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ORIGINAL ARTICLE

Classification of reflux patterns in patients with great saphenous vein insufficiency and correlation with clinical severity

Sezen Yılmaz
Burçak Çakır Peköz
Neris Dincer
Sinan Deniz
Levent Oğuzkurt

PURPOSE
This study aims to establish a clinically applicable classification of reflux patterns in patients with great saphenous vein insufficiency and to evaluate the relationship between this classification, the demographics, and severity of clinical findings.

METHODS
This is a retrospective study from prospectively collected data of 503 patients who had the complaint of varicose vein. All patients had complete physical examination and their medical history was recorded. Lower limbs of all patients were examined with Doppler ultrasonography. A total of 787 limbs with great saphenous vein insufficiency were included in the analysis. The reflux patterns of great saphenous vein insufficiency were classified into 4 types as: type 1, great saphenous vein reflux without involvement of malleolar region and saphenofemoral junction (SFJ); type 2, reflux involving malleolar region with competent SFJ; type 3, reflux involving SFJ with competent malleolar region; and type 4, reflux involving both the SFJ and the malleolar region. We evaluated the association between the classification of great saphenous vein insufficiency and age, sex, body mass index (BMI), disease duration, clinical, etiological, anatomical and pathophysiological elements (CEAP) classification and venous clinical severity score (VCSS).

RESULTS
The mean age of the patients was 45.3±11.7 years, with a male-to-female ratio of 2:3. The most common reflux pattern in patients with great saphenous vein insufficiency was type 3 (48.9%), while 14.8% of patients had type 1, 10.4% had type 2, and 25.7% had type 4. Patients with type I reflux pattern were younger in age ($p = 0.002$), had lower BMI ($p = 0.002$), fewer number of children ($p = 0.008$), as well as milder clinical severity score ($p = 0.002$) compared to other reflux types. Duration of disease symptoms was not significantly correlated with the reflux patterns, but VCSS increased with the involvement of malleolar region as in type 2 compared to type 1 (2.82±1.67 vs. 2.74±2.31), and further increased with the involvement of SFJ as in type 3 (4.13±2.92 vs. 2.82±1.67). Patients with diffuse reflux pattern (type 4) had the most severe clinical presentation (4.59±2.9).

CONCLUSION
We developed a clinically applicable classification of reflux patterns in patients with great saphenous vein insufficiency based on the involvement of malleolar region and/or SFJ. We showed an association between weight, BMI, VCSS, CEAP classification and the extent of insufficiency.

From the School of Medicine (S.Y., N.D.), Koç University, Istanbul, Turkey; University of Health Sciences (B.Ç.P.), Adana Health Practices and Research Center, Adana, Turkey; Department of Diagnostic and Interventional Radiology (S.D., L.O. ✉ *loguzkurt@yahoo.com*), Koç University Hospital, Istanbul, Turkey.

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The appearance of varicose veins in the lower extremities is a prevalent condition associated with a wide range of lower limb symptoms such as pain, heaviness, night cramps, itchiness, swelling, and numbness (1–3). It is commonly caused by chronic venous insufficiency in superficial venous system, and great saphenous vein (GSV) comprises most of the superficial venous insufficiencies (82.7%), followed by small saphenous vein insufficiencies (10.9%) (4). Superficial venous insufficiency shows segmental involvement as demonstrated by previous studies (5). However, a standardized anatomical classification of superficial venous insufficiencies based on Doppler ultrasonography mapping is not readily available.

