

The cutoff value for the diameter of the saphenous vein in predicting the presence of venous insufficiency

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Abstract

Aim: In this study aimed to investigate the relationship between saphenous vein diameters and reflux and to present their sensitivity and specificity values in predicting venous insufficiency (VI).

Material and Methods: This study included 162 symptomatic patients admitted to our radiology clinic with complaints of VI in 317 of their lower extremities (LEs) and 67 asymptomatic healthy volunteers with their 134 LEs having no varicose veins. A total of 451 LEs were evaluated for VI with Doppler ultrasonography (US) in the standing position.

Results: The saphenous vein diameters were higher at a statistically significant level in the symptomatic patient group than in the asymptomatic healthy volunteers ($p < 0.001$). They were also higher at a statistically significant level in the LEs with clinically significant reflux ($p < 0.001$). A cutoff value of a 5.35 mm diameter for insufficiency in great saphenous vein (GSV) led to 80.20% sensitivity and 79.20% specificity; a 4.85 mm diameter for insufficiency in small saphenous vein (SSV) led to 82.10% sensitivity and 83.60% specificity.

Conclusions: A GSV diameter of ≥ 5.35 mm and a SSV diameter of ≥ 4.85 mm are the best cutoff values, which could be used as an additional parameter, for predicting VI with high sensitivity and specificity.

Keywords: Doppler Ultrasonography; Saphenous Vein Diameter; Venous Insufficiency.

INTRODUCTION

Venous insufficiency (VI) is a common chronic disease leading to clinical complaints, such as pain, edema, skin disorders, and ulceration in patients. Chronic VI is observed in 20% and varicose veins are seen in 7% of the population (1). Doppler ultrasonography (US) has become a major diagnostic tool in the diagnosis of VI and in assessing its etiology and anatomy (2,3). In our daily clinical practice, particularly in the superficial venous system, it is widely known that more frequent reflux is detected as the venous diameter increases, but there are only few studies (3,4) in the literature on this subject. A high-sensitivity cutoff value, which could propose the diagnosis of venous reflux as a warning sign for radiologists and clinicians, has thus far been investigated in a limited number of studies (3,4). To the best of our knowledge, this is the first study investigating the correlation between insufficiency, the flow volume of reflux, and the venous diameter of the saphenous vein in the Turkish population. In this study, we

aimed to investigate the correlation between saphenous vein insufficiency and diameters and to evaluate the best cutoff value for the great saphenous vein (GSV) and small saphenous vein (SSV) diameters for predicting insufficiency.

MATERIAL and METHODS

This study was conducted at our institution between November 2016 and July 2017. The study was approved by the local research ethics committee. All participants (patients and asymptomatic healthy volunteers) were informed, and written informed consent was obtained before the Doppler US examination. All Doppler US examinations of the lower extremities (LEs) were performed by a radiologist (M.S.D) with 12 years of experience in Doppler US, using a high-frequency (4–14 MHz) linear array transducer, Toshiba Aplio 500 (Toshiba Medical System Corporation, Tokyo, Japan). Patients with thrombophlebitis or acute deep venous thrombosis, elderly patients having difficulties in standing, patients who could

Received: 19.12.2017 Accepted: 17.01.2018

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not cooperate with the Valsalva maneuver, patients with heart failure, and patients who underwent endovascular or surgical treatment for VI were excluded from the study.

A total of 229 participants, 451 LEs were included in the current study; 317 of the LEs were symptomatic, and 134 of the LEs were asymptomatic. In symptomatic patients, at least one of these VI symptoms, including leg pain, cramps, ulcers, itching, swelling in the legs or ankles (edema), lipodermatosclerosis, atrophy, thickening of the skin, color change around the ankles of the skin (pigmentation, eczema), and a feeling of tension in the legs, was present and the appearance of millimetric or prominent varicose veins was also present. Symptomatic patients with reflux in the saphenous vein were also divided into two subgroups according to their VI symptoms. Those having trophic changes (skin pigmentation, eczema, lipodermatosclerosis, atrophy, hemosiderin deposition) or venous ulcers in the lower extremity (LE) were included in the severely symptomatic subgroup (according to the CEAP classification, C4s, C5s, C6s patients (5)). Those having no trophic changes or venous ulcers in the LE were included in the moderately symptomatic subgroup (according to the CEAP classification, C1s, C2s, C3s patients (5)).

