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Venous leg ulcers and prevalence of surgically correctable reflux disease in a national registry

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ABSTRACT

Background: Chronic venous disorders are common, with varicose veins occurring in ~40% of the population. Venous leg ulcers affect 1% to 2% of the population, with the prevalence increasing ≤4% for those aged >65 years. Both conditions are expensive and together are responsible for ≤2% of the annual healthcare budget expenditure of Western societies. The ESCHAR (effect of surgery and compression on healing and recurrence) and EVRA (early venous reflux ablation) trials demonstrated that surgical correction of superficial venous reflux reduced ulcer recurrence, resulted in faster healing times (EVRA), and was proved cost-effective. Largescale data regarding patients with chronic venous leg ulcers presenting to venous centers with treatable superficial venous insufficiency has not been previously reported. Our study was designed to evaluate the percentage of patients with leg ulcers presenting to dedicated vein centers who were found to have surgically correctable superficial venous insufficiency.

Methods: The American Vein & Lymphatic Society Patient Reported Outcome Venous Registry began collecting data in 2014 and is one of two national registries focused on chronic venous disorders. The database was queried first for the presence of an ulcer using the CEAP (clinical, etiologic, anatomic, pathophysiologic) classification (C6 status). These de-identified data were further correlated by crossing the number of ulcers for the same limb using the revised venous clinical severity score (rVCSS). The demographics, index duplex ultrasound details, and rVCSS features for ulcer duration and compression use were analyzed. Once the presence of an ulcer had been validated by CEAP and rVCSS, the population was divided into groups according to the ultrasound-reported anatomic pathology (eg, normal, reflux, obstruction, reflux plus obstruction). The query was directed toward all patients seeking a venous evaluation at participating centers from January 2018 through January 2022.

Results: More than 270,000 unique patient records were reviewed. Of the 270,000 records, 163,027 (60%) had had duplex ultrasound scans available, for 1794 unique patients (1879 limbs), representing 1.1% with a leg wound. Of these patients, 55.4% were men and 44.6% were women. Group S included patients with isolated superficial pathology (n = 1291; 68.7%). Group M included patients with mixed superficial and deep pathology (n = 238; 12.7%). Group D included patients with isolated deep vein pathology (n = 58; 3.1%). Finally, group N included patients with leg wounds but no venous pathology (n = 292; 15.5%). The rVCSSs for groups S and M were significantly higher than those for group N. In group S, the dominant patterns involved the great saphenous vein (GSV) above the knee (54.8%), the small saphenous vein (30.7%), and the anterior accessory GSV (14.4%). The frequency of single, double, and triple axial vein reflux identified 1.45 vessels eligible for ablation treatment per limb. In group M, the dominant patterns involved the GSV above the knee (61.7%), the small saphenous vein (26.2%), and the anterior accessory GSV (12.1%), for 1.52 axial segments per limb. Of the 84.4% of venous ulcer patients, duplex ultrasound analysis revealed that 97% of this large subset had had surgically correctable disease.

Conclusions: The American Vein & Lymphatic Society Patient Reported Outcome Venous Registry demonstrated that 85% of the leg wounds in the present study were venous in origin and 97% possessed surgically correctable disease. Our findings support early referral to dedicated vein centers with appropriate venous reflux management as a part of the multidisciplinary team caring for patients with venous leg ulcers. (J Vasc Surg Venous Lymphat Disord 2023;11:511-6.)

Keywords: AVLS; PRO; Vein Registry; Venous leg ulcer; Wound care

The presence of a venous leg ulcer (VLU) represents the sequela of progressive end-stage chronic venous disease (CVD). VLUs result from complex macro- to micro-venous and lymphatic pathophysiology, with phenotypic and genetic contributions in the setting of environmental factors. VLUs are known to be associated with increased resource usage (ie, office visits, diagnostic testing), an increased incidence of interventions, and an increased