Venous insufficiency mapping is important to decide the treatment planning for an individual patient. The main aim of the current treatment in venous insufficiency is to alleviate the complaints of the patients and to prevent future complications and recurrences. Treat-

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ment options for the saphenous vein insufficiency are increasing and diversifying. Current mainstream treatment modalities are surgery, endovascular ablation therapy and sclerotherapy (6). Surgery has been used as a longstanding therapy model for venous insufficiency for years. During surgical operation, GSV is stripped just below the popliteal level including saphenofemoral junction (SFJ) with high ligation (7). On the other hand, endovascular ablation therapies aim to obliterate part or all of the saphenous vein(s) and have been recommended as a first-line treatment method in recent years (6). Ablation of the whole GSV may result in some adverse effects like saphenous nerve damage by thermal ablation methods applied below the knee (6). On the other hand, if any area with insufficiency is left untreated, patients may continue to have symptoms and may have recurrent varicose veins over the long-term (6). Thus, it is necessary to identify the involved segment and plan the treatment accordingly for each patient.

A standardized mapping method may lead to the development of a relation between GSV insufficiency types and a directed treatment modality to these specific types. There have been some suggested classifications of GSV refluxes in the literature, all with their own strengths and weaknesses. Engelhorn et al. (8) prospectively mapped extremities of a wide population of women and classified their reflux patterns in six groups. Their study defined GSV reflux patterns by involving segmental and multisegmental patterns as separate groups, which can be gathered under the same type for simplicity. The fact that the study only included women and had different types that can practically be united makes their method clinically less applicable (8). The classification system established by Chastanes et al. (9) and another by Pittaluga et al. (4) had also a detailed and complex typology which made them difficult to be used in daily clinical practice. A widely accepted clinical classification of venous insufficiency has not yet been established. There is a need for a simple, clearly understandable, and user-friendly reflux pattern classification.

In our study, we primarily aimed to establish a clinically understandable and easily applicable classification of reflux patterns in patients with GSV insufficiency. Our secondary endpoint was to evaluate the demographic and clinical findings based on this classification system.

Main points

- We described a practical and clinically applicable classification system for great saphenous vein insufficiency based on the involvement of malleolar region and/or saphenofemoral junction (SFJ) with the aim of suggesting a standardized number for major types of insufficiency, omitting the types which can be subcategorized under major ones and those that are clinically insignificant since they do not alter the treatment choice.
- These reflux types correlate with disease severity and can lead the physician to choose the best treatment modality.
- Clinical severity of the disease increases as the disease involves or progresses to the most distal or proximal parts of the limb, especially with the involvement of SFJ, and diffuse pattern seems to be the most extensive form of the disease.

Methods

Study population

This study was approved by the ethics committee of the university (Project no: KA 13/205) and adhered to the tenets of the declaration of Helsinki. We retrospectively reviewed the prospectively collected data from 503 patients who presented to the interventional radiology department with the complaint of varicose veins. Patients were informed about the study and their consents were obtained. All patients had a complete physical examination and their medical history was recorded including age, sex, weight, height, body mass index (BMI), number of children, presence of symptoms, and duration of varicosities. Clinical status of patients was assessed by the clinical, etiological, anatomical and pathophysiological elements (CEAP) classification (10). CEAP scores were grouped into two categories; mild chronic venous insufficiency (CVI) (C1-C2) and severe CVI (C3-C6). Venous clinical severity score (VCSS) was also identified for each patient based on clinical evaluation (11). Doppler ultrasonography (US) was performed on a total of 1006 lower extremities of patients. Doppler US mappings of lower limb venous systems were recorded.

Exclusion criteria

We excluded the patients who did not have any GSV insufficiency in the Doppler US examination. In order to have a more homogeneous population, we did not include limbs with reflux in the small saphenous vein or reflux in only tributary veins. We also excluded files with missing medical history and/or ultrasound mapping, as well as patients who had already undergone surgery for varicose veins or had a history of superficial or deep vein thrombosis.

Doppler ultrasound examination

All Doppler US examinations were performed by an experienced physician trained in interventional radiology. Lower limbs of all patients were examined in the standing position with 9 MHz or 13 MHz multifrequency transducers (Antares, Siemens) on both the transverse and longitudinal planes all along the course of the GSV. Reflux was defined as flow in an inverse direction to physiological flow with duration greater than 0.5 seconds after provocation maneuvers (squeeze and release maneuver with or without Valsalva maneuver) (12).