The body mass index (BMI) was calculated prior to the Doppler US examination. The Doppler US examination began with a standard US examination in the supine position to exclude deep and superficial venous thrombosis. The patients were then evaluated for VI in the standing position. Venous Valvular competence was evaluated at rest with the Valsalva Maneuver and with the augmentation of the calf. The calf was squeezed in each patient at the same level (middle portion of the cruris) while the venous reflux was investigated by distally compressing the extremity.

The saphenous veins diameters were recorded. Since the Valsalva Maneuver increases the vein diameter, all patients were evaluated while breathing spontaneously, and the examined extremities were in a neutral position. The Valsalva maneuver was performed with equal duration (seven seconds) for each segment of each patient being examined. The presence of the retrograde flow with durations longer than 0.5 seconds was used as a criterion for significant reflux. To provide standardization for the study, measurements (diameter, reflux, and the volume of reflux) were performed in a standing position, GSV was measured at the level of the distal thirds of the thigh, SSV was measured five cm distal to the saphenopopliteal junction in the proximal cruris. In these segments, the largest diameter of the GSV and SSV was chosen to analyze the relationship between the diameter, reflux, and volume of reflux.

The flow volume of the reflux was automatically calculated (reflux flow volume=cross-sectional area×time-averaged velocity) by the built-in software of the US device after the B-mode image was captured in the saphenous veins. The reflux flow volume measurements were repeated

three times for each vessel, and the mean value of these measures was recorded (Figure 1).

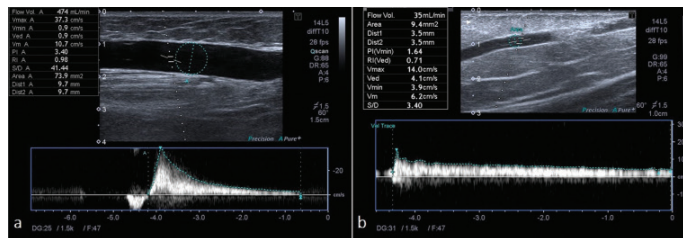


Figure 1. The measurements of flow volume of reflux in saphenous vein after the augmentation of the calf. **(a)** The flow volume of reflux was measured as 474 mL/min in great saphenous vein with a diameter of 9.7 mm. **(b)** The flow volume of reflux was measured as 35 mL/min in small saphenous vein with a diameter of 3.5 mm.

The average time per lower extremity (LE) Doppler US examination was about 20 minutes.

VI, the flow volume of the observed reflux in the saphenous vein, age, BMI were compared with the GSV and SSV diameters.

Statistical analysis

Statistical analysis was performed using the SPSS Packet Program (Statistical Package for Social Sciences, version 15, SPSS Inc., Chicago, Illinois, USA) to evaluate the data. A normal distribution of continuous variables was tested using the Kolmogorov-Smirnov test. Primarily, definitive statistics related to the variables were evaluated. Descriptive statistics were expressed as mean, standard deviation, frequency, and percentile values. Statistical analysis was performed with χ^2 and Student's t-test to compare the mean diameter of normal and refluxed saphenous veins. A P-value of equal or less than 0.05 was considered statistically significant. Receiver operating characteristic (ROC) curve analysis was used to determine the best cutoff diameter of the saphenous vein for predicting insufficiency. The sensitivity and specificity of VI in the GSV and SSV were calculated based on the diameters of GSV and SSV.

RESULTS

A total of 229 participants, 451 LEs [(226 right limbs (50.1%) and 225 left limbs (49.9%), 164 males (36.4%), 287 females (63.6%)] were examined. Of the participants enrolled in the study, 162 of the them (62 male, 100 female) were symptomatic [(317 lower extremities, 159 right limbs (50.2%) and 158 left limbs (49.8%), 203 female limbs (64.03%) 114 male limbs (35.96%)] and VI symptoms and varicose veins were present in the thigh and/or crural region. Sixty-seven volunteers [(67 right limbs (50%) and 67 left limbs (50%), 84 females (64.7%), 50 males (35.3%)] who were included in the study were asymptomatic, and none of the VI symptoms, varicose veins, or reflux in deep and superficial veins was present on physical and Doppler examination.

