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Author manuscript

*J Vasc Surg Venous Lymphat Disord.* Author manuscript; available in PMC 2018 September 01.

Published in final edited form as:

*J Vasc Surg Venous Lymphat Disord.* 2017 September ; 5(5): 647–657.e1. doi:10.1016/j.jvsv.2017.04.013.

## Age is Not a Barrier to Good Outcomes After Varicose Vein Procedures

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### Abstract

**Background**—The Vascular Quality Initiative Varicose Vein Registry (VQI VVR) represents a patient-centered database launched in January 2015. Previous work describing overall trends and outcomes of varicose vein procedures across the United States demonstrates a benefit from these procedures. The existing gaps in evidence to support current and future Medicare coverage of varicose vein procedures necessitate further description of clinical outcomes in patients  $\geq 65$  years old compared to the  $< 65$  year old population.

**Methods**—This study analyzed prospectively captured anatomic, procedural, and outcome data for all patients in a national cohort of all VQI VVR-participating centers. The VQI VVR database was queried for all patients undergoing varicose vein procedures between January 2015 and July 2016. Pre-procedural and post-procedural CEAP classification, venous clinical severity score (VCSS), and patient reported outcomes (PROs) were compared between patients  $< 65$  and  $\geq 65$  years old. Univariate descriptive statistics of demographic and procedural data were performed. Student's t tests were then performed on change in CEAP classification, VCSS score and PROs (heaviness, aching, throbbing, swelling, itching, appearance and impact on work) for each group.

**Results**—There were 4,841 varicose vein procedures performed from January 2015 to May 2016. There were 3,441 procedures performed in 2,691 patients (3631 limbs) in the  $< 65$  years old group and 1,400 procedures performed in 1,068 patients (1467 limbs) in the  $\geq 65$  years old group. Truncal veins alone were the most common veins treated in both groups. The majority of patients were white and female in both groups. Most of the demographic characteristics were clinically similar, (although statistically different), in both groups with the exception of a higher BMI in the  $< 65$  group and a history of bilateral varicose vein treatment, and anticoagulation being more common among patients  $\geq 65$ . Patients in both groups experience statistically significant

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Presented in part at the 29<sup>th</sup> Annual American Venous Forum, New Orleans, LA, February 17, 2017.

Conflicts of Interest: None

improvement in VCSS, PROs and CEAP. There was no difference in overall complications between age groups.

**Conclusion**—All patients demonstrated an associated improvement in both clinical outcomes (CEAP, VCSS), and PROs. There was no significant difference in the improvement in CEAP and VCSS between patients less than and greater than 65 years old, although the younger population reported greater improvement in PROs. Given these findings, patients older than 65 appear to benefit from varicose vein procedures and should not be denied interventions on their varicose veins and venous insufficiency based only on their age.

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## Introduction

Varicose veins are estimated to affect up to 30% of Americans in the United States, and up to 10% of those patients develop skin changes.<sup>1-5</sup> While varicose veins are very common, they are often overlooked by providers due to an under appreciation of the associated morbidity. Nonetheless, venous disease is associated with significant functional limitations and decreased health-related quality of life.<sup>6</sup> Despite national SVS/AVF guidelines on treatment recommendation for varicose veins, there is currently a wide variation of interventions for varicose veins<sup>7</sup>. The Vascular Quality Initiative Varicose Vein Registry (VQI VVR) was developed with an incentive to query patient outcomes of various venous procedures and facilitate physician decision making in developing a treatment strategy with patients for optimal vein care.

Initial data from the VQI VVR suggests that despite the wide variation in clinical practice and physician preference, there is consistent benefit to varicose vein procedures.<sup>7</sup> Overall, patients experience improved Clinical, Etiology, Anatomy and Pathophysiology (CEAP) class, Venous Clinical Severity Score (VCSS), and Patient Reported Outcomes (PROs), suggesting that these procedures be an important tool for providers in the treatment of varicose veins.<sup>7-9</sup> However, there is a paucity of data describing age related benefit to varicose vein procedures despite overwhelming evidence to suggest the prevalence of varicose veins increases with age.<sup>3, 4</sup>

Presently, Medicare reimburses varicose vein procedures only after a period of conservative management.<sup>10</sup> The appropriateness of this requirement is currently a topic of significant debate, as this is contrary to SVS-AVF evidence based guidelines (1B), which recommend against compression therapy as primary treatment of symptomatic varicose veins.<sup>1</sup> The potential exists that Medicare aged patients will not be covered at all. This issue was recently discussed at a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting.<sup>10</sup> To better inform these decisions; it is imperative to explore the outcomes of varicose vein procedures in older patients. Our objective was to investigate clinical outcomes based on age, those  $\geq 65$  years of age compared to those  $< 65$  years old in regards to (1) CEAP class, (2) Venous clinical severity score (VCSS), (3) patient reported outcomes (PROs) and (4) overall complication rates. Our hypothesis is that patients  $\geq 65$  years of age benefit to the same extent as the patients  $< 65$  years old in clinical outcomes without higher complication rates.

## Methods

### Data source and data capture

The Vascular Quality Initiative Varicose Vein Registry (VQI VVR) is one of the 12 registries under the umbrella of the Vascular Quality Initiative (VQI). This registry started in January 2015 and currently has 24 participating centers within 13 regions across 46 states and Ontario. This registry includes all superficial varicose vein procedures for  $\geq$ C2 disease and excludes the treatment of deep veins, veins treated for trauma and superficial veins in patients with C0–C1 disease. Once a center agrees to participate, every consecutive superficial varicose vein procedure is captured. Either the physician who performs the procedure or a designated trained individual for that center completes the data entry. Each data entry has a preoperative assessment, procedure related assessment which includes the assessment of systemic complications as well as whether or not a patient requires hospitalization after the procedure, and post-procedural follow up at two time points, early (0–3 months) and late (>3 months). The follow up then determines if the patient is either discharged or returns to clinic for an additional evaluation of other varicose vein procedures.

