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Original article:

A study to assess the Association between Chronic Venous insufficiency of Lower limbs and Hemorrhoids

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Abstract

Introduction: The risk factors for both Hemorrhoidal disease and chronic venous insufficiencyof lower limbs include conditions that generally increase intra- abdominal pressure, such as constipation, diarrhea, pregnancy, delivery, obesity, standing for extended time periods, and chronic coughing.

Aims and objectives: To evaluate the prevalence of varicose veins among patients with hemorrhoidal diseases and to determine the association between hemorrhoidal disease and lower extremity chronic venous insufficiency.

Materials and method: The present study is a Case control study. This study is conducted at the department of Vydehi Institute of Medical Sciences and Research Centre. 82 patients wereincluded in this study.

Results: We showed that, more number of patients had chronic venous insufficiency in case group [24 (58.5 %)] compared to Control [13 (31.7%)] which was statistically significant (p=0.0024) and we also found that, more number of patients had Constipation [14 (34.4%)] in Control compared to Case [13 (75.6%)] it was statistically significant (p=0.0001).

Conclusion: We concluded that lower extremity chronic venous insufficiency is more common in patients with hemorrhoidal disease which increases intra-abdominal pressure. Factors identified as having a statistically significant association with hemorrhoids were CVD CEAP class and constipation. Further studies are needed to confirm the correlation between HDand CVD so that a common targeted Medical therapy can be developed for both these diseases.

Keywords: Hemorrhoidal disease, chronic venous disease.

Introduction

Hemorrhoidal disease is a very common condition that affects the anorectal area andis characterized by the distal displacement of the anal cushions, which results in associated symptoms.3 It is estimated that about half of the population would have hemorrhoidal disease at some point in their life and at any given point of time approximately 5% suffer from hemorrhoidal disease. 4 The prevalence of haemorrhoids when patients are assessed proctoscopically far outweighs the prevalence of symptoms, and the term should only be used when patients have symptoms referable to them.1Chronic venous disease (CVD) is an often overlooked disease manifested by a range of signs including edema , varicose veins, and reticular veins.The incidence of varicose veins in the Western population is estimated to be 25%-30% among women and 10%- 20% among men. The risk factors for both Hemorrhoidal disease and chronic venous insufficiency of lower limbs include conditions that generally increase intra-abdominal pressure, such as constipation, diarrhea, pregnancy, delivery, obesity, standing for extended time periods, and chronic coughing 5

Data on the coexistence of hemorrhoids with other conditions are also sparse 5

Most population-based information on anal symptoms is collected via patient surveys alone.However, many HD

symptoms are nonspecific, and without any confirmatory anal examination prevalence results can vary widely.[6,7] Some data are consistent with a common pathophysiological link between straining at stool, constipation, and obstetrical events such as pregnancy and delivery. Thesefactors are also involved in the development of chronic venous disease (CVD). So need for study is to evaluate the prevalence of chronic venous insufficiency of lowerlimbs among patients with hemorrhoidal disease and to compare its prevalence among patients not having signs and symptoms of hemorrhoidal disease and to confirm the correlation between hemorrhoidal disease and chronic venous insufficiency of lower limbs so that a common targeted therapy can be developed for both these diseases.

Methods

A prospective comparative assessment study of 82 (41 each group) patients attending OPD and admitted in the surgical department of Vydehi Institute of Medical Sciences and Research Centre. All patients underwent clinical examination with relevant investigations after obtaining an informed written consent.

Inclusion criteria:

1) All patients above the age of 18 years.
2) Patients of both sexes.
3) All patients with features of chronic venous insufficiency.
4) All patients with features of hemorrhoidal disease.
5) All patients willing to give informed consent.

Exclusion criteria:

1) Patients diagnosed as DVT.
2) Presence of concurrent arterial and venous diseases.
3) Patients attending emergencies.

After obtaining approval and clearance from the institutional ethics committee, the Patients coming to General Surgery OPD and IPD, patients fulfilling the inclusion criteria were enrolled for the study after obtaining informed consent.

Data will be collected on a pre-tested proforma which includes,

- History taking
- Clinical examination
- Outcome of the study.

