Keywords: Chronic venous disease; Body mass index; Obesity; Venous duplex.

1. Introduction

Chronic venous insufficiency (CVI) affects the lower limbs' venous system. It is a spectrum of disorders that affect the skin and subcutaneous tissue, with venous ulcerations being the most severe symptom.

The Vein Consult Program assessed more than 91000 patients from various locations and discovered that CVI was 63.9% prevalent globally. [1] It is the major factor behind leg ulcers.[2] Although active or healed ulcers are found in roughly 1.0% of the adult population, the prevalence of venous ulcers is estimated to be around 0.3%.[3]

Venous ulcers are an important concern in the healthcare system due to the morbidity they cause, the significant socioeconomic toll they take on in terms of costs, and most importantly the diminished quality of life they are connected with.[4] Venous ulcers are difficult to heal and require longterm therapy. 97 percent of patients get recurring ulcers Within 10 years of 1st ulcer. According to a systematic review Venous ulcer moreover have a deleterious effect on all elements of everyday life.[5] A systematic review showed that venous ulcers, hence, have a negative impact on all aspects of daily living.[6] Lifestyle modifications continues to be crucial in the treatment of venous ulcers. Thus, significant thought has gone into identifying the elements that raise the likelihood of ulceration in venous disease patients. This would enable us to target people who are more likely to develop ulcers early and take the necessary precautions to stop the disease's progression.

Older age, male sex, obesity, familial history, a history of phlebitis, and prior leg injuries are some of the risk factors for chronic venous insufficiency.[7] Yet, there is debate concerning the significance of obesity. According to several studies, being overweight is a separate risk factor for skin changes in venous illness and that there is a positive relation between body mass index and the clinical severity of venous disease.[8] According to recent research, obesity is a risk factor for females compared to males. Western studies that have examined this area have largely been descriptive studies, with a few employing appropriate controls. Also, compared to the Indian population, where we typically see more patients with advanced forms of venous illness, the population included in our trials had more incidences of early disease.

The purpose of this study is to compare individuals with venous ulceration to patients who have venous illness but no ulceration while taking into account the aforementioned information.

2. Aim

The aim of this study is to evaluate the impact of Body Mass Index on the occurrence of ulceration in venous disease patients.

3. Material and methods

3.1. Study design

This study is an institutional based prospective case control study.

3.2. Study area

Study was conducted at Alluri Sitarama Raju Academy of Medical Sciences (ASRAM) of Eluru District, Andhra Pradesh.

3.3. Study period

Study was conducted for two years from March 2020 to February 2022.

3.4. Study Population

Patients with a documented venous insufficiency using a duplex scan were enrolled into the study after signing an informed consent.

3.5. Sample size

A total of 260 patients of which 130 were cases with venous ulcers that were either active or healed and 130 were controls without ulcers. (who fits inclusion and exclusion criteria).

3.6. Methodology

The data was collected based on questionnaire, venous duplex scan, clinical examination. Their BMI was also calculated from weight in kilograms and height in meters. The BMI was classified as per criteria for Asian

population, under weight (<18.5kg/m²), normal weight (18.5-22.9kg/m²), over weight (23-24.9 kg/m²), obese 1 (25-29.9 kg/m²), obese 2 (≥30 kg/m²). In the Out Patient Department, patients who had been enrolled in trial underwent a clinical examination applying the Clinical, Etiological, Anatomical, and Pathophysiological (CEAP) classification.

3.7. Inclusion criteria

Cases: Patients having a duplex scan confirming venous insufficiency and having an active or healed ulcer.

Controls: Patients having a duplex scan confirming venous insufficiency and did not have an active or healed ulcer.

Rationale for selecting controls: As compared to the general population, selecting controls who also have venous illness but no ulceration would help remove confounding factors that can contribute to the development of venous disease without necessarily causing the disease to proceed.

3.8. Exclusion criteria

Those who are not willing to participate or answer the questionnaire.

All patients with congenital vascular malformations

All patients with C0-C1 disease

All patients with ulcers due to causes other than chronic venous disease

Patients with acute deep vein thrombosis

Patients not advised duplex scanning

3.9. Diagnostic tool

All the patients who were recruited had a documented venous Doppler confirming venous insufficiency. The venous Doppler scans of bilateral lower limbs were done in the Department of Radiology, ASRAM, Eluru in TOSHIBA Xario ultrasound machine.

3.10. Statistical analysis

Data from the case report form was entered into the Epidata v 3.1 data entry software and then exported to SPSS. The analysis was performed by trained biostatisticians. Data was summarized as mean ± SD / median (range) for continuous variables, frequency along with percentage for categorical variables. Independent *t*-test was used to compare the continuous variables among the case and control. Similarly the Chi-square test was performed to compare the categorical variables among the case and control. The estimate of effect size were presented as odds ratio (95% CI). A multiple logistic regression was performed to analyse the adjusted effect of variables over the case and control. The goodness of fit was tested using Hosmer-lemshow test and McFadden's R square was reported. Additionally the continuous variables among the BMI sub-grouping was analyzed using ANOVA/ Kruskal-wallis test based on the normality along with pair wise comparison, the categorical variables were compared using chi-square test. All the analysis were performed using STATA I/C 13.1.