The preoperative assessment includes the recording of a pre-procedure Clinical Etiology Anatomy and Pathophysiology (CEAP) class, Venous Clinical Severity Score (VCSS), and Patient Reported Outcomes (PRO). At this time if a preoperative ultrasound study is performed, this is also recorded. Following the preoperative assessment, the patient proceeds to the operating or procedure room for the varicose vein procedure. During the isolated varicose vein procedure, a patient can have up to 6 veins treated in either one or both limbs. Procedures performed on each vein are recorded as either ablation or surgery. We define ablation as “minimally invasive” procedures and include radiofrequency ablation (RFA), laser ablation, mechanicochemical ablation, chemical ablation (by way of sclerosing agents) and embolic adhesive. Within the VQI VVR, surgery is defined as high ligation and stripping, stripping, stab phlebectomy, trivex phlebectomy, open ligation and endoscopic ligation. During the peri-procedural period, systemic complications are assessed and include mild or severe allergic reactions, migraine, visual disturbance, cough/chest tightness, systemic infection, PE, TIA, stroke, and death. Of note, systemic complications are not assessed again at any point in the follow up period. Finally, the patient is then seen in clinic for follow up at two time points, early (0–3 months) and late (>3 months) during which time post-procedure CEAP class, VCSS and PROs are assessed (Figure 1). The post-procedure CEAP class, VCSS and PROs scores that are captured in the VQI VVR dataset are the values recorded at the most recent follow-up.

### Procedure selection

The use of the VQI VVR was granted after submission and approval of the scientific protocol through the national VQI application process and through a local standard institutional review board (IRB) approval. All patient information was de-identified and did not require informed consent. Once access was granted, the dataset of all procedures in the VQI VVR from January 2015 to August 2016 was made available. On initial review of the database, we found 46 procedures from 2014. Given these were likely “back logged” as the VVR VQI was initiated in January 2015 we excluded these procedures. We also excluded all

procedures that occurred after May 2016 and did not have an early follow-up documented. This exclusion avoided case capture appearing to be missing follow up, when in reality insufficient time had passed to allow for early follow up (0–3 months) after the procedure (Figure 2).

## Outcomes

Our primary endpoints were CEAP class improvement, which we defined as moving from a higher C class to a lower C class, VCSS and PROs score improvement. Our secondary endpoints were systemic and leg specific complication rates as well as overall mean improvement between the two age groups (< 65 years old and ≥65 years old). All outcomes are assessed by thorough chart review of operative, progress, and clinic notes by the physician or the designated trained clinical data abstractor. VCSS scores are broken into 10 different components that include: pain, varicose veins, edema, pigmentation, inflammation, induration, active ulcers, ulcer duration, ulcer size, and use of compression.<sup>11</sup> Each component is scored on a scale of 0–3 and the total VCSS is determined by adding the various components. PROs scores are based off of 7 components including: heaviness, aching, swelling, throbbing, itching, appearance and impact on work.<sup>12, 13</sup> These are assessed on a scale 0–5 via patient survey that is given to the patient during each clinic follow up (early and late). These scores are then combined to create the overall PROs score. The VQI VVR then captures the most recent VCSS and PROs score. For the primary endpoints we only analyzed procedures that had pre and post procedure scores and excluded all procedures missing this data from the analysis. Systemic complications are recorded only in the immediate perioperative period whereas leg specific complications are only recorded at the early follow up clinic appointment. Finally, the overall mean improvement comparing both age groups used the average improvement in VCSS and PROs for both cohorts.

## Statistical analysis

Statistical analysis was performed using Stata 14.0 software (StataCorp LP, College Station, TX). Univariate analysis was performed to evaluate baseline demographics and patient characteristics. The  $\chi^2$  was used for comparison of categorical variables. Student t-test was used for continuous variables as they were normally distributed. All primary and secondary outcomes were compared using  $\chi^2$ . A p value of < .05 was considered statistically significant.

## Results

In total there were 4,841 varicose vein procedures performed from January 2015 to May 2016. There were 3,441 procedures performed in 2,691 patients (3631 limbs) in the < 65 years old group and 1,400 procedures performed in 1,068 patients (1467 limbs) in the ≥65 years old group. Bilateral procedures were performed in 190 patients < 65 years old and in 67 patients ≥65 years old. The total number of veins treated in each age group was 6,147 in the younger group compared to 2,366 veins treated in the older group (Figure 2).

## Patient characteristics and clinical presentation

Table I examines the differences in patient demographics between both age groups. The < 65 group had a higher percentage of females and an overall higher BMI. The ≥65 group had a higher percentage of Caucasians, were more likely to have a history of bilateral varicose vein procedures and be on prior anticoagulation. Other patient demographics and characteristics were similar between both groups. The most common pre-procedural CEAP classification was C3 in both groups (Figure 3A). Patients < 65 years old presenting to clinic had C3 disease 40% (N=1,329) of the time, followed by C2 disease in 34.17% (N=1,135) of procedures and C4a disease in 14.09% (N=468). Patients in the ≥65 group presenting to clinic had 33.92% (N=466) with C3 disease, 25.40% (N=349) with C2 disease and 23.22% (N=319) with C4a disease. Only 4.09% (N=136) of procedures performed in patients < 65 had active ulceration, whereas a higher percentage, 7.13% (N=98) of procedures performed were for active ulceration in the ≥65 year old group.

## Anatomic and Procedure Breakdown

The breakdown of procedures based on anatomy is described in Table II. Truncal treatment refers to treatment of axial veins and cluster treatment refers to treatment of varicose vein tributaries. The most frequent varicose vein procedure in the VVR during the time period examined was a truncal only procedure (48.9% for patients < 65, 51.6% for those patients ≥ 65), followed by truncal + cluster procedures for both age groups (39.6% of patients < 65, 36% for patients ≥65). The least common procedure for patients < 65 years old was a cluster + perforator procedure. The least common procedure performed on patients ≥65 years old was truncal + perforator procedure. Of all procedures performed, every anatomic segment was treated individually or in conjunction with treatment of truncal, cluster and perforators in each age group. In other words, all possible combinations of treatment were seen in each group. When examining the types of procedures performed between the two age groups, the patients ≥65 years old were treated with a significantly higher percentage of “minimally invasive” procedures compared to the patients < 65 (62.3% vs. 52.1%,  $p < .001$ ).