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economic burden to both patients and society.[1,2] The increased recurrence rates are often attributable to failure to treat and/or incomplete management of chronic superficial venous insufficiency.[3,4] Persistent chronic VLUs have been associated with higher rates of cellulitis and concomitant hospitalizations, contributing to the increased cost of care per episode.[5] A recent prospective cohort study examining the association between CVD and major cardiovascular events suggested that severe CVD might be an independent risk factor for myocardial infarction, stroke, and/or cardiovascular death due to the increased levels of systemic inflammatory biomarkers and potential endothelial dysfunction.[2,6-8] Most leg ulcers will be venous in origin and etiology, with associated lymphatic dysfunction. However, the "upstream" clinical diagnosis of venous hypertension will often be incompletely assessed with performance of a diagnostic venous reflux ultrasound, resulting in wound nonresolution or unabated progression.[9-11]

Level I evidence exists to support early intervention for VLUs, with concomitant enhancement of ulcer healing, a reduction in recurrence rates, and proven cost-effectiveness.[12-15] Our study was designed to evaluate the percentage of patients with a leg ulcer presenting to dedicated vein centers who had had surgically correctable superficial venous incompetence. Our hypothesis was that most patients with a VLU will have treatable superficial chronic venous insufficiency that was directly contributing to VLU occurrence.

ARTICLE HIGHLIGHTS

- **Type of Research:** A retrospective analysis of prospectively collected data to investigate the epidemiology and prevalence of reflux for ulcer patients presenting to the American Vein & Lymphatic Society Patient Reported Outcome Venous Registry
- **Key Findings:** More than 15% of patients with wounds presenting to a vein practice will not have wounds related to venous reflux. Of the 85% with a vein problem, 3.1% will have pure post-thrombotic syndrome, 68.7% will have isolated superficial reflux, and 12.7% will have mixed deep and superficial reflux.
- **Take Home Message:** Most leg ulcers will be caused by venous pathology due to reflux or obstruction, or both. In this cohort population with a venous etiology, 97% had had a contributing superficial axial reflux condition that was amenable to ablation therapy.

METHODS

Data source

The American Vein & Lymphatic Society (AVLS) Patient Reported Outcome (PRO) Venous Registry began collecting data in 2014 and is one of two registries focused on CVD.[16] The database pulls structured data from electronic medical records of all encounters and offers insight into the disease patterns presented from all CEAP (clinical, etiologic, anatomic, pathophysiologic) classes and the care provided over time.[17] The participating provider pool is diverse, and >60% are diplomats of the American Board of Venous & Lymphatic Medicine. Providers have enrolled in the registry without motivation other than a desire to participate in quality reporting. The database is owned by the AVLS (Chicago, IL). Dendrite Clinical Systems (Reading, UK) operates and maintains the data systems. The query was directed toward all patients who had entered the participating centers from January 2018 through January 2022.

Variable selection

The registry scientific committee reviewed the study proposal, and the fields were chosen to specifically study the epidemiology of the VLU population in the database. Demographic variables (ie, age, sex, race, body mass index [BMI]), revised venous clinical severity score (rVCSS), and duplex ultrasound findings from the index visits of each limb with a documented leg ulcer were recorded. The duplex ultrasound scans were interrogated for normal, reflux, obstruction, or a combination of reflux and obstruction to distinguish patients with isolated superficial pathology, mixed deep and superficial pathology, and isolated deep vein pathology.

Institutional review board

This project was conducted in accordance with the Declaration of Helsinki. The data were anonymized, and our process to protect the privacy of the patients enabled a retrospective review of de-identified prospectively collected data that was exempt from formal institutional review board review.[18,19]

Data validation procedures

Practice level. All the practices had complete the validation procedure with the AVLS and Dendrite Clinical Systems staff to ensure the correct data formats were used and the consistency of the required minimum data points. Most of the United States is represented in the provider pool, adding to the heterogeneity of the data and being more reflective of real-world situations. The practices are not identifiable via the fields we used.

Patient level. The data for all patients were queried first for the presence of an ulcer using the CEAP classification (C6 status). This was further correlated by crossing the number of ulcers for the same limb using the rVCSS. Next, the demographics, index duplex ultrasound details, and rVCSSs for ulcer duration and compression use were analyzed.