Classification of GSV insufficiency

We classified GSV reflux patterns into 4 types based on Doppler US mapping (Fig. 1): type 1, GSV reflux without involvement of malleolar region and saphenofemoral junction (SFJ); type 2, GSV reflux involving malleolar region with competent SFJ; type 3, GSV reflux involving SFJ with competent malleolar region; type 4, GSV reflux involving both SFJ and malleolar region.

Associations between the reflux pattern type and age of the patients, weight, BMI, number of children, presence of symptoms, duration of varicosities, VCSS score, CEAP classification were investigated.

Statistical analysis

Statistical analysis was performed by using SPSS software version 26.0 (IBM Corp.). Means and standard deviations (SDs) were calculated for continuous variables and frequencies and percentage were reported as descriptive statistics of categorical variables. Two-sided student t test was used to compare continuous variables. Chi-square test was used to compare categorical variables including sex, CEAP group and presence of any symptom related to the type of GSV insufficiency. The one-way analysis of variance (ANOVA) was used to determine any statistically significant differences between the means of two or more independent groups, where a p value less than 0.05 was considered to indicate statistical significance. Then, *post hoc* test was run

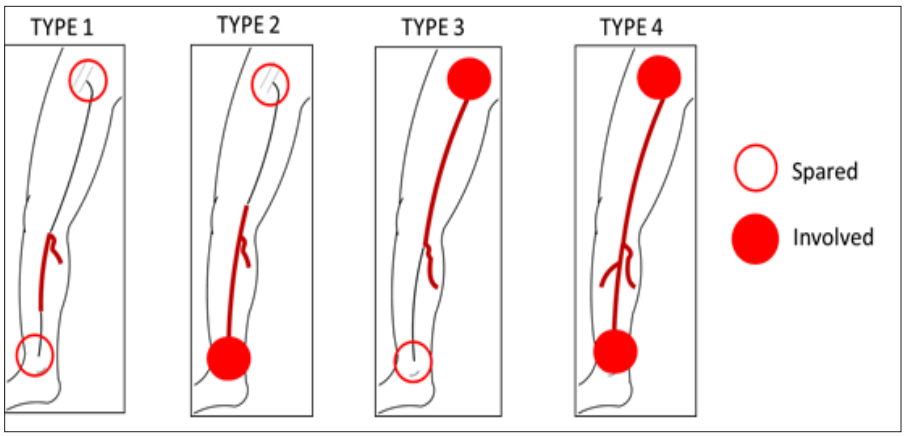

Figure 1. Patterns of great saphenous vein (GSV) reflux. The *filled* circles show involvement and *empty circles* show absence of involvement.