## Outcomes

CEAP class improvement was examined for all patients that had a pre-procedural and post-procedural CEAP class assessment (Figure 3B). For all procedures performed in patients < 65 years old, 57.4% had an improvement (95% improved or stable) and for procedures performed in patients ≥65 years old 52% had an improvement (92% improved or stable). VCSS and PROs score improvement was also examined in all patients that had a pre and post10 procedural assessment. VCSS improvement was seen in both patients < 65 years old undergoing procedures of 3.83 (CI 3.67–3.98,  $p < .001$ ) and patients ≥65 years old undergoing procedures of 3.72 (CI 3.46–3.98,  $p < .001$ ) (Figure 4A). PROs score improvement was seen in both age groups, with a mean improvement of 9.96 (CI 9.61–10.31,  $p < .001$ ) for procedures performed in < 65 and 9.07 (CI 8.58–9.56,  $p < .001$ ) for procedures ≥65 (Figure 4B). When examining the breakdown of VCSS and PROs scores pre to post-procedural for both age groups all components had a significant improvement (Supplemental Table I and II). When comparing the mean improvement between age groups in regards to VCSS and PROs scores we found that there was no difference for VCSS (3.83

vs. 3.72,  $p = .42$ ); however, with PROs scores (9.96 vs. 9.07,  $p < .004$ ), the patients  $< 65$  years old had a higher mean improvement (Figure 4C). The full breakdown of components in regards to mean improvement is described in Table III.

### Complications

Complications recorded in the VQI VVR are systemic and leg specific and are captured at different time points. Systemic complications are documented during the perioperative period and were overall low and not statistically different for patients  $< 65$  years of age and  $\geq 65$  years of age and were 0.70% and 0.79% respectively ( $p = .742$ ) (Table IV). Leg specific complications are documented during the early (0–3 month) follow up appointment. Leg specific complications were also low at  $< 2\%$  for each leg complication. The overall rate of any leg complication for patients  $< 65$  years of age was 6.71% (N=101) and 6.17% (N=39) for patients  $\geq 65$  years of age. The most common complication for both age groups was paresthesia followed by DVT. The only leg complication that was statistically different between age groups was wound infection (.20% vs. .95%,  $p = .015$ ) although this occurred extremely infrequent (Table V).

### Follow-Up

Of 4,841 procedures, 45.3% (N=2,195) of procedures had early follow-up (within 3 months), 16.9% (N=820) of procedures had late follow-up and 37.7% (N=1,826) procedures were missing follow up.

### Discussion

Our study addresses an important, timely question of whether or not patients  $\geq 65$  years of age benefit from varicose vein procedures and if the benefit is to the same extent as patients  $< 65$  years old. This data demonstrates that not only do patients  $\geq 65$  years of age have improvement of clinical and patient reported outcomes, this group has just as much of a positive response as their younger counterparts in regards to VCSS. Importantly, this benefit does not come with a higher risk of complications and in fact, the older patient group had no associated increased risk of complications with the exception of wound complications. Ultimately, these results have the potential to directly impact federal policy on Medicare coverage in this vulnerable patient population.

### Not only a problem of the young

Varicose veins affect approximately 23% of adults in the United States, with a mean age of 33–55 reported in the literature and affects both men and women.<sup>12, 14–16</sup> Although many overlook the significant morbidity varicose veins cause, the prevalence increases with age and increases in severity with time.<sup>17</sup> With all of these factors to consider, it is surprising to see such a potential gap in coverage. Thus, we set out to confirm or refute the hypothesis that older patients  $\geq 65$  benefit to the same extent as the patients  $< 65$  years old in clinical outcomes without higher complication rates.

### Clinical improvement and patient reported outcomes

One potential concern for treating patients  $\geq 65$  is the concern for associated increased risk without similar benefit seen in the younger patient population. However, our data does not support this assumption. On the contrary, in our study the procedures performed in patients  $\geq 65$  years of age had statistically significant improvements in VCSS (OR 3.72, CI 3.46–3.98,  $p < .001$ ), and PROs (OR 9.07, CI 8.58–9.56,  $p < .001$ ). When comparing the two age groups mean improvement in VCSS and PROs, we found that there was no difference for VCSS, however the younger population had a greater mean improvement in PROs. When examining potential reasons to explain this phenomenon, we broke down the PROs into the different components to see what were the largest contributors to this difference (Table III). The five components that were significant clinical contributors to the higher mean improvement in the younger population are the exact components that we believe are the main clinical factors aligning with varicose veins, which happens to be C2 in the CEAP classification. These included heaviness, achiness, throbbing, itching, and appearance. In addition, when accounting for types of procedures performed, the older age group did have a higher percentage of “minimally invasive” procedures (62.3%), which was significantly different ( $p$  value  $< .001$ ) than the younger  $< 65$  patient cohort (52.1%). The association of type of treatment on outcome is unclear and warrants further investigation. However, it is interesting to speculate that this data would indicate that older patients are more often treated for symptoms of chronic venous insufficiency (pain and swelling) and not for their varicosities while younger patients are more often treated for their branch varicosities. Additionally, this may help to explain the difference in mean improvement in VCSS component score for varicose veins before and after treatment (Table III).

### Comparing complications

Overall complications were low amongst all patients and not associated with any significant difference between the two groups of patients. This finding supports the safety of the varicose vein procedures in patients  $\geq 65$ ; although it is important to note that we did find a higher percentage of “minimally invasive” procedures being performed in the older cohort. Despite this finding, current practice patterns appear to be safe and effective in patients over the age of 65. The overall incidence of the complications seen in VQI VVR is similar to rates published in the literature.<sup>1, 14, 18, 19</sup> The only complication that was higher within the older group was wound infection, although the rate was extremely low ( $< 1\%$ ) and much lower than the approximate 3–6% wound infection rate seen in the literature. Although we do not have the granularity within this dataset to know specific reasons behind the wound infection, we did note that 11% of patients in the  $\geq 65$  group were on perioperative anticoagulation, which may be one potential reason this occurred. On the other hand, knowing that approximately 16% of elderly patients treated in our cohort, were on perioperative anticoagulation and still had a low complication rate may ease some clinicians when approached with an older patient who is on anticoagulation for a comorbid condition in their pre-procedure clinic. Another potential explanation of the increased wound infection rate in the older population could be immunosuppression secondary to comorbid conditions such as diabetes that are unfortunately not captured in the VQI VVR.