3.11. Ethical issues

Clearance from the institutional ethical committee was obtained prior to the start of the study. Written consent was taken beforehand for their participation.

4. Results

A total of 269 participants were enrolled in the trial. 9 patients were ultimately excluded, of which 4 patients had C1 disease and 5 patients lacked a venous Duplex. A total of 130 cases with C5 or C6 disease and 130 controls with C2 to C4 disease were examined. They all had venous duplex scans that were documented and showed venous insufficiency.[Graph 1]

Table 1. Age in different body mass index categories

BMI	n	Mean	SD	Range
18.5 - 24.9	54	46.02	13.92	18 - 80
25 -29.9	101	47.96	11.50	24 - 77
>= 30	101	46.24	11.21	22 - 70

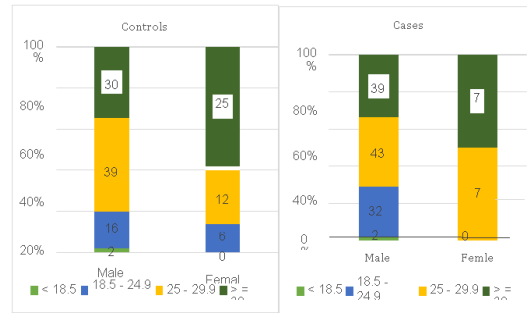


Figure 1. PRISMA flow diagram

[Table 1] Out of the 260 participants that were recruited for the study, 203 were men and 57 were women, with more men than women in both the case and control groups. Between the cases and controls, there was a statistically significant difference (OR 4.09 95

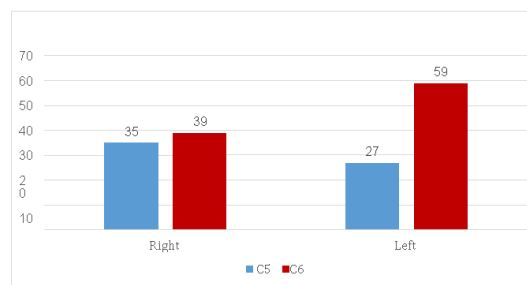


Figure 2. PRISMA flow diagram

Graph 2: Out of 130 cases, 30 patients have venous ulcers in bilateral limbs, making total number of effected limbs as 160, out of 160 effected limbs 74 are right lower limbs out of which 35 have C5 disease 39 have C6 disease and out of 86 affected left lower limbs 27 have C5 disease and 59 have C6 disease.

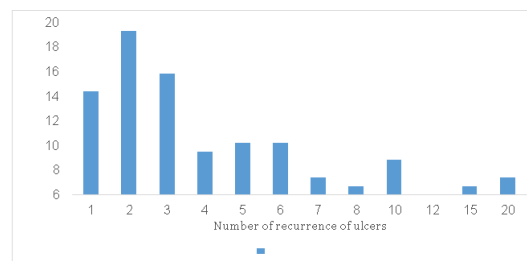
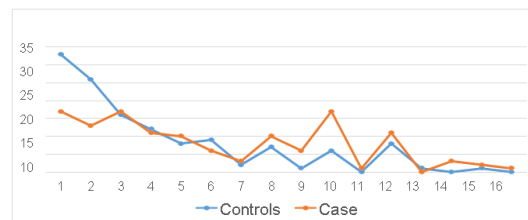


Figure 3. PRISMA flow diagram

72 patients (55.4%) of the cases developed recurrent ulcers, with a mean recurrence of 4.08 (Range- 1 - 20) Those who were overweight or obese experienced increased recurrences, however this was not statistically significant. (0.702) (p value) [Graph 3]

Table 2. Multivariate Analysis

Variables		OR(95% CI)	p-value
Age		1.03(1.01,1.06)	0.007
Deep Vein Thrombosis	No	ref	<0.001
	Yes	13.16(3.44,50.31)	
Gender	Female	Ref	<0.001
	Male	3.27(1.49,7.18)	
Body Mass Index		1.02(0.97,1.07)	0.4
Smoking	No	Ref	0.18
	Yes	1.6(0.81,3.16)	
Deep Venous Reflux in the Popliteal Vein	No	Ref	0.11
	Yes	1.75(0.88,3.48)	
Saphenofemoral junction Incompetence	No	Ref	0.06
	Yes	2.66(0.95,7.45)	
		1.64(0.77,3.51)	0.2

**Figure 4.** PRISMA flow diagram

In the study population, average standing time was 5.08 hours per day. Long times of standing between the controls and cases were statistically significant. p value equals 0.034 As a result, it can be regarded as one of the variables that is linked to ulceration in venous disease patients. (OR 1.16, 95% CI 1.08 - 1.26) [Graph 4] Using the factors that were found to be significant, a multivariate analysis was done.