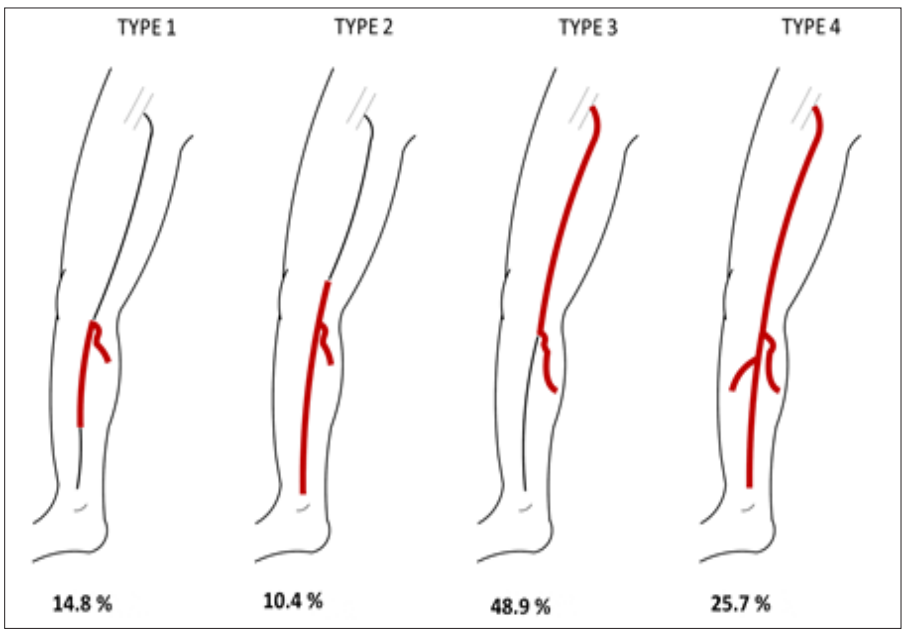

Figure 2. Prevalence of GSV reflux patterns.

to confirm where the differences occurred between groups and t test was performed for comparison after a significant ANOVA. The Bonferroni correction was applied to reduce type I error and a p value less than 0.008 was considered significant for an individual test.

Results

We examined 1006 limbs of 503 patients with Doppler US; of these, 219 limbs failing to meet the study criteria were excluded. A total of 787 limbs with GSV insufficiency were included in the analysis. Overall, 537 of the limbs belonged to female patients (68.2%) and 250 of the limbs belonged to male patients (31.8%). The mean age of the patients was 45.5±11.6 years and the male-to-female ratio was 1:2. Patients had a mean weight of 76.5±15.1 kg, a mean height of 167±7 cm and the mean BMI of 27.2± 4.6 kg/m^2. Of the female patients, 90.8% had children and the mean number of children was 2.5±1.2.

There were one or more symptoms of chronic venous insufficiency in 648 limbs (94.5%), while no symptoms were mentioned in 38 limbs (5.5%). The mean duration of varicosities was 12.4±9.5 years. The CEAP classification of the limbs was as follows: 406 limbs were classified as mild in C1 to C2 (85.7%) and 68 limbs were classified as severe in C3 to C6 (14.3%). None of our patients were classified as C5 and C6. The mean VCSS was 4.0±2.8.

The Doppler US mappings were grouped according to our GSV reflux pattern classification shown in Fig. 1. The most common reflux pattern in patients with GSV insufficiency was type 3, seen in 385 limbs (48.9%), which showed reflux in the SFJ with a competent malleolar region. Next, 203 limbs (25.7%) had type 4 reflux pattern with insufficiency both in the SFJ and malleolar region. In 117 limbs (14.8%), there was GSV insufficiency without involvement of the SFJ and malleolar region (type 1). Only in 82 limbs (10.4%), GSV insufficiency involved malleolar region with the competent SFJ, classified as type 2 (Fig. 2).

The mean±SD of demographical and clinical findings of the patients based on their reflux type can be seen in the Table. The one-way analysis of variance revealed statistically significant differences among group means of age, weight, BMI, number of children, VCSS and CEAP score. To understand the differences between each group, further *post hoc* and two-sided student t tests were run with the Bonferroni correction.

According to the results, patients with type 1 reflux pattern were found to be the youngest in the patient population, while age of the patients tended to increase with the GSV insufficiency involving malleolar region as in type 2 (p = 0.034) or involving SFJ as in type 3 (p = 0.021) compared to type 1; however, the differences in age were not significant according to the Bonferroni corrected p value.

Weight (p = 0.002), BMI (p = 0.007) and number of children (p = 0.008) were also significantly different among groups and their mean values increased with the reflux pattern extending from type 1 to type 4. Patients with type 1 reflux pattern were found to have lowest weight (69.15±11.11 kg) compared to patients with type 2 (76.15±13.35 kg), type 3 (77.16±15.75 kg), and type 4 (80.40±15.35 kg) (p = 0.035, p = 0.003, and p < 0.001, respectively); there was statistically significant difference between type 1 and type 3, as well as type 4. Likewise, type 1 insufficiency was correlated with lower number of children compared to type 3 (p = 0.033) and type 4 (p = 0.025), while the number of children was not significantly different between the groups.