## Limitations

One of the main limitations is the poor follow up within the VVR VQI with only 62.2% of procedures had follow up. This became apparent after our first look at the registry<sup>7</sup> and has not been a unique problem with the VQI VVR as other studies have had similar problems with lost to follow up rates as high as 50%.<sup>18</sup> We have been in the process of working with the VQI in an effort to establish quality measure metrics for the VQI VVR. Our proposal includes a number of measures: the percentage of patients with pre-procedure VCSS, the percentage of patients with a pre-procedure venous duplex assessing reflux, the percentage of perforator procedures in patients with C5 or C6 disease to ensure proper patient selection for perforator vein ablation, the percentage of patients avoiding hospital admission after varicose vein procedures, and lastly, the percentage of phlebectomy procedures that have prescribed post-procedure compression therapy. Ultimately, many of these measures aim to improve the “trackable” outcomes and reduce the number of unindicated procedures, with the goal of improving overall clinical venous care. Another limitation of the study is the potential for selection bias as this is a procedural registry only capturing patients undergoing varicose vein procedures. With the VQI VVR we do not have the true denominator of patients with venous disease that present to clinic and are treated with conservative management and never go onto have a procedure. This is potentially very important in the  $\geq 65$  group, as many that did not subsequently undergo a procedure could have extensive comorbidities. What we can say however is that the patients  $\geq 65$  that are currently being selected over the study period for varicose vein procedures are achieving significant benefit with low complication rates. Finally, VCSS and PRO scores are based on subjective components that rely on both patient and provider input and reporting that may be biased in favor of improvement following varicose vein procedures. However this subjective bias would likely occur across both patient age groups and there is no evidence to suggest this bias would differentially affect age groups.

## Conclusion

In summary, all patients demonstrated an associated improvement in both clinical outcomes (CEAP, VCSS), and PROs. There was no significant difference in the improvement in CEAP and VCSS between patients less than and greater than 65 years old. Although patients  $< 65$  years old had a statistically significant mean improvement in PROs compared to the patients  $\geq 65$  years old, it remains unclear whether or not this is clinically significant result. Given these findings, patients older than 65 appear to benefit from appropriate varicose vein procedures and should not be denied interventions on their varicose veins and venous insufficiency based only on their age.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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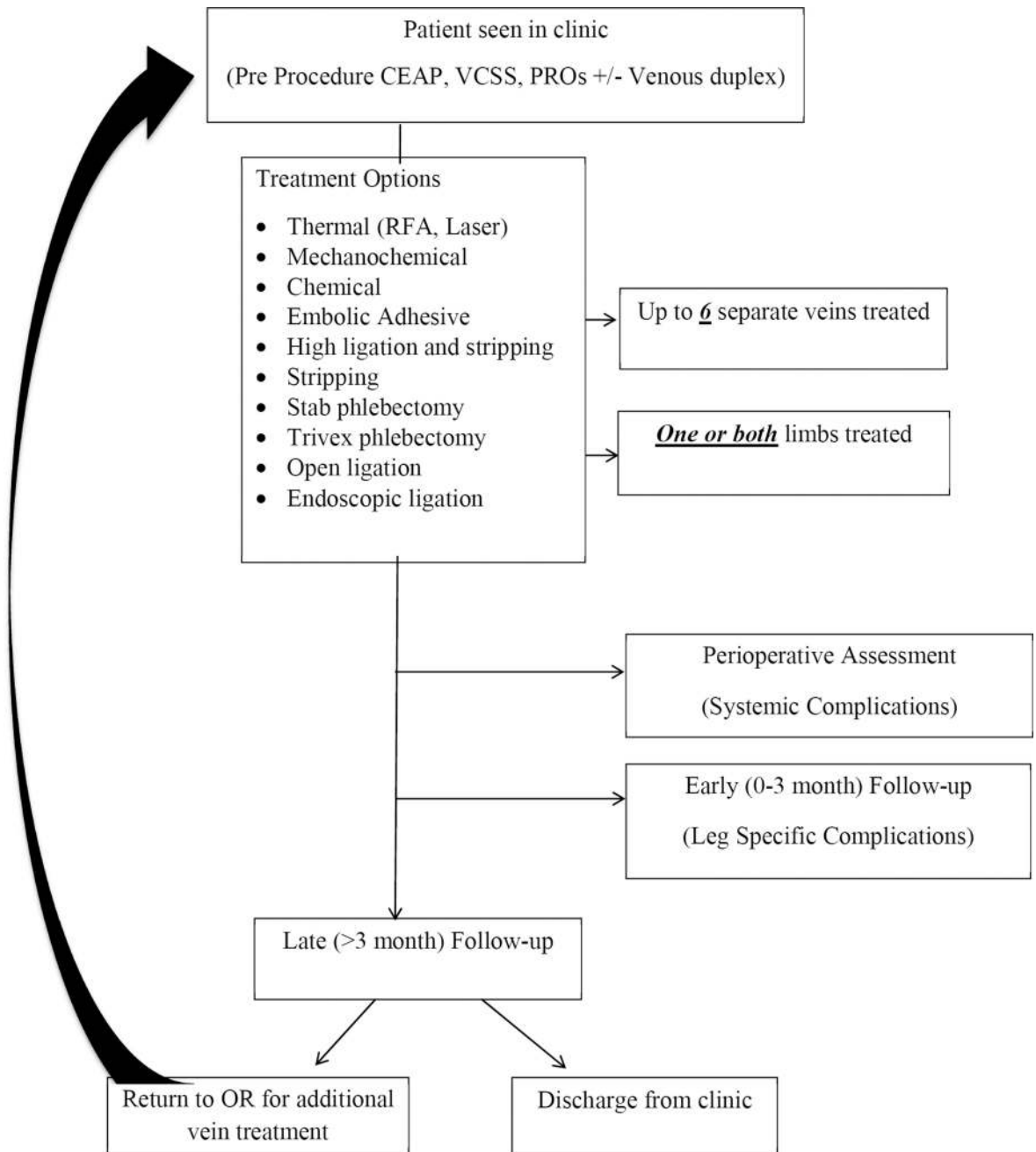