Sample size was calculated by assuming the proportion of Varicose veins in the controlgroup as 35 and OR as 1.03 as per the study by Ekici U et al.1 The other parameters considered for sample size calculation, included were 80% power of study and 5% twosided alpha error. The ratio of cases and controls considered was 1:1 for sample size calculation. The following formula proposed by Kirkwood BR et al was used for samplesize calculation. 2

P1: Prevalence of exposure in cases group = 35 P2: Prevalence of exposure in control group = 18OR: Expected Odds Ratio =1.03

r: Sample size ratio Control / Case. =1

Alpha (α): Type 1 error rate= 0.84 Beta (β): Type 2 error rate = 1.960

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As per the above mentioned calculation, the required sample size was 39 cases and 39 controls. To account for non-participation of about 5%, another 2 cases and 2 controls will be included.
Hence the final required sample size would be 41 cases and 41 controls.

For statistical analysis data were entered into a Microsoft Excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the teststatistic is a chi-squared distribution when the null hypothesis is true. Without other qualifications, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fisher's exact test, as appropriate.
p-value ≤ 0.05 was considered statistically significant.

RESULT & ANALYSIS

Table 1: Grades of haemorrhoids in case group

Grades Of Haemorrhoids	Case
I	9
II	19
III	11
IV	2
Total	41

In Case Group, 9 (22.0%) patients had Grade I Haemorrhoids, 19 (46.3%) patients had Grades II Haemorrhoids,11 (26.8%) patients had Grades III Haemorrhoids and 2 (4.9%) patients had Grades IV Haemorrhoids.

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Table 2 : Comparison of Presence of varicose veins between the groups

Presence of varicose veins	Case	Control	TOTAL
Yes	24	13	37
No	17	28	45
TOTAL	41	41	82

Chi-square value: 5.9592; **p-value:** 0.0146

Odds Ratio: 3.0407 (1.2303, 7.5153)

In the Case group, 24 (58.5%) patients had Chronic venous insufficiency.

In the Control group, 13 (31.7%) patients had Chronic venous insufficiency.

Association of Presence of chronic venous insufficiency between the groups isstatistically significant (p=0.0146).

Table 3) Presence of varicose veins

Presence Of Varicose Veins	Case	Control	Total
C0	17	28	45
C1	10	5	15
C2	7	4	11
C3	4	2	6
C4	2	2	4
C5	1	0	1
C6	0	0	0
Total	41	41	82

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In Case, 17 (41.5%) patients had no signs of chronic venous insufficiency, 10 (24.4%)patients had C1, 7 (17.1%) patients had C2 and 4 (9.8%) patients had C3, 2 (4.9%) patients had C4 and 1 (2.4%) patient had C5.In Control, 28

(68.3%) patients had no signs of chronic venous insufficiency , 5 (12.2%)patients had C1, 4 (9.8%) patients had C2 and 2 (4.9%) patients had C3 and 2(4.9%) patients had C4.

Table4: Association of Constipation (Yes/No) between the groups

Constipation(Yes/No)	Case	Control	Total
No	10	27	37
Yes	31	14	45
Total	41	41	82

Chi-square value: 14.2330; **p-value:** 0.0001

Odds Ratio: 0.1673 (0.0639, 0.4376)In Case, 13 (75.6%) patients had Constipation (Yes/No).

In Control, 14 (34.4%) patients had Constipation (Yes/No).

Association of Constipation (Yes/No) among groups is statistically significant(p=0.0001).

Association of Age, sex, standing for prolonged period of time, Pregnency/Delivery between Groups is not statistically significant (p=0.7299).

DISCUSSION

Lower extremity venous insufficiency and hemorrhoidal disease are two clinical conditions that are commonly observed and negatively affect the quality of life of the patients.Chronic venous insufficiency is often associated with underlying modifiable(smoking, obesity, pregnancy, standing, straining during defecation and constipation, and deep vein thrombosis) or non-modifiable (female sex and genetic predisposition) risk factors. In most cases, hemorrhoidal disease stems from causes associated with anincrease in the intra-abdominal pressure (constipation, pregnancy, ascites, obesity, chronic coughing, and prostatism).