Patients with type 1 GSV insufficiency were less likely to present symptomatically than patients with type 2 insufficiency (91% vs. 98.6%, p = 0.019) and type 4 insufficiency (91% vs. 97.2%, p = 0.023). When comparing patients with type 2 and type 3, GSV insufficiency involving malleolar region as

Table. Demographical and clinical findings of patients with different reflux types

	Type 1	Type 2	Type 3	Type 4	*p*
Age (years)	43.39±11.02	46.90±11.87	46.18±11.76	44.36±11.94	0.046
Weight (kg)	69.15±11.11	76.15±13.35	77.16±15.75	80.40±15.35	0.002
BMI (kg/m^2)	25.02±3.85	27.34±4.56	27.65±4.83	27.84±4.53	0.007
Number of children	2.21±0.86	2.24±1.02	2.67±1.22	2.83±1.33	0.008
Duration of varicosities (years)	12.23±10.14	12.08±11.19	12.36±9.23	12.82±9.22	0.970
Venous clinical severity score	2.74±2.30	2.82±1.69	4.13±2.91	4.59±2.90	0.002

Data are presented as mean±standard deviation.
BMI, body mass index.

in type 2 revealed more symptomatic presentation than GSV insufficiency involving SFJ as in type 3 (98.6% vs. 93.2%, $p = 0.030$). However, these differences were not significant using the Bonferroni correction.

Furthermore, patients with type 1 reflux pattern had the lowest VCSS which increased with the involvement of SFJ as in type 3 and was highest in type 4 ($p = 0.008$ and $p = 0.001$, respectively), while the involvement of malleolar region as in type 2 did not show any statistically significance compared to type 1 ($p = 0.882$). Similarly, patients with type 2 reflux pattern had significantly lower VCSS compared to patients with type 4 reflux pattern ($p = 0.006$), while there was no difference in mean VCSS between type 2 and 3 ($p = 0.037$), as well as type 3 and type 4 ($p = 0.241$).

CEAP score of patients was also significantly associated with the reflux pattern ($p = 0.002$). Majority of the patients with type 1 and type 2 reflux pattern had mild CVI (94% and 96.6%, respectively), while only 6% and 3.4% of them were classified as severe CVI, respectively. On the other hand, 15.9% of the patients with type 3 and 21.6% of the patients with type 4 had severe CVI classified as C3 to C6. Comparison of the mean values showed that clinical status of patients was significantly milder in type 1 compared to type 4, but not statistically different compared to type 2 or type 3 ($p = 0.005$, $p = 0.037$, $p = 0.515$, respectively). On the other hand, patients with type 2 also had significantly milder clinical status compared to patients with type 4 ($p = 0.002$).

As a result of chi square test, sex was significantly different among various reflux patterns ($p = 0.003$). However, upon further analysis, we showed that there was no statistically significant difference in sex distribution among different types of reflux patterns. Our study also could not show any significant correlation of duration of varicosities with the reflux patterns ($p = 0.970$). Moreover, none of the demographical and clinical variables were significantly different between patients with reflux pattern type 3 and type 4.

Discussion

Great saphenous vein reflux is a major entity of superficial venous insufficiencies and it is not uniformly distributed in all patients. Rather, it shows a segmental distribution. This segmental distribution necessitates a standardized classification and mapping for each patient. The effect of segmental distribution on clinical presentation of patients has not been identified yet.