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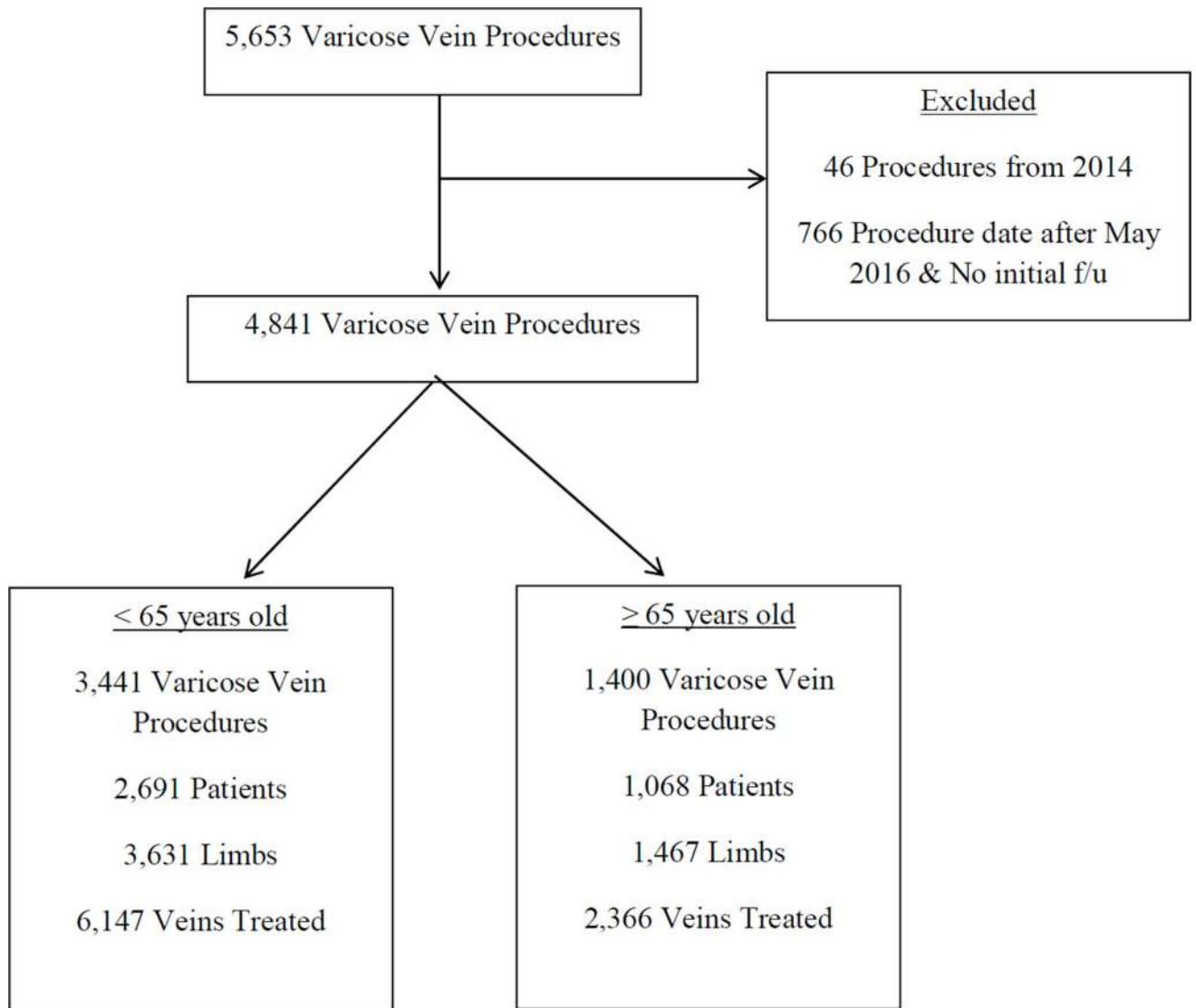
**Type of Research:** Retrospective review of prospectively collected data of the VQI Varicose vein registry

**Take Home Message:** Procedures for varicose veins in 1,068 patients > 65 years of age resulted in similar improvement in CEAP class and VCSS than in 2,691 younger patients. Younger patients had more improvement in patient reported outcomes.

