

alone (radiofrequency or laser). Symptom severity change is assessed using the pretreatment and 1-month follow-up Venous Clinical Severity Score (VCSS). Bivariate statistics are calculated comparing the CT and UT groups, with *P* values calculated using the Student *t*-test or Pearson  $\chi^2$  test as appropriate. A multivariable linear regression model assesses the association of CT with the change in VCSS.

**Results:** There were 1031 patients included for analysis (UT, 478; CT, 553). UT patients were older (35.9% were >64 years vs 20.7%; *P* < .001), were more likely to be white (79.3% vs 65.5%; *P* < .001) and to have a higher initial VCSS (7.28 vs 6.15; *P* < .001), and were assessed at an earlier follow-up visit (25.9 days postoperatively vs 32.9 days; *P* < .001). Compared with UT, CT was associated with an additional 1-point reduction in VCSS on bivariate analysis (−3.50 points for UT vs −4.54 points for CT; *P* < .001; Table). Thrombotic complications were not different between the two groups (UT, 1.04%; CT, 0.72%; *P* = .58). On the multivariable model, after adjustment for follow-up day, age group, ethnicity, and initial VCSS, CT was associated with a reduction in VCSS of 1.07 points beyond the reduction seen in UT alone (*P* < .001).

**Conclusions:** Invasive treatment of C2<sub>s</sub> chronic venous insufficiency improves symptom severity. Whereas treatment of venous reflux is essential to address venous symptoms, our results suggest that patients further benefit from additional direct treatment of varicosities. For select patients, combined therapy may present a more effective treatment strategy than saphenous ablation alone.

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### Economic Benefit of a Novel Dual Mode Ambulatory Compression Device for Treatment of Chronic Venous Leg Ulcers



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**Objective:** Compression is critical to heal chronic venous leg ulcers (VLU). A novel dual mode ambulatory pneumatic compression (APC) device was tested in comparison to multilayered compression bandaging systems for the treatment of nonhealing VLUs in a prospective randomized clinical trial (RCT).

**Methods:** Patients with VLUs measuring between 2 and 50 cm<sup>2</sup> present for 1 to 12 months were randomized to treatment with the APC device (ACT group; Actitouch; Tactile Medical, Minneapolis, Minn) or multilayered compression bandaging (MLB) with either Profore (Smith & Nephew, Memphis, Tenn) or Coban 2 (3M Health Care, St. Paul, Minn) compression systems. Patients in the ACT group were asked to wear the device for sustained or intermittent compression throughout the day and to wear a light compression stocking at night. The ACT group patients were seen every 2 to 3 weeks for follow-up to 16 weeks, allowing more in-home care. The MLB group was seen in the outpatient clinic weekly. Other aspects of VLU care were standardized between the two groups. The primary study objective was to compare wound size reduction at 16 weeks between the two groups in a noninferiority RCT. Secondary objectives assessed the effect of each therapy on medical resource utilization and the direct cost of care.

**Results:** There were 58 patients who were randomized to treatment with either MLB (*n* = 30) or ACT (*n* = 28). Both groups experienced similar rates of wound healing during the 16-week follow-up period, with ACT group patients decreasing from 4.01 ± 2.4 cm<sup>2</sup> to 1.21 ± 2.5 cm<sup>2</sup> and MLB-treated wounds decreasing from 7.6 ± 7.9 cm<sup>2</sup> to 2.5 ± 6.1 cm<sup>2</sup>. There was no significant difference between groups in percentage of wound closure, incidence of complete wound healing, or improvement in Venous Clinical Severity Score. ACT-treated wounds had lower utilization of non-study-related clinic visits compared with the MLB cohort (50.0% vs 63.3%, respectively). In addition, there were fewer ACT-scheduled patient visits without any associated complications, resulting in lower direct medical costs compared with the MLB cohort (− difference [−\$2733; *P* = .06]). The trial was halted before full

randomization to make improvements to the ACT device to increase the patient's comfort and usability, as suggested by both participating physicians and patients.

**Conclusions:** In this preliminary RCT, a novel APC device achieved similar VLU wound healing results in comparison to MLB but with lower direct costs. The study has led to important changes in device design that will allow confirmation of these findings in a larger RCT.

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### The Impact of Great Saphenous Vein Size on Gender, Clinical Severity, and Outcome of Patients Undergoing Vein Ablation for Varicose Veins



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**Objective:** Policies of insurance carriers have used truncal vein size as a criterion for coverage. The objective of this study was to compare the effect of great saphenous vein (GSV) size ≥5 mm vs <5 mm on the patient's presentation and clinical outcomes.

**Methods:** Patients in a national cohort were prospectively captured in the Vascular Quality Initiative Varicose Vein Registry. From January 2015 to October 2017, the Vascular Quality Initiative Varicose Vein Registry database was queried for all patients undergoing varicose vein procedures. Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) class, Venous Clinical Severity Score, and patient-reported outcomes were compared for GSV size <5 mm (group 1) vs size ≥5 mm (group 2) before and after the procedures. Two-sample Wilcoxon test was performed to assess the difference between the two groups as defined by GSV size. To assess for improvement after the procedure in this population, a matched pairs signed rank Wilcoxon test was performed for each group separately.

**Results:** During the study period, 5757 vein ablation procedures were performed for GSV: 770 GSV size <5 mm and 4987 GSV size ≥5 mm. Group 1 patients were more likely to be female (81.7% vs 68.4%; *P* = .001) and older (56.8 years vs 55.6 years; *P* = .012). CEAP scores were higher in group 2 compared with group 1 (*P* = .001). Maximal GSV diameter in group 2 was significantly higher (8.32 mm vs 3.86 mm; *P* = .001); 64% of group 2 underwent radiofrequency thermal ablation compared with 59.2% of group 1 (*P* = .001). There were no deaths in either group. Group 2 had more complications after the procedure (0.6% vs 0%; *P* = .027), required postoperative anticoagulation (8.8% vs 5%; *P* = .001), developed partial recanalization rate (0.8% vs 0.3%; *P* = .001), and missed more work days (2.32 days vs 1.6 days) compared with group 1. A similar rate of hematoma developed in both groups, but there was a higher rate of paresthesia in group 1. Both groups had improvement in the Venous Clinical Severity Score and HASTI (heaviness, achiness, swelling, throbbing, and itching) score. The degree of symptomatic improvement between the groups was similar (Table).

**Conclusions:** All patients demonstrated improvement in both clinical outcomes and patient-reported outcomes after endovenous ablation regardless of size. Patients with preoperative GSV size ≥5 mm had similar

**Table.** Venous Clinical Severity Score (VCSS) and heaviness, achiness, swelling, throbbing, and itching (HASTI) improvements based on great saphenous vein (GSV) size

	Group 1, GSV <5 mm	Group 2, GSV ≥5 mm	<i>P</i> value
VCSS improvement	2.78	3.16	.833
HASTI improvement	5.61	5.71	.719