We have collected our patients under four major reflux categories and analyzed them accordingly. The most prominent GSV insufficiency pattern was type 3, which involves the SFJ but spares malleolar junction. We showed a significantly positive correlation between weight, BMI, VCSS, CEAP classification and their reflux pattern, although the duration of varicosities was not significantly correlated with the reflux pattern. Type I insufficiency which spares SFJ and malleolar region was correlated with younger age, lower weight and milder clinical scores, which can denote early or beginning phase of the reflux. On the other hand, older age, higher BMI, higher number of children, higher VCSS and CEAP score were associated with the involvement of malleolar region and/or SFJ, which might show advanced disease compared to non-involvement of the end segments. To understand the clinical effect of SFJ involvement, comparison between type 1 and type 3 showed that SFJ involvement caused higher VCSS score, while there was no significant difference in VCSS score between type 1 and type 2. These findings suggest that SFJ may be involved in advanced stages of disease with severe clinical status, while malleolar involvement may be seen in milder forms.

Patients with varicose veins commonly complain about leg symptoms such as heaviness, pain, and night cramps. However, these symptoms are very common in the general population independently of the presence or absence of visible signs of venous disease (13). The factors responsible for the various symptoms that patients with varicose veins suffer individually and whether or not there will be increasing severity of symptoms are not well known. Presence of symptoms and disease progression appear to be related to the extent of venous valvular incompetence. The study of Chiesa et al. (13) investigated chronic venous disorders to provide correlations between valve incompetence and clinical feature of disease severity. They found a correlation between reflux and presence of subjective symptoms in the legs (13). However, they did not compare different reflux patterns and symptoms, and they cannot explain the underlying reason of this correlation (13). In their study, older people were more severely affected than young people, and presence of reflux correlated positively with increasing CEAP score (13). In this study, we show that patients with GSV reflux with the involvement of SFJ and/or malleolar region were older in age and presented more symptomatically with higher CEAP score compared to patients having the other reflux patterns without involvement; thus, we can conclude that involvement of SFJ with or without malleolar region may be advanced form of disease seen with the progression of disease in elderly people, which is why they suffer more severe disease symptoms. This could signify that patients with older age and severe disease may have more extended GSV insufficiency and that treatment in younger ages and early stages of insufficiency could be preventive for further extent of disease.

The relation of disease severity and extent is important to enlighten the long-standing debate on origin of reflux. The traditional idea assumes that primary reflux develops starting at the SFJ level and proceeds in a retrograde manner (14). However, Labropoulos et al. (14) indicated in their study that reflux may develop at one or different locations and can progress in a retrograde or antegrade manner, and in

both directions. Results of our study support antegrade theory based on the presence of venous insufficiency without SFJ involvement in some patients and association between milder disease scores and type 1 reflux with competent SFJ.

There are a few studies investigating the association between the clinical severity of primary varicose veins and different reflux patterns in the literature. However, they primarily focused on one particular aspect of reflux, such as involvement of SFJ, rather than comparing different reflux patterns (15, 16). Garcia-Gimeno et al. (17) investigated this relation by evaluating a total of 2036 limbs using Doppler US and the CEAP classification grouped into two categories, mild to moderate CVI (C1–C3) and severe CVI (C4–C6). Although we classified C1–C2 as mild and C3–C6 as severe, their study and ours have some similar results. According to their findings, SFJ reflux of the GSV was associated with the most severe form of the disease, whereas competent SFJ of the GSV with reflux from proximal veins and the pure non-saphenous reflux were associated with mild-to-moderate CVI (17). Moreover, they showed that obesity increased the frequency of severe CVI 2.7 times; being a woman also increased the frequency of more severe disease 1.3 times (17). The study of Chiesa et al. (13) also showed that frequency of venous disease increased with family history (p = 0.001) and BMI (p = 0.001). Compatible with those studies, we revealed increased involvement of SFJ and/or malleolar region with higher weight and BMI. These findings may suggest the role of intraabdominal pressure on venous insufficiency as a contributing risk factor for the extent of the disease.

