To evaluate the differences of risk factors in patients with lower extremity venous disease

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ABSTRACT

Objective: To determine whether there is a difference between risk factors in patients diagnosed to have clinically documented lower extremity venous disease after confirming the diagnosis radiologically by ultrasonographic and venographic evaluation.

Methods: This study was performed from January 2002 to January 2005 in Bursa, the fourth biggest city of Turkey, situated in the west of the country in the Marmara Region. The study center is a private imaging center working in conjunction with the Department of Health, which performs diagnostic, and therapeutic vascular protocols in the region. Five hundred and fifty-three cases with clinically and radiologically documented diagnoses were evaluated with Multi-Variate Statistical Package 3.13 for the presence of pre-defined clusters of 14 different variables. Other statistical analyses were performed by the Statistical Package for Social Sciences, version 13.0.

Results: Three different clusters were defined. The variables used to define the clusters were: age, gender, educational level, presence of smoking, amount of smoking (pack/per year), disease symptoms, presence of heart disease, and radiologically documented diagnosis.

Conclusions: Chronic venous insufficiency and varicose veins are venous system diseases that are most commonly present in association with more than one concomitant risk factor.

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Lower extremity venous diseases refer to a spectrum of illnesses that are common and that can present with a wide range of clinical findings and symptoms.[1-7] They are one of the leading causes of increased morbidity.[2,8-23] In developed countries, they affect more than half of the population.[24-29] They reduce quality of life and the productivity of the working population.[4] The etiological cause is insufficiency of the perforating veins leading to venous reflux. Reflux causes attenuation in the strength of the venous wall, as well as hemodynamic dysfunction.[2,24,30-32] Deep veins and their valves lose their functions leading to formation of a new current from thin, inflexible deep veins through surface veins. This reversed current is referred to as reflux. Formation of varicose veins secondary to reflux is the result. Pain, edema, color change, ulcers, and trophic changes in the legs are the main symptoms. Diagnosis is usually reached via physical examination and clinical findings. Doppler ultrasonography and venography help to differentiate secondary etiologic factors that may cause chronic venous failure and also help to evaluate deep venous structures.[21,33] Although the presented data are insufficient and controversial, previous studies for risk factors of chronic venous insufficiency and varicose veins suggest age, gender, working conditions, duration of work in a standing position, genetic tendency, and geographical differences as predisposing factors.[8,9-15] It is estimated by the authors that one-third of men and women aged between 18-64 have varicose veins.[14] Diseases most frequently accompanying chronic venous insufficiency include diabetes mellitus (DM) in women and hypertension (HT) in men.[2,5] In most of the epidemiological studies, particularly those held in Europe, chronic venous failure and varicose veins are considered risk factors for the population.[2,5,6,24-29] The non-hospitalized population has much less knowledge about risk factors.[8] In Turkey, most of the studies focus on deep venous thrombosis (DVT), which is one of the main causes of hospitalization. No clinical or epidemiological studies have been reported. Although there are various studies on the prevalence, epidemiology, risk factors and preventive methods for arterial diseases,

no consensus on venous diseases has been reached, and hence, no classification of risk factors is available.[34-37] An abundance of lower extremity venous diseases and their broad clinical spectrum are the main reasons for this confusion.[7] In this study, patients diagnosed to have already clinically documented lower extremity venous disease underwent radiological investigation for making lower extremity venous disease definite and, the results have been discussed for the presence of any differences concerning age, gender, occupation, and concomitant chronic illnesses. This is a structure research study. Our purpose is looking for the structure differences in this type of patient. If there are differences, to look for the source of differences and discuss the effect of structure differences with the literature.

Methods. Bursa is the fourth largest city of Turkey, situated in the west of the country in the Marmara Region. Most of the city's population works in the industrial sector. The study center is a private imaging center working with the Department of Health, which performs diagnostic, and therapeutic vascular protocols in the region. Doppler US and venography performed on 900 cases with a pre-diagnosis of lower extremity venous system disease that were referred from primary and secondary health care centers from January 2002 to January 2005 were included in the study. Ethical approval informed consent of patients were obtained prior to the study. Pediatric patients, patients with trauma, and patients with a history of previous venous surgery were excluded. Patients that received medical treatment without surgery were included. With the help of medical staff previously informed and educated on the study, patients were asked to complete a questionnaire composed of 14 questions regarding their age, gender, educational level, occupation, disease symptoms, smoking habits, and the presence of any accompanying DM, HT, ischemic heart disease and familial vascular disease. Questionnaires were reviewed and collected each month. Every patient underwent a Doppler US and venographic investigation by a radiologist. According to the results, patients with chronic venous insufficiency, patients with chronic venous insufficiency accompanied by varicose veins, and normal subjects were included (n=820). For the reliability of the study data, patients that did not answer all of the questions and patients that submitted an "I do not know" answer to any of the questions were excluded (n=267). For the 553 patients that constituted the study population, clusters defined according to the 14 variables were examined. The 14 variables used to define clusters were: age, gender, educational level, occupation, presence of smoking, amount of smoking (pack/per year), disease symptoms, the presence of heart disease (HD), radiologically documented diagnosis, the presence of HT, the presence of DM, the presence of hyperlipidemia (HLIP), previous medical follow-up, and history of familial vascular disease.