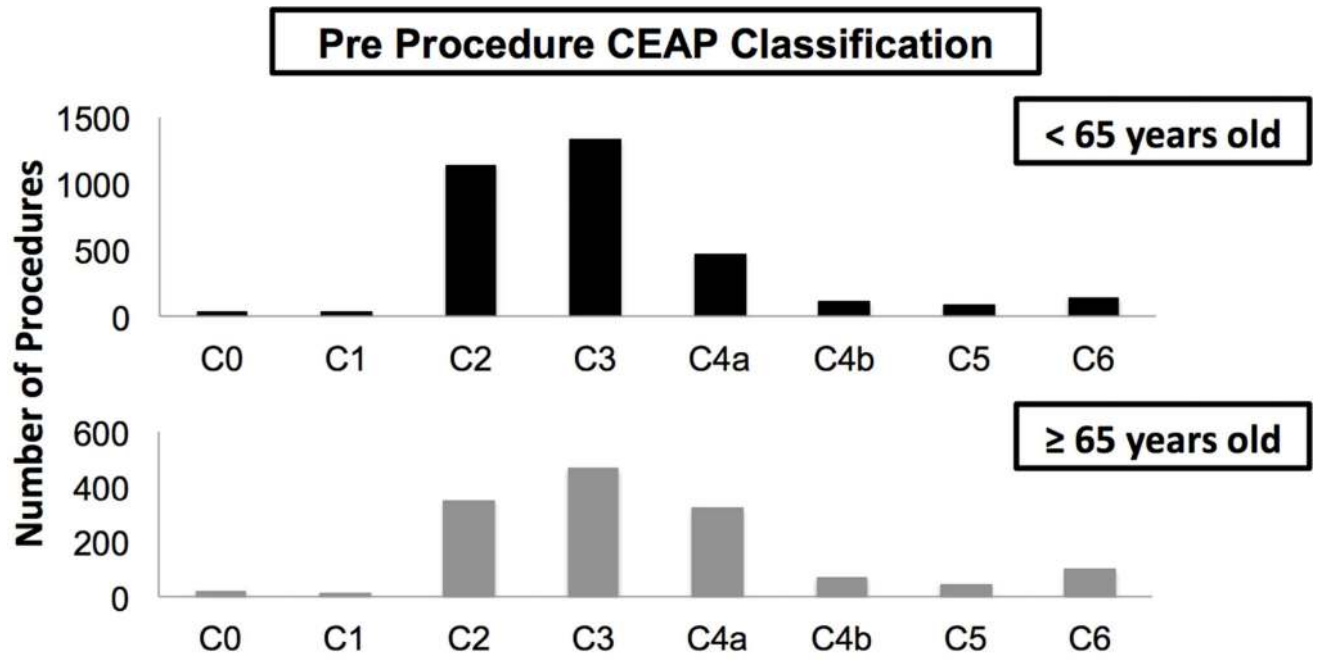
**Recommendation:** The authors recommend that Medicare beneficiaries should not be denied vein procedures based on age alone.



**Figure 1.**  
Flow chart demonstrating patient flow in the VQI VVR.



**Figure 2.**  
Flow diagram of procedure breakdown in each age group.



a.

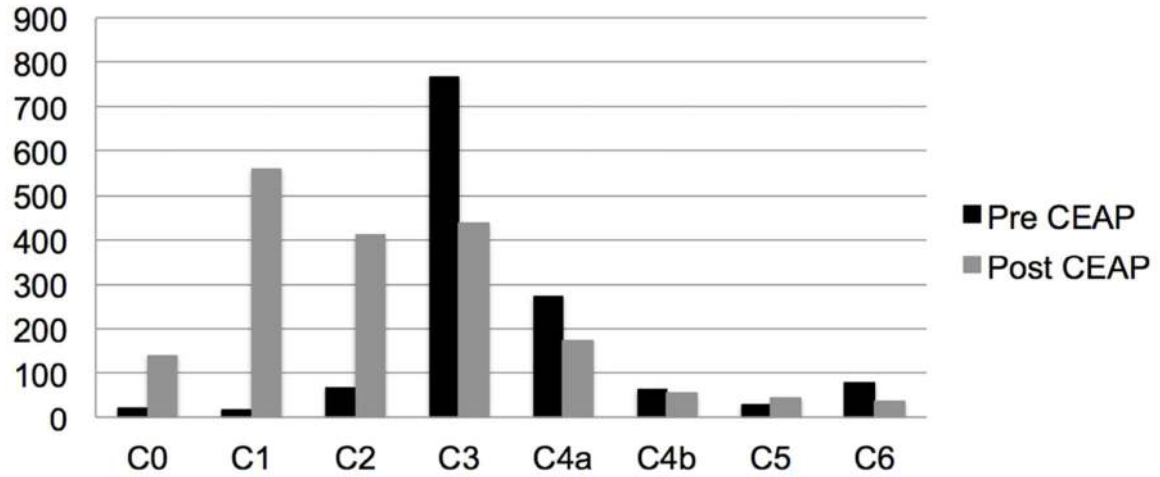
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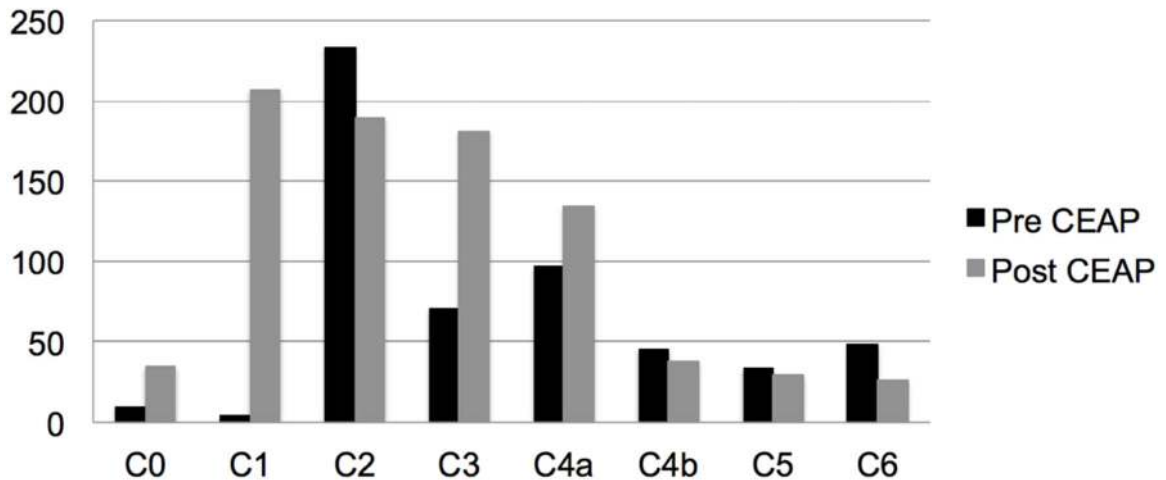
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### Pre and Post CEAP Classification in patients < 65 years old