The patients were in the age range of 18–76 (mean, 44.05±13.35). The mean age of the symptomatic patient

group was 43.63±12.69, asymptomatic group was 45.02±14.80. The BMI of the symptomatic group was 28.48±5.03; asymptomatic group was 27.77±4.83. The difference was not statistically significant between the two groups in terms of age, sex, and BMI (p> 0.05). Moreover, there were no significant differences between the saphenous vein diameters and age, sex, or BMI (p> 0.05).

The mean saphenous vein diameter of the symptomatic group and asymptomatic volunteers were summarized in table 1.

Table 1. The mean diameter in asymptomatic volunteers and symptomatic patients

	Asymptomatic Group	Symptomatic Group	Statistical Analysis (*)
Mean diameter GSV(mm)	4.65±0.90	5.90±1.98	(p<0.001) (t= -6.088)
Mean diameter SSV(mm)	3.89±1.33	4.76±1.76	(p<0.001) (t= -4.481)

*P<0.05 was considered to indicate a significant difference
GSV: great saphenous vein; SSV: small saphenous vein

The saphenous veins diameters were higher at a statistically significant level in the symptomatic group than in the asymptomatic volunteers (p<0.001). Varicose veins and at least one accompanying symptom of VI may be predicted with 67.8% sensitivity and 66.2% specificity (if the cutoff value for the GSV diameter is considered as 4.75 mm) and with 64.0% sensitivity and 64.2% specificity (if the cutoff value for the SSV diameter is considered as 3.65 mm).

The percentage of insufficiency in the GSV was revealed as 52.7% (n:167); Whereas the percentage of insufficiency in SSV was 24.6% (n:78) for the LEs in symptomatic patients. The largest saphenous veins diameter with and without insufficiency and the smallest saphenous veins diameter with insufficiency were summarized in table 2.

Table 2. The largest saphenous veins diameter with and without insufficiency and the smallest saphenous veins diameter with insufficiency

	Symptomatic Group	Asymptomatic Group
Largest diameter GSV without insufficiency	7.7 mm	6.8 mm
Largest diameter SSV without insufficiency	10.70 mm	10.70mm
Largest diameter GSV with insufficiency	16.4 mm	-
Largest diameter SSV with insufficiency	11 mm	-
Smallest diameter GSV with insufficiency	3.5 mm	-
Smallest diameter SSV with insufficiency	3.5 mm	-

GSV: great saphenous vein; SSV: small saphenous vein

The mean diameter of saphenous veins with and without reflux were summarized in table 3. The GSV and SSV diameters were higher at a statistically significant level in the LEs with VI (p<0.001). The ROC curve analysis of the diameters for saphenous vein insufficiency and best cutoff values are shown in the figure 2.

Table 3. The mean diameter of saphenous veins in the lower extremities with and without reflux

	Lower extremities with reflux	Lower extremities without reflux	Statistical Analysis (*)
Mean diameter GSV(mm)	6.85±2.03	4.50±1.18	(p<0.001) (t= -15.511)
Mean diameter SSV(mm)	6.52±1.83	3.97±1.23	(p<0.001) (t= -15.511)

*P<0.05 was considered to indicate a significant difference
GSV: great saphenous vein; SSV: small saphenous vein