Methods used for the analysis were the hierarchical agglomerative method for clustering, the simple connection method to join the clusters,[38,39] and the Gower[40] assimilation coefficient to define the similarities. After defining the clusters, the tests used to determine the variables causing the differences were Kruskall Wallis, Mann Whitney U, Chi Square, and Fisher Chi Square. The software used for statistical evaluation was Multi-Variate Statistical Package, version 3.13 for the cluster analysis, and Statistical Package for Social Sciences, version 13.0 for the rest of the analysis.

Results. According to the 14 variables defined, investigation of the structure of the 553 cases revealed 3 different clusters at 0.929 correspondence level: Cluster 1 consisted of 258 (46.65%) units; Cluster 2 constituted 163 (29.5%) units; and Cluster 3 constituted 39 (7%) units. **Table 1** presents variables that were found to have an influence on cluster formation, as well as statistical significance. Ninety-three of the cases (16.8%) were considered to have incongruous values, since they could not be clustered. **Table 2** indicates that there were differences between the clusters according to age and the amount of smoking pack/year. Distribution and activity of factors like gender, previous medical history, DM, HLIP, HD, HT, and familial vascular disease history that take part in cluster formation are shown in **Table 3**. However, **Table 4** presents distribution and activity of factors such as smoking habit, radiological results, educational level, occupation, and disease symptoms that take part in cluster formation. Age, gender, educational level, occupation, presence of smoking, amount of smoking (pack/per year), disease symptoms, presence of HD, and radiologically documented diagnosis were considered as variables that constituted the clusters. Hypertension, DM, hyperlipidemia, previous medical follow-up, and history of familial vascular disease were variables that did not affect cluster formation.

Discussion. Lower extremity venous diseases are a frequently considered group of illnesses in today's world due to industrialization trends, and the diseases' high prevalence among the working population.[3,17] These illnesses have a negative influence on the life quality and productivity of those people they affect.

Three clusters were set according to the defined variables in our study. It is striking that previous medical follow-up; the presence of DM, HLIP, or HT and history of familial vascular disease did not play a part in cluster formation. However, previous studies[8]

Table 1 - Characteristics of study population.

Characteristics	Cluster 1 (N = 258)	Cluster 2 (N = 163)	Cluster 3 (N = 39)
Age (mean ± SE)	39.8±0.7	35.1±0.9	35.2±1.4
Gender (%)			
Male	34.9	68.1	79.5
Female	65.1	31.9	20.5
Education Level (%)			
Illiterate	6.6	0.6	0
Literate	5.0	0	0
Primary school graduate	66.3	71.2	84.6
High school graduate	19.4	28.2	15.4
Occupation (%)			
Housewife	41.5	19.6	10.3
Worker	45	65.6	66.7
Self-employed	1.2	3.7	10.3
Smoking (packs/year) (mean ± SE)	0.0	12.7±0.8	13.7±1.6
Smoking habit (%)			
Yes	0.4	96.9	100
No	99.6	0	0
Quitter	0	3.1	0
Have a heart disease	7.8	1.8	0
Disease symptoms (%)			
Leg pain	20.9	0	87.2
Varices	46.1	58.3	0
Swelling in the leg	1.9	0	5.1
Leg pain + varices	24.8	41.1	0
Leg pain + color change	0.8	0	7.7
Radiological results (%)			
Insufficiency	22.1	0	100
Insufficiency + varices	70.9	99.4	0
Normal	7.0	0.6	0

Table 2 - Characteristics of cases in the clusters regarding age and smoking (packs/year).