### Pre and Post CEAP Classification in patients ≥ 65 years old



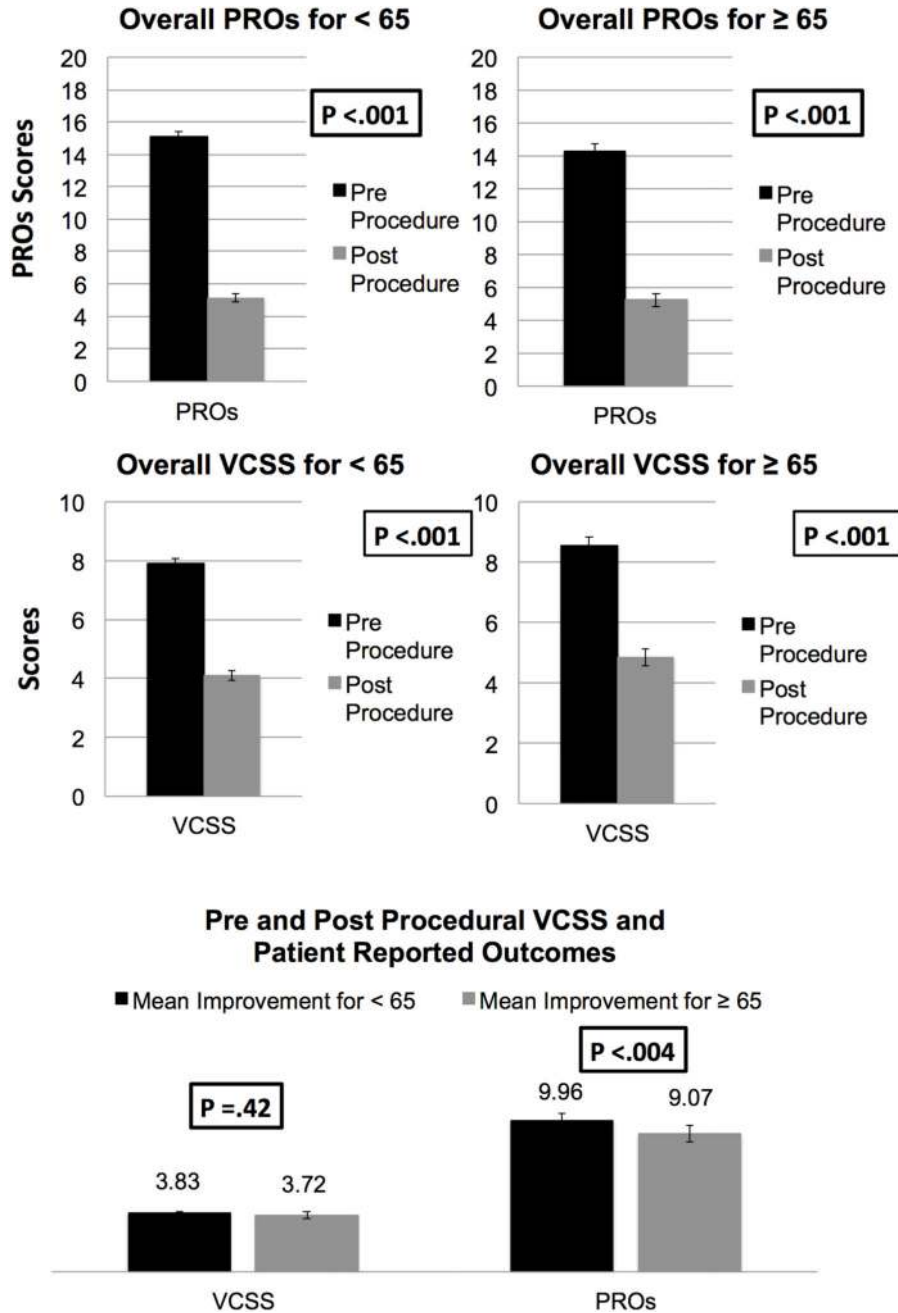
**b.**

**Figure 3.**

A. Number of procedures performed for each pre procedure CEAP class within each age group for all procedures (N=4,841).

B. Pre and post procedure CEAP classification in patients < 65 years old and ≥65 years old.

Note: Only procedures with both a pre and post procedural CEAP are included (N=2,697).



**Figure 4.**  
 A. Pre and post procedure VCSS in patients < 65 years old and ≥65 years old. Note: Only procedures with both a pre and post procedural VCSS are included (N=2,623).  
 B. Pre and post procedure PROs in patients < 65 years old and ≥65 years old. Note: Only procedures with both a pre and post procedural PROs are included (N=2,342).  
 C. Overall mean improvement of pre and post procedural clinical score and patient reported outcomes in patients < 65 years old compared to patients ≥65 years old.

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**Table I**

Demographics of patients above and below 65 years of age.

	< 65 years old (n=2691), No. (%)	≥65 years old (n=1068), No. (%)	<i>P</i> value
Age, years (SD) <sup>a</sup>	48.89 ±10.24	71.94 ± 5.93	<.001
Sex (female)	1967 (73.10)	742 (69.48)	.026
Race <sup>b</sup>			
White	2084 (77.44)	885 (82.87)	<.001
Black	180 (6.69)	45 (4.21)	.004
Asian	41 (1.52)	10 (.94)	.160
Other	363 (13.49)	126 (11.8)	.164
BMI (SD) <sup>c</sup>	30.11 ± 7.58	29.45 ± 6.39	.013
Prior VV treatment <sup>d</sup>			
Unilateral	517 (19.23)	208 (19.49)	.855
Bilateral	295 (10.97)	142 (13.31)	.044
History of DVT <sup>e</sup>			
Unilateral	140 (5.22)	72 (6.77)	.063
Bilateral	26 (.97)	16 (1.51)	.160
Receiving Anticoagulation <sup>f</sup>			
No	2555 (95.02)	897 (84.07)	<.001
Yes - continued	115 (4.28)	124 (11.62)	<.001
Yes - stopped perioperatively	19 (.71)	46 (4.31)	<.001

<sup>a</sup>(SD) indicates continuous variables with summary measure of mean (standard deviation) and *P*value from Student's t-test.

<sup>b</sup>Data missing on 2 individuals.

<sup>c</sup>Data missing on 8 individuals.

<sup>d</sup>Data missing on 4 individuals.

<sup>e</sup>Data missing on 13 individuals.