Another study by Chastanes et al. (9) revealed results supporting our findings. Their study classified reflux patterns into 5 types and 10 subtypes based on the presence of varices and/or incontinent saphenous vein. They showed that most common reflux pattern was varices with GSV reflux and an incompetent SFJ, which may be analogous to type 3 in our study and which is consistent with our result (9). They also investigated the correlation between reflux patterns, age and CEAP score. Their results revealed that the patient's age and CEAP score were correlated with the extent of GSV reflux, which again supports the findings of our study (9). However, their complex classification system made it difficult to apply in daily practice, like the study of Pittaluga et al. (4) which also included reflux without varicose veins and reflux in a tributary of the SFJ. Pittaluga et al. (4) have also shown that older age was correlated with presence of reflux at SFJ and malleolar region. On the other hand, Engelhorn et al. (8) defined GSV reflux patterns differently by involving segmental and multi-segmental patterns and they described the most common pattern as segmental with competent SFJ. This may be equal to type 1 and 2 in our classification system, since we did not divide multi-segmental patterns into a separate type in our system as it does not have a major effect on treatment decision. Engelhorn's classification system would be simplified and practical, if they gathered patterns without clinical significance under the major types. Hach et al. (18) first mentioned the importance of SFJ terminal valve in 1982. Later on, Hach et al. (19) graded the severity of the reflux according to the presence or absence of the SFJ involvement and extension of the reflux down to the knee or to the ankle. However, this classification was more for severity of the reflux rather than for pattern of segmental distribution. Another classification of different reflux patterns was published by Stücker et al. (20). Their study primarily focused on incompetence of the SFJ considering the terminal and preterminal valve and concluded that the differentiation of the distinct types of SFJ incompetence allows for a more individual and more effective therapy (20). However, they omitted the effect of malleolar region involvement and segmental distribution in different types of SFJ incompetence.

A classification of GSV reflux patterns can be important to describe different types of venous insufficiencies and their therapeutic implications. There are various treatment modalities for venous insufficiency in current practice, including surgery and thermal and nonthermal endovenous treatments. Surgery has been used as a longstanding therapy model for venous insufficiency, which includes stripping of GSV just below the popliteal level including SFJ with high ligation (7). Endovenous thermal ablation methods are new treatment modalities recommended as the first-line treatment of venous insufficiency in recent years, but endovenous therapy to the GSV below a certain level distal to the knee is usually not applicable because of possible damage to the saphenous nerve, as the nerve and the GSV run in a very closed contact under this line (7). The segment below that level can be treated with foam sclerotherapy after thermal ablation of the proximal part. Endovenous nonthermal therapies do not cause nerve injury and can be safely used for above or below the knee GSV insufficiencies (21). Demonstrating the segmental distribution of the GSV with mapping enables us to administer selective surgical and endovascular treatments for individual patients. Thus, unnecessary treatments ablating normal GSV segments or undertreatment with possible recurrences or complications may be avoided. We do not know whether treatment at an early phase without involvement of the malleolar region or the SFJ prevents further extension of the disease process.

We acknowledge some limitations in our study. We have a limited number of subjects in certain segmental involvement types that may be widened to acquire more population-based results. One limitation of the study is that grading of segmental distribution was not validated with clinical outcome. To demonstrate its clinical value there is a need for a further study. Another limitation of our study is that we analyzed only the presence of symptoms and not various types of symptoms with respect to segmental distribution.

In conclusion, we described a practical and clinically applicable classification for GSV insufficiency patterns with the aim of suggesting a standardized number for major types of GSV insufficiency, omitting the types which can be subcategorized under major ones and those that are clinically insignificant since they do not alter the treatment choice. We suggest that written reports of venous insufficiency by physicians are not sufficient for the best treatment that can be offered to the patient and a drawing of a venous insufficiency map by Doppler ultrasonography is necessary. Clinical severity of the disease increases as the disease involves or progresses to the most distal or proximal parts of the limb, especially with the involvement of SFJ, and diffuse diseases seem to be the most extensive form of the disease.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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