Table 2: The model fit was good (p-value=0.48, Hosmer-lemshow fit statistics) and the variables included in the model have an r-square of 0.1998 (Mcfadden's). Hence, the following were found to be statistically associated with venous ulceration: Older age, male gender, Deep Vein Thrombosis and prolonged periods of standing.

5. Discussion

The most frequent venous problem observed in our institution's general surgery department is chronic venous insufficiency. Venous ulcers heal slowly and frequently reoccur. Because of this, they are linked to high morbidity and place a significant economical cost on both the patient and society [9]. Obesity prevalence is on the rise everywhere, even in India. Non-communicable diseases and obesity are strongly correlated [13].

In order to clarify the relationship between rising body mass index and ulceration in patients with venous insufficiency, we conducted this study in this context. With the aid of a standardised questionnaire, we also investigated additional risk factors that could accelerate the development of the condition into an ulcer. 130 cases had ulcers that were either active or healed, whereas 130 controls had no ulcers but had venous insufficiency that was medically confirmed. At a mean age of 46.7 years, the majority of our patient population was in their middle years. There were more men than women here. Only 21.9% of the participants in our study were female, despite the fact that females are typically thought to have more varicose veins than males. We discovered a substantial correlation between venous disease ulceration and male gender. Of the 260 patients that were enrolled, 38.8% of them were obese and another 38.8% were overweight. Inactive or healed ulcers were present in 45.5% of the obese patients. It was clear that majority of the venous insufficiency patients were obese or overweight. Regarding body mass index, there was no statistically significant difference between individuals who had ulcers and those who did not.

Obesity and severe stages of vascular disease have been associated as per prior studies that were conducted [10]. Yet, the majority of them have been linked to women but not to men [11]. A confirmed venous

insufficiency on a venous Doppler was a requirement for enrollment in our study. Research by Padberg et al. and the Bonn Vein study suggested that the pathogenesis in obese people is likely different because there may not be any anatomical evidence of venous insufficiency in them [12]. Examining additional etiological factors linked to late stages of the disease was secondary objective of our research. Age, gender, recurrent ulcers, hours spent standing, history of limb injuries, and history of deep vein thrombosis were among the variables we looked at. vein thrombosis, lifestyle choices, smoking, medical conditions, use of compression stockings, venous illness in the family, and oral contraceptive pill use are all risk factors [14]. With a mean recurrence of 4.08, recurring ulcers were present in 55.4% of the patients. This emphasises the significant morbidity that is linked to venous ulcers. Repeated ulcers would result in longer hospital stays, more missed workdays, and a greater total socioeconomic cost for the patient [15]. Overweight or obese individuals made up 77.8% of the patients with recurrent ulcers.

Only 41.9% of the study population had worn compression stockings, according to our data. Despite the fact that compression is the cornerstone of venous insufficiency treatment, this problem still arise. Just 10% of the patients reported routinely exercising, and the majority of them maintained sedentary lifestyles. Smokers made up 32.30 percent of the cases, which was a statistically significant difference between the two arms of study.

Most likely, we need to raise our patient's knowledge of the need to adjust their lifestyles and wear compression stockings as prescribed for the treatment of venous illness. In the study population, standing time averaged 5.08 hours per day.

Data showed a statistically significant difference between the controls and cases. Deep vein thrombosis and venous ulcers were highly correlated in our study, as has been the case in the majority of similar investigations. The duplex features of the patients and controls were also evaluated, and we discovered that they were comparable in both groups and throughout all body mass index ranges.

A significant relationship between ulceration in venous disease and older age, male gender, deep vein thrombosis, and prolonged durations of standing was discovered after multivariate analysis.

6. Limitations

We made every effort to try and reduce selection bias by trying to recruit contiguous patients. While our data on the etiological factors was based on the histories provided to us by the patients, we did have the recall bias component. Our data may not be typical of the full population because only those patients who presented to the hospital were used to recruit our patients from the out-patient clinic.

7. Conclusion

There was no association between body mass index and ulceration in patients with venous disease. Venous ulceration was linked to advanced age, male gender, deep vein thrombosis, and periods of extended standing. However, the researchers did take into account the likelihood that obese people may have a different pathophysiology of venous illness, and as a result, they concluded that venous duplex alone might not be a sufficient diagnostic tool to choose obese patients for subsequent trials. We suggest conducting more research in this area and keeping track of the obese patients in the control group to determine if they go on to develop ulcers. Then and only then will we be able to identify obesity as a risk factor.

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Conflicts of Interest: "The authors declare that they do not have any competing interests."

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