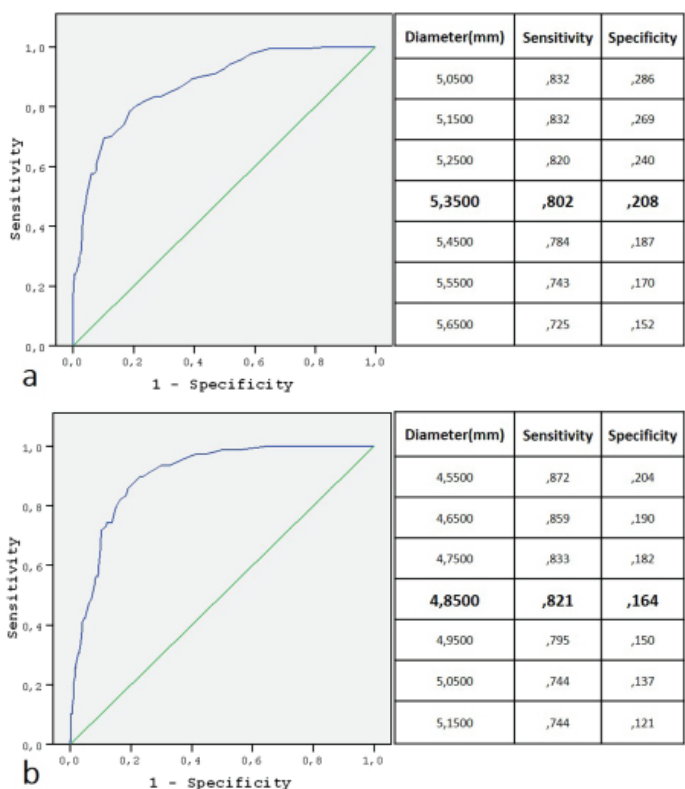


Figure 2. Receiver operating characteristics curve analysis of saphenous vein diameter for determining the best cutoff value for diagnosing venous insufficiency. (a) 5.35 mm was the best cutoff value to predict venous insufficiency for the great saphenous vein. (b) 4.85 mm was the best cutoff value to predict venous insufficiency for the small saphenous vein

Reflux was not detected in spectral Doppler imaging, while the GSV diameter was greater than 6 mm in 24 LEs of the symptomatic group and 6 LEs of the asymptomatic group (a total of 6.65%). Reflux was not demonstrated in spectral Doppler imaging, while the SSV diameter was greater than 6 mm in 22 LEs of the symptomatic group and 7 LEs of the asymptomatic group (a total of 6.43%). Furthermore, reflux was demonstrated in spectral Doppler imaging in the

symptomatic group, while the GSV diameter was smaller than 4.5 mm in 20 LEs (a total of 4.43%), and the SSV diameter was smaller than 4 mm in 9 lower extremities (a total of 1.99%).

In the symptomatic group of patients with GSV insufficiency, the mean flow volume of reflux was measured as 45.36 ± 79.45 mL/min, and the mean flow volume of reflux was measured as 20.18 ± 55.80 mL/min in the SSV. A statistically significant increase in the GSV and SSV diameters was also found with the increase in the severity of reflux in the GSV and SSV ($p < 0.001$). A strong positive correlation was found between the saphenous diameter and the flow volume of reflux ($p < 0.001$, $r = 0.777$ for the GSV, $r = 0.555$ for SSV). In the moderately symptomatic subgroup of the LE, the mean flow volume of reflux in the GSV was measured as 25.36 ± 34.56 mL/min, and in the SSV, it was measured as 14.32 ± 36.79 mL/min. In the severe subgroup of LE, the mean flow volume of reflux in the GSV was measured as 78.36 ± 66.37 mL/min, and in the SSV, it was measured as 38.98 ± 88.95 mL/min. When the moderately and severely symptomatic subgroups with reflux in the saphenous veins were compared with each other, the reflux flow in the LEs was significantly higher in the severely symptomatic subgroup than in the moderately symptomatic subgroup ($p < 0.001$).

DISCUSSION

The distention of the vein due to overfilling, volume overload, or increased hydrostatic pressure (HP) also cause the vein to dilate because the leaflets could not close properly. (6,7). The enlargement of the venous diameter leads to the incompetency of valves, which may be concluded as further caudal venous dilatation and valvular incompetence (8,9,10). The superficial venous system is affected easily and rapidly from HP changes and VI is generally seen with an increased diameter (3,10,11). We found significant relationship between the increase in the diameter and VI, saphenous vein diameters were higher at a statistically significant level in the LEs with VI than without insufficiency ($p < 0.001$). In our study, reflux was not seen in 59 LEs with a saphenous vein diameter greater than 6 mm. Moreover, reflux was seen in 20 LEs with a GSV diameter smaller than 4.5 mm and in 9 LEs with a SSV diameter smaller than 4.0 mm. For these reasons, we obtained the following results: The diameter could be an indirect indicator of VI; however, saphenous vein diameter alone cannot be used as an indicator of significant reflux, it can be helpful as an additional parameter.

The measurement of the GSV diameter could be a promising clinical parameter that could be closely associated with VI symptoms (12). We also found that a significant association between the presence of VI symptoms and an increase in the saphenous vein diameter. However, due to the low sensitivity and specificity this supports the conclusion that an increase in diameter can be used as an additional parameter, not as a stand-alone criterion for predicting the symptoms of VI and the presence of varicose veins.