The present study is a Case control study. This study was conducted at the Department of Vydehi Institute of Medical Sciences and Research Centre over the period of October 2022 to November 2022. 82 patients were included in this study.The data of the patients, such as those related to age, height, and weight, were similar between the groups . These data are important for ensuring that the patients in the study and control groups have similar demographic characteristics.

There was a significant association between the two groups in terms of the incidence ofvaricose veins and chronic constipation ($p < 0.05$). Particularly, the incidence of C1and C2 varicose veins was significantly higher in the study group than that in the control group (28% and 17%, respectively;p=0.0146). This higher incidence in Case group suggests that hemorrhoidal disease and lower extremity chronic venous insufficiency may be caused by similar etiological factors.

In the present study, the incidence of chronic constipation was significantly higher in the study group (75.6%) than that in the control group (34.1%) ($p < 0.0001$).More number of patients had Constipation [14 (34.4%)] in Control compared to Case [31 (75.6%)] it was statistically significant (p=0.0001).Other variables such as sex, the number of births, working in a sitting or standing position for extended time periods, and chronic diseases were similar

between the two groups ($p > 0.05$).These findings were considered significant for demonstrating that chronic constipation may be a common cause of both the conditions. The study by Arora G et al. determined that chronic constipation is associated with many clinical conditions such as gastroesophageal reflux, anal fissures, anal fistula, diverticulosis, and colon cancer but particularly with hemorrhoidal disease.[7] A case control study was conducted by Ekici U et al in 2019 concluded that Lower extremity chronic venous insufficiency is more common in patients with hemorrhoidaldisease which increases intra-abdominal pressure which trigger both lower extremity chronic venous insufficiency and hemorrhoidal disease.

We showed that, lower number of patients had Pregnancy/delivery [9 (60.0%)] in Control compared to Case [13 (72.2%)] though it was not statistically significant ($p=0.4583$).

We observed that, lower number of patients had [18 (43.9%)] Standing for long time periods in Control compared to Case [23 (56.1%)] but this was not statisticallysignificant ($p=0.2694$). And most of the patients had [13 (31.7%)] chronic diseases in Control compared to Case [12 (29.3%)] but this was not statistically significant($p=0.8104$).

HD and CVD may have a common cause in the form of loss of vascular integrity, but there are few published papers on the coexistence of the two disorders and recent data are lacking.An early review of epidemiologic evidence for a link between HD and CVDhypothesized that chronic constipation associated with a low fiber diet was involved byincreasing intra abdominal pressure. It was suggested that this pressure would easily betransmitted to the hemorrhoidal plexus, which have no valves. The valves of the lowerlimb veins would offer initial protection but would eventually become incompetent andexpose the veins to elevated pressure. This hypothesis is supported by data from a Hungarian epidemiologic study of pregnant women, which found that around half witha diagnosis of HD also had constipation.

In a study conducted by Douglas MacKay et al concluded that the use of diet,lifestyle,and hydrotherapy in addition to botanical agents such as Aesculus hippocastanum, Ruscus aculeatus, Centella asiatica, Hamamelis virginiana, and bioflavonoids(Bioflavonoids: Diosmin, OPCs, and Hesperidin)can intervene in the pathogenesis of decreased vascular integrity.These bioflavonoids exhibit phlebotonic activity, vasculoprotective effects, and antagonism of the biochemical mediatorsof inflammation. Early intervention with these non-invasive therapies mayprevent time-consuming and expensive complications of both varicose veins and hemorrhoids.

CONCLUSION

Our prospective observational study demonstrated that lower extremity chronicvenous Insufficiency is more common in patients with hemorrhoidal disease which increases intra abdominal pressure. A chronic increase in this pressure causes conditions, such as constipation, which trigger both lower extremity chronic venous insufficiency and hemorrhoidal disease. Factors identified as having a statistically significant association with hemorrhoids were CVD- CEAPclass and constipation.Further studies are needed to confirm the correlation between HD and CVD so that a common targeted therapy can be developed forboth these diseases.

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