Group categorization procedures

Once the presence of an ulcer had been validated by the CEAP class and rVCSS, the population was further

Table. Comparisons of demographic variable

Variable	Superficial vein pathology (group S; n = 1291)	Mixed deep and superficial pathology (group M; n = 238)	Deep vein pathology (group D; n = 58)	No vein pathology (group N; n = 292)
Age, years	64.2 ± 14.5	62.1 ± 14.4[a]	66.8 ± 14.1	66.0 ± 14.0
Female/male ratio, %	45.8:54.2	31.5:68.5[b]	37.9:62.1	48.3:51.7
BMI, kg/m^2	35.1 ± 10.2	32.8 ± 8.0[a]	31.7/10.2	35.5 ± 10.7
Race, %				
White	71	65	62	52
Black	16	17	21	21
Latino	6	9	3	15
Other	7	9	15	12
rVCSS	13.1 ± 4.5[c]	13.8 ± 4.7[c]	12.3 ± 4.1	11.7 ± 4.6
Ulcer duration, %				
rVCSS 0	29	28	26	29
rVCSS 1	36	23	37	39
rVCSS 2	27	37	26	23
rVCSS 3	8	12	11	10
Active compression, %				
rVCSS 0	33	25	34	44
rVCSS 1	16	14	23	18
rVCSS 2	18[a]	17[a]	11	13
rVCSS 3	34[a]	43[a]	32	26

BMI, Body mass index; *rVCSS,* revised venous clinical severity score.
Data presented as mean ± standard deviation, unless noted otherwise.
[a] $P < .05$.
[b] $P < .001$.
[c] $P < .0001$.

distinguished into groups according to the ultrasound-reported anatomic pathology (eg, normal, reflux, obstruction, reflux plus obstruction). We first identified those patients with isolated deep vein pathology, followed by the patients with only superficial vein concerns. The remaining patients were included in either the mixed or no pathology groups and sorted accordingly. Thus, we identified four groups to compare and analyze. Group S included patients with isolated superficial pathology. Group M included patients with mixed superficial and deep pathology. Group D included patients with isolated deep vein pathology. Finally, group N included patients with leg wounds but no venous pathology.

To be included in group M, the patients with mixed disease were required to have contiguous segments of deep vein reflux or evidence of residual scarring. Those with common femoral vein or popliteal vein reflux associated with the adjacent refluxing great saphenous vein (GSV) or small saphenous vein (SSV) were reassigned to group S. We separated these patients because reflux of the adjacent deep vein will likely resolve after treating the superficial component. Additionally, for the patients initially included in the deep vein group, when the finding was isolated reflux in the common femoral vein without signs of residual obstruction, these patients were assigned to group N.

Statistical analysis

SAS statistical software (SAS Institute, Cary, NC) was used for data cleaning and analysis. First, we separated limbs and patients into the four groups (group S, M, D, and N), including limbs considered to have false-positive results. We also identified and analyzed the various patterns of reflux in each limb. For the demographic comparisons only, patients with two limbs in the same group were consolidated into a single entry.

To compare the categorical demographic variables (ie, sex, race, ulcer duration, and active compression use) across the four groups, a χ^2 test was initially used to check for significantly different proportions. If a significant difference was detected between the groups, post hoc subset pairwise χ^2 tests were performed, controlling for the overall type I error rate.

To compare the numerical demographic variables (ie, age, BMI, and rVCSS) across the groups, analysis of variance was used to determine whether significantly different mean values were present. If a significant difference was detected between the groups, Tukey's method was used to identify the specific deviations.

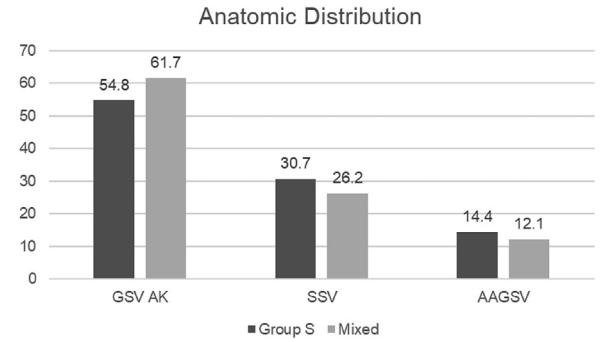

Fig 1. Distribution of axial reflux among those with isolated superficial pathology and those with mixed superficial and deep pathology (groups S and M, respectively). *AA,* Anterior accessory; *AK,* above the knee; *GSV,* great saphenous vein; *SSV,* small saphenous vein.