Clusters	Age	Pack/Year
Cluster 1		
Number	258	258
(M±SEM)	39.83±0.723	0.00581±0.005814
Cluster 2		
Number	163	163
(M±SEM)	35.19±0.882	12.69479±0.859091
Cluster 3		
Number	39	39
(M±SEM)	35.21±1.429	13.69872±1.642346
Significant	<0.001	<0.001
Binary comparison		
clusters 1-2	<0.001	<0.001
clusters 1-3	<0.05	<0.001
clusters 2-3	NS	NS

M - mean, SEM - standard error of mean, vs - versus, NS - non significant.

demonstrate that HT is the disorder most frequently accompanying venous diseases. Similarly, it is known that familial vascular diseases and genetic features play important roles as risk factors in venous failure.[3,10] It is reported that having a parent with chronic venous insufficiency doubles the risk for children, whereas having 2 parents with chronic venous insufficiency triples that risk.[19] The results of our study do not support this idea. This discrepancy is probably due to the lack of knowledge on the study group's familial follow-up protocols. Examination of our clusters revealed the following results:

Cluster 1. The mean age of this group is 39.8 years, which is higher than the other clusters. There are more women than men in this group. Members of this group do not smoke or smoke very little, their educational level is generally at primary school degree level (this is the only group containing non-educated subjects), and most of the housewives are in this group. Members of this group generally suffer from increased vascularization accompanying leg pain and color changes. The rate of previous HD is also higher in this group compared to the other 2. Most of the cases in this cluster congregate in the venous insufficiency with varices group. According to these results, we can speculate that housewives approximately 40 years of age, with previous HD, who do not smoke or smoke very little, are at risk for venous failure with varices. Of this group's members, 22% are at the venous insufficiency phase and another 7% of them are normal. The fact that members of this group sought medical help in the early phases of the disease, may explain the results. The higher risk for venous disease in spite of lower smoking rates may be explained by the great influence of working conditions as a risk factor for this disease. This finding is consistent with previous reports stating a higher incidence of venous insufficiency in the population who work in a standing position.[16,18] The rate of HD in this group is higher than any other group. This finding may indicate that women with HD are under a great risk of venous failure despite smoking much less.

Cluster 2. The mean age of this group is 35.2 years. Members of this group smoke more than 12 packs per year, and the percentage of heavy smokers is high; members either have a primary school education or have obtained a high school degree. There is a worker and male dominance in this group. The most common complaint in this group is increased vascularization. Leg pain and increased vascularization are the second most common complaints in this group. Heart disease risk in this group is less, than in the first group. The most striking feature in this group is that almost every member (99.6%) group has radiologically proven venous insufficiency and varices. Smoking leads to

Table 3 - Distribution and activity of factors like sex, previous medical history, diabetes mellitus (DM), hyperlipidemia (HLIP), heart disease (HD), hypertension (HT), and familial vascular disease history that take part in cluster formation.

Factors	Cluster 1 (N = 258)	Cluster 2 (N = 163)	Cluster 3 (N = 39)	Binary comparison
		n (%)		
Gender				
Male	90 (34.9)	11 (68.1)	31 (79.5)	Cluster 1 vs cluster 2*
Female	68 (65.1)	52 (31.9)	8 (20.5)*	Cluster 1 vs cluster 3*
				Cluster 2 vs cluster 3‡
Previous medical follow-up				
Yes	52 (20.2)	35 (21.5)	10 (25.6)	Not significant
No	206 (79.8)	128 (78.5)	29 (74.4)	
DM				
Yes	9 (3.5)	2 (1.2)	0 (0)	Cluster 1 vs cluster 2‡
No	249 (96.5)	161 (98.8)	39 (100)	Cluster 1 vs cluster 3‡
				Cluster 2 vs cluster 3‡
HLIP				
Yes	4 (1.6)	1 (0.6)	1 (2.6)	Cluster 1 vs cluster 2‡
No	254 (98.4)	162 (99.4)	38 (97.4)	Cluster 1 vs cluster 3‡
				Cluster 2 vs cluster 3‡
HD				
Yes	20 (7.8)	3 (1.8)	0 (0)	Cluster 1 vs cluster 2†
No	238 (92.2)	160 (98.2)	30 (100)†	Cluster 1 vs cluster 3‡
				Cluster 2 vs cluster 3‡
HT				
Yes	20 (7.8)	7 (4.3)	4 (10.3)	Not significant
No	238 (92.2)	156 (95.7)	35 (89.7)	
Familial vascular disease history				
Yes	81 (31.4)	55 (33.7)	9 (23.1)	Not significant
No	177 (68.6)	108 (66.3)	30 (76.9)	

* - Significant (p<0.001), † - Significant (p<0.01), ‡ - Not significant, vs - versus

Table 4 - Distribution and activity of factors like smoking, radiological results, educational level, occupation, and symptoms that take part in cluster formation.