Recent research in which patients were examined in the recumbent position and saphenous vein diameters were measured 5 cm distal from the junctions showed that when a cutoff value of a 5.05 mm diameter for insufficiency in the GSV led to 76% sensitivity and 60% specificity, 3.55 mm diameter for insufficiency in the SSV led to 87% sensitivity and 71% specificity (3). In another study in which patients were examined in the supine position and only the GSV diameter was investigated, the GSV diameter thresholds were greater than 7 mm at the saphenofemoral junction and 4 mm at the thigh, respectively, found most accurately predicted VI (13). Navarro et al. evaluated only the GSV in the supine position and revealed that a cutoff value for the GSV of 5.4 mm at the distal thirds of the thigh predicted critical reflux with 80% sensitivity and 73% specificity (14). It is difficult to assess the proximal segments of the GSV in terms of augmentation and reflux. When assessed with the Valsalva Maneuver, differences that can be overlooked due to the fact that a low level of cooperation during the examination can occur among patients (3,15). We studied the findings obtained from the GSV segment in the distal third of the thigh where both the Valsalva maneuver and augmentation can be effective. Since the Valsalva maneuver would be less effective for the SSV, we investigated the presence of reflux in SSV by squeezing the middle third of the calf muscle. The venous diameter naturally changes according to the patient position (3). In our study, we performed venous Doppler US examination in a standing position. The diameter is found to be higher in measurements made while standing (16). In our study, a GSV diameter of ≥ 5.35 mm (80.20% sensitivity and 79.20% specificity) and a SSV diameter of ≥ 4.85 mm (82.10% sensitivity and 83.60% specificity) were found the best cutoff values for predicting VI.

According to these cutoff values, the presence of reflux can be predicted with high sensitivity and specificity. In particular, these cutoff values can be used as an important parameter to predict the reflux in patients who cannot perform the Valsalva Maneuver, who are not cooperative with the Doppler US examination, who are unable to stand during the time required for venous Doppler US examination, and who cannot be effectively investigated for reflux with augmentation due to obesity. These cutoff values can also be used when screening for VI in large populations because the measurement can be made in a very short time.

While the superficial venous system diameter is moderately enlarged and patients are presenting with clinical complaints due to elevated venous hydrostatic pressure, significant reflux cannot be seen on Doppler US imaging (7,8,10). In this paper, the percentage of insufficiency in the GSV was revealed as 52.7%, and that of the SSV was 24.6% for the LEs in symptomatic patients. In spectral Doppler US, VI was not detected in 24 (7.57%) LEs when the GSV diameter was above 6 mm and in 22 (6.94%) LEs when the SSV diameter was above 6 mm in the symptomatic patient group (317 LEs). Excluding VI may lead to unnecessary further evaluation and expenditures

in patients presenting with clinical symptoms of VI and in those with no detected reflux. In these symptomatic patients in whom reflux is not observed when there is a diameter increase in the saphenous veins, an increase in diameter can be used as an additional parameter to predict VI in the future.

The reflux flow volume has been considered as a severity criterion (3,12). Several studies have correlated the intensity of venous reflux with the diameter of the vein, with the severity of the symptoms, and with an increase in the venous pressure (12,14). In our study, we found a statistically significant increase in the diameter of saphenous veins, which was found with an increased severity of reflux in the saphenous vein ($p < 0.001$). A strong positive correlation was found between the saphenous vein diameter and the flow volume of reflux. Moreover, the reflux volume in the LEs was significantly higher in the severely symptomatic subgroup than in the moderately symptomatic subgroup ($p < 0.001$). Since the reflux volume is related to the duration of reflux, the velocity of reflux, and the vessel diameter, it can be used as a follow-up parameter in the evaluation of progression-regression in patients with clinical follow-up, especially with conservative treatments.

There are limitations in our study. Inter-observer variation cannot be evaluated because of the length of the examination time, to provide standardization, measurements documented for the study were performed in the GSV at the level of distal third of thigh and in the SSV at the level of the proximal cruris.

CONCLUSION

GSV diameter of ≥ 5.35 mm and a SSV diameter of ≥ 4.85 mm are the best cutoff values for predicting VI with high sensitivity and specificity. These cutoff values could be helpful as an additional parameter, an indirect indicator of VI, but the diameter alone cannot be used as an indicator of VI.

Conflict of Interest; The authors declare that there are no financial or other relations that could lead to a conflict of interest. The authors declare that there is no conflict of interest.

Ethical statements; The approval of the ethics committee was obtained. Patients were provided with detailed information about the procedures and they signed written consent forms. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

The manuscript has not been previously published or accepted for publication and is not submitted or under simultaneous review for publication elsewhere.

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