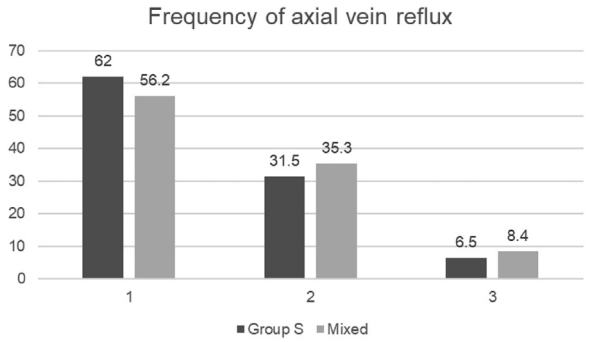

Fig 2. Bar graph depicting frequency of refluxing axial veins in those with isolated superficial pathology and those with mixed superficial and deep pathology (groups S and M, respectively).

Many of the patients had had missing or nonrecorded data, and group D had had a comparatively small sample size. Additionally, some patients had been included in two different groups because of different limb pathologies. For the purposes of the demographic comparisons, these patients were considered as independent sampling units.

RESULTS

More than 270,000 unique patient records were reviewed. Of the 270,000 records, 163,027 (60%) had had duplex ultrasound scans available, for 1794 unique patients (1879 limbs) who had presented with a leg wound (1.1%). Of these 1794 patients, 55.4% were men and 44.6% were women, with 1291 in group S (68.7%), 238 in group M (12.7%), 58 in group D (3.1%), and 292 in group N (15.5%). The demographic variables are presented in the Table. Group M was significantly younger than group N. Group M also had a significantly lower proportion of women than groups S and N. In addition, group M had a significantly lower BMI with groups S and N. Finally, the rVCSSs for groups S and M were significantly higher than those for group N.

Analysis of race when compared with the 2020 census revealed a low representation of the Latino population and higher representation of White, Black, and other races. Statistical significance was not assessed owing to the large percentage of unreported races.

The specific rVCSS variables of ulcer duration and compression therapy use were compared among the groups. However, a χ^2 test did not demonstrate a significant difference in terms of the rVCSSs for ulcer duration. Greater than 33% of any group had reported an ulcer duration of >3 months before presenting to a dedicated vein center and 8% to 12% of the patients had had an ulcer for >12 months.

The rVCSSs for compression compliance revealed that groups S and M had had significantly greater compliance scores compare with group N. However, of more concern was the report that no form of compression had been used at presentation for 25% to 34% of groups S, M, and D.

Anatomic assessment

Isolated superficial group (group S). Of the 1291 limbs in group S, the dominant patterns involved the GSV above the knee (54.8%), the SSV (30.7%), and the anterior accessory GSV (14.4%; Fig 1. The frequency of axial veins per leg was analyzed. Using simple algebra (frequency of one axial vein × 1 plus frequency of two axial veins × 2 plus frequency of three axial veins × 3), the limbs in group S would be eligible for 1.45 ablation procedures per limb (Fig 2). Essentially, nearly one of every two ulcer patients with isolated superficial reflux might require more than one axial vein ablation procedure.

Isolated deep group (group D). One third of the 58 limbs in group D had demonstrated common femoral vein involvement, with 50% extending through the popliteal vein and 50% only to the femoral vein. Another one third had had only popliteal vein involvement, with the remainder found to have mixed combinations of femoral and popliteal involvement.

Mixed deep and superficial group (M group). Of the 238 limbs in group M, the dominant patterns paralleled those seen for the superficial group (group S): GSV above the knee, 61.7%; the SSV, 26.2%; and the anterior accessory GSV (12.1%; Fig 1). We evaluated group M for single, double, and triple axial frequencies (Fig 2). Applying the same algebraic formula, the limbs in group M would be eligible for 1.52 ablations per limb, suggesting that one of every two limbs would have two axial veins eligible for ablation.