<sup>f</sup>Data missing on 3 individuals. Categorical variables are summarized by No. (%), and *P*values are calculated from the  $\chi^2$  test. Anticoagulation in the VQI VVR includes: warfarin, dabigatran, rivaroxaban, unfractionated heparin, low molecular weight heparin (LMWH) or other anticoagulation and does not include aspirin.



**Table II**

Breakdown of anatomic segment treated during a single procedure performed in patients < 65 years old and ≥ 65 years old.

	< 65 years old (n=3441), No. (%)	≥65 years old (n=1400), No. (%)	<i>P</i> value
Truncal Only	1682 (48.88)	722 (51.57)	.090
Cluster Only	256 (7.44)	120 (8.57)	.182
Perforator Only	65 (1.89)	21 (1.50)	.353
Truncal-Cluster Only	1363 (39.61)	504 (36)	.019
Truncal-Perforator Only	19 (.55)	9 (.64)	.706
Cluster-Perforator Only	16 (.46)	12 (.86)	.103
Truncal-Cluster-Perforator	40 (1.16)	12 (.86)	.350

Truncal refers to treatment of axial veins. Cluster refers to treatment of varicose vein tributaries.

**Table III**

Mean improvement in VCSS and PROs with corresponding component breakdown for patients < 65 years old and ≥65 years old.

	Mean Improvement for < 65	Mean Improvement for ≥65	≥65 vs. < 65 P value
VCSS Score <sup>a</sup>	3.83 (p<.001 <sup>*</sup> )	3.72 (p<.001 <sup>*</sup> )	.420
Pain	1.10 (p<.001 <sup>*</sup> )	1.05 (p<.001 <sup>*</sup> )	.234
Varicose veins	1.24 (p<.001 <sup>*</sup> )	1.05 (p<.001 <sup>*</sup> )	<.001
Venous edema	.47 (p<.001 <sup>*</sup> )	.51 (p<.001 <sup>*</sup> )	.233
Skin pigmentation	.13 (p<.001 <sup>*</sup> )	.21 (p<.001 <sup>*</sup> )	<.001
Inflammation	.20 (p<.001 <sup>*</sup> )	.24 (p<.001 <sup>*</sup> )	.138
Induration	.15 (p<.001 <sup>*</sup> )	.19 (p<.001 <sup>*</sup> )	.139
Active ulcers	.03 (p<.001 <sup>*</sup> )	.04 (p<.001 <sup>*</sup> )	.688
Ulcer duration	.04 (p<.001 <sup>*</sup> )	.04 (p=.0005 <sup>*</sup> )	.952
Active ulcer size	.03 (p<.001 <sup>*</sup> )	.05 (p=.0002 <sup>*</sup> )	.330
Compression therapy	.44 (p<.001 <sup>*</sup> )	.33 (p<.001 <sup>*</sup> )	.026
PROs Score <sup>b</sup>	9.96 (p<.001 <sup>*</sup> )	9.07 (p<.001 <sup>*</sup> )	<.004
Heaviness	1.61 (p<.001 <sup>*</sup> )	1.37 (p<.001 <sup>*</sup> )	<.001
Achiness	1.70 (p<.001 <sup>*</sup> )	1.53 (p<.001 <sup>*</sup> )	.018
Swelling	1.53 (p<.001 <sup>*</sup> )	1.50 (p<.001 <sup>*</sup> )	.736
Throbbing	1.44 (p<.001 <sup>*</sup> )	1.19 (p<.001 <sup>*</sup> )	<.001
Itching	.92 (p<.001 <sup>*</sup> )	.77 (p<.001 <sup>*</sup> )	.020
Appearance	1.60 (p<.001 <sup>*</sup> )	1.48 (p<.001 <sup>*</sup> )	.064
Impact on work/activity	1.09 (p<.001 <sup>*</sup> )	1.18 (p<.001 <sup>*</sup> )	.168

<sup>a</sup>VCSS Data missing on 1,636 procedures in the < 65 group and 582 procedures in the ≥65 group.

<sup>b</sup>PROs Data missing on 1,855 procedures in the < 65 group and 644 procedures in the ≥65 group.

\* P value signifies that there was significant improvement from pre procedure to post procedure VCSS and PROs scores for each age group.

**Table IV**

Systemic complications of procedures performed on patients above and below 65 years of age.

	< 65 years old (n=3441), No. (%)	≥65 years old (n=1400), No. (%)	<i>P</i> value
Overall systemic complication	24 (.70)	11 (.79)	.742
Mild allergic reaction	4 (.12)	1 (.07)	.660
Severe allergic reaction	1 (.03)	0	.524
Migraine	1 (.03)	0	.524
Visual disturbances	1 (.03)	0	.524
Cough/chest tightness	1 (.03)	0	.524
Systemic infection	0	1 (.07)	.117
PE	2 (.06)	0	.367
TIA	0	0	--
Stroke	0	0	--
Death	0	0	--
Other	16 (.46)	8 (.64)	.434

PE, pulmonary embolism; TIA, transient ischemic attack. Systemic complications are recorded in the *perioperative* period (day of procedure until discharge from the hospital or outpatient facility).

**Table V**

Leg specific complications of procedures performed on patients above and below 65 years of age.

	<65 years old (n=1505), No. (%)	65 years old (n=632), No. (%)	P value
Any leg complications	101 (6.71)	39 (6.17)	.645
Bleeding requiring reintervention	0	0	--
Skin blistering	3 (.20)	1 (.16)	.841
DVT	12 (.80)	9 (1.42)	.180
Hematoma	8 (.53)	2 (.32)	.506
Paresthesia	30 (1.99)	10 (1.58)	.522
Pigmentation	10 (.66)	3 (.47)	.607
Superficial phlebitis	11 (.73)	1 (.16)	.106
Induced ulcer	1 (.07)	0	.517
Wound infection	3 (.20)	6 (.95)	.015
Proximal thrombus extension (EHIT)	14 (.93)	6 (.95)	.967

2,646 procedures did not have early follow-up. Of the 2,195 procedures that did have early follow-up, leg specific complication data missing in 58 procedures (44 from < 65 and 14 from ≥65). Leg specific complications are only recorded in *early* (0–3) follow-up. EHIT, endothermal heat induced thrombosis.

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