Factors	Cluster 1 (N = 258)	Cluster 2 (N = 163)	Cluster 3 (N = 39)	Binary comparison		
		n (%)		Cluster 1-2	Cluster 1-3	Cluster 2-3
Smoking habit						
Yes	1 (0.4)	158 (96.9)	39 (100)	<0.001	<0.001	NS
No	257 (99.6)	0 (0)	0 (0)	<0.001	<0.001	-
Quitter	0 (0)	5 (0)	0 (0)	<0.01	-	NS
Radiologic results						
Insufficiency	57 (22.1)	0 (0)	39 (100)	<0.001	<0.001	<0.001
Normal	18 (7.0)	1 (0.6)	0 (0)	<0.01	NS	NS
Insufficiency + Varices	183 (70.9)	162 (99.4)	0 (0)	<0.001	<0.001	<0.001
Education						
Illiterate	17 (6.6)	0 (0)	0 (0)	<0.001	NS	-
Literate	13 (5.0)	0 (0)	0 (0)	<0.01	NS	-
Primary school graduate	171 (66.3)	116 (71.2)	33 (84.6)	NS	<0.05	NS
High school graduate	50 (19.4)	46 (28.2)	6 (15.4)	<0.05	NS	NS
Institution	7 (2.7)	1 (0.6)	0 (0)	NS	NS	NS
Occupation						
Housewife	107 (41.5)	32 (19.6)	4 (10.3)	<0.001	<0.001	NS
Worker	116 (45.0)	107 (65.6)	26 (66.7)	<0.001	<0.05	NS
Officer	2 (0.8)	0 (0)	0 (0)	NS	NS	-
Farmer	1 (0.4)	0 (0)	0 (0)	NS	NS	-
Self-employed	3 (1.2)	6 (3.7)	4 (10.3)	NS	<0.01	NS
Unemployed	1 (0.4)	1 (0.6)	0 (0)	NS	NS	NS
Retired	28 (10.9)	17 (10.4)	5 (5)	NS	NS	NS
Disease symptoms						
Leg pain	54 (20.9)	0 (0)	34 (87.2)	<0.001	<0.001	<0.001
Varices	119 (46.1)	95 (58.3)	0 (0)	<0.05	<0.001	<0.001

vs - versus, NS - non significant.

increased hemoglobin production; particularly patients with defective venous structures may experience venous thrombosis. Nevertheless, when varicose veins are considered on their own, there are reports stating that smoking has no influence on varicose veins.[16] However, smoking must be considered as a risk factor for lower extremity venous disease, not only due to hardening of varicose veins as an isolated disease, but also due to its effects on DVT formation. Varicose veins and venous failure can be seen together in 35 year-old male workers with a primary school education level who are actively smoking more than 12 packs per year. They are suffering from increased vascularization with low risk for HD.

Cluster 3. The mean age of this group is 35.21 years. Members of this group smoke more than the other groups. All members of this group smoke actively. They have the highest educational level. Most of them are workers, but the number of self-employed members is also higher than in any other group. The group has the highest number of males compared to the other groups. The main complaint in this group is leg pain. There are no subjects with HD, and all members of this group have documented venous insufficiency.

It can be speculated that male workers aged 35 with no heart disease, smoking more than 13 packs per year, and suffering from leg pain and swelling are candidates for the venous insufficiency class of venous diseases classification.

Venous diseases tend to appear earlier in women than in men.[2] However, for people above 45 years of age, it begins to be much more common among men, and in the 55-64 age group, venous diseases are seen in men twice as frequently as in women.[15] We think that the results demonstrating that men having venous diseases at younger ages than women are due to the young, actively-working population of the study group. The results suggest that women over the age of 40 are more susceptible to venous diseases than men, despite the fact that they do not smoke. These results suggest the potential influence of HD on venous disease formation.

Males aged over age 35, smoking more than 12.7 packs per year are under high risk for venous failure accompanying varicose veins These cases may have advanced diseases that might require surgical intervention. It is probably due to the relatively good working conditions that males over the age of 35, working in jobs for which they are qualified, have venous diseases that have not progressed beyond a chronic venous insufficiency phase, even though they smoke more than 13.7 packs per year. Symptoms of these patients are limited to leg pain, swelling and color change, which verifies the clinical diagnosis of insufficiency. In 100% of this group's members, the diagnosis is venous failure. Financial and occupational losses can be reduced by prescribing medical treatment and follow-up protocols for these cases due to a high chance of response to medical therapy.

In conclusion, chronic venous insufficiency, and varicose veins are venous system diseases that are found in association with more than one factor. Age, gender, occupational classes, educational level, smoking more than 12.7 packs per year, and having HD are the most important risk factors observed in the study.

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