Duplex ultrasound analysis of groups S and M found a prevalence of surgically correctable venous reflux disease in 97% of the patients in the present study.

DISCUSSION

For patients with chronic lower extremity wounds, venous ulcers represent a disproportionately large

number of individuals in the United States. The estimated annual incidence of VLUs is 2.2% of the Medicare population. Significant barriers to care include societal structural and medical infrastructural impediments that delay definitive vein care once a patient has developed a leg wound, a delay recognized to impair expedient wound healing.[13,20-22] In addition, >85% of wound patients presenting to a vein practice will possess vein pathology. Patients with chronic venous ulcers associated with venous hypertension will typically be older and less mobile and will have significant comorbidities resulting in quality of life and psychological impairment.[23-27] Societal guidelines can serve as evidence-based resources for implementing standards of care, including the use of compression before and after treatment,[28] and database-supported interventions for the management of chronic venous hypertension.[29-31] Despite the many challenges, the sustained efforts to create multidisciplinary teams have offered opportunities to improve patient care and clinical outcomes.

Adequate compression for VLUs has been the reference standard treatment.[32] The use of an effective dose and achieving compliance have been challenging because of many factors, including limbs that will not fit within standard stocking sizes.[32,33] Limb girth reduction and maintenance can be achieved using many methods, including multilayer compression wraps and Velcro inelastic garments. Lymphatic impairment is now a well-recognized complication for all patients with venous ulcers, further emphasizing the need for compliance with compression. Certified lymphedema therapists and advanced pneumatic compression devices have proved to be of benefit for improving the long-term outcomes.[34,35]

Diagnostic testing is critical to establishing the underlying hemodynamic impairment yet is not considered standard for venous ulcer evaluations at all wound centers. Venous duplex ultrasound testing for deep and superficial pathology will provide an accurate assessment of correctable pathology.[36-38] Iliac lesions should be suspected when leg ulcers present with typical wounds but minimal reflux.[39] Patients with prior iliac vein stent placement might require more interventions than those without active ulcers.[40] For patients with suspected mixed venous and arterial disease (eg, diabetes, metabolic syndrome, tobacco use), an arterial brachial index (ABI) should be performed and if inconclusive or falsely elevated, a toe brachial index will be necessary.[32,41,42]

Early referral from wound centers to vein centers has the potential to improve patient outcomes and decrease venous ulcer recidivism rates.[12,13] Our results have been affirmed by the findings reported by Crawford et al.[43] They demonstrated a significant burden of axial vein reflux for those with VLU.[43]

The study limitations included our inability to precisely identify the etiology of the leg wounds for the patients without superficial or deep vein pathology. Group N could potentially have had contributing causes, including proximal venous obstruction, lymphedema, lipedema, or malignancy. Also, some ulcer patients could have had mixed arterial and venous pathology; however, correlations with ABI data are not available at present within the AVLS PRO Venous Registry. Given the increasing number of risk factors for the development of peripheral arterial disease within the U.S. demographics, collection of the ABI data should be strongly considered.

We believe multidisciplinary teams are necessary for the appropriate management of patients with VLUs. Significant collaborative overlap between vein and wound centers with shared common pathways for treatment and patient education has the potential to enhance outcomes and decrease ulcer recidivism rates.

CONCLUSIONS

Most leg ulcers will be caused by venous pathology due to reflux or obstruction, or both. To the best of our knowledge, vein center participation in the AVLS PRO Venous Registry database has provided the largest reported experience to date. In the patient population with leg ulcers, 97% were found to have had a contributing superficial venous reflux component that was amenable to ablation therapy.

We wish to recognize the 144 active contributing sites to the AVLS PRO Venous Registry for their attention to detail in both the documentation and the quality of care these providers deliver.

AUTHOR CONTRIBUTIONS

Conception and design: MS, TK
Analysis and interpretation: MS, MM, TK
Data collection: MS
Writing the article: MS, MM, TK
Critical revision of the article: MS, MM, TK
Final approval of the article: MS, MM, TK
Statistical analysis: MS, MM, TK
Obtained funding: Not applicable
Overall responsibility: MS

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