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 χ^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 $C2_S$ 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 (VLUs). 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^2 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^2 to 1.21 ± 2.5 cm^2 and MLB-treated wounds decreasing from 7.6 ± 7.9 cm^2 to 2.5 ± 6.1 cm^2. 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	*P* value
VCSS improvement	2.78	3.16	.833
HASTI improvement	5.61	5.71	.719

improvement in symptoms but sustained an increased complication rate. Patients with smaller vein size should not be denied intervention or coverage on the basis of size criteria.

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Unexpected Frequency and Clinical Significance of Nontarget Superficial and Deep Vein Occlusion After Foam-Form Sclerotherapy

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Objective: Ultrasound-guided foam-form sclerotherapy (UGFS) appears to be a safe procedure associated with a low number of clinically relevant venous thromboembolism events. However, the incidence and clinical relevance of silent occlusions of deep and superficial veins that were not a target for treatment have not been carefully studied. The aim of this study was to address this knowledge gap.

Methods: This retrospective analysis focused on the electronic medical records of patients treated with UGFS at a private clinic in Moscow between 2015 and 2017. In accordance with the internal protocol, all patients underwent serial duplex ultrasound (DUS) examination at 1 to 2 weeks and 1 month, 3 months, 6 months, and 12 months after UGFS with mandatory fixation of the results in the electronic medical record. Serial DUS was used to identify nontarget venous occlusion, recognized as incomplete compression of any deep or superficial vein not subjected to obliteration. The analysis included patients who underwent at least one DUS examination 1 to 2 weeks after UGFS.

Results: The analysis included data on 257 lower limbs of 196 patients with varicose veins: 139 women and 57 men (mean age, 44.2 ± 12.2 years) with the following Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) clinical class distribution: C2, 74.0%; C3, 20.0%; C4, 4.5%; and C5, 1.5%. UGFS was performed in addition to laser ablation of the great saphenous vein in 54.9%, small saphenous vein in 10.5%, perforating veins in 26.1%, Giacomini vein in 3.9%, or anterior accessory saphenous vein in 1.9%.

Nontarget venous occlusion was detected in 60 limbs (23.3%) and was symptomatic in only three cases (1.2%). The majority of occlusions were localized in the untreated great saphenous vein trunk (n = 23) or the calf muscle veins (n = 15). Specific drug treatment was prescribed for only two patients; 91%, 66%, 37%, and 11% of all limbs were followed-up at 1 month, 3 months, 6 months, and 12 months, respectively. There were no cases of thrombus progression or symptomatic pulmonary embolism. At 6 months, no occlusions persisted. Recurrence of varicose veins at 12 months was noted in 16 cases (6.2%) by DUS. There were no differences between limbs as a function of occlusions (10.0% vs 5.1%; $P = .218$).

Conclusions: The frequency of nontarget vein occlusion after UGFS revealed by serial DUS may be as high as 23.3%. These occlusions tend to resolve by 6 months and do not affect clinical outcomes.

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Early Results of a Randomized Clinical Trial of Mechanochemical Ablation Versus Cyanoacrylate Adhesive for the Treatment of Varicose Veins

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Objective: Endovenous thermal ablation techniques have become the first-line treatment of truncal veins. However, these techniques use heat and have need of tumescent anesthesia, which are often associated with pain. To overcome these side effects, novel nonthermal techniques, such as mechanochemical ablation (MOCA) and cyanoacrylate embolization (CAE), have been developed; these do not require tumescence or use heat. This randomized controlled trial aimed to assess the degree of pain resulting from MOCA compared with CAE. We are herein reporting the early results of this randomized clinical trial.

Methods: Patients with saphenous vein incompetence were randomized to receive treatment with either MOCA or CAE. The primary end point is pain score immediately after completion of truncal ablation, measured by a 100-mm visual analog scale. The secondary end points include entire treatment pain scores, clinical scores, and quality of life scores. Additional assessments include ecchymosis scores, occlusion rates, and time to return to usual activities/work at 2 weeks. Patients are observed at 2 weeks, 3 months, 6 months, and 12 months.

Results: So far, 84 patients have been recruited (66% women; mean age, 56 years). The vein treated was the great saphenous vein in 86% of cases, and 51% of the cases were randomized to cyanoacrylate ablation. Both groups had similar baseline characteristics. Patients in both groups experienced similar maximum pain score by visual analog scale (CAE: median 24 mm (interquartile range [IQR], 9-45 mm); MOCA: median, 23 mm (IQR 11-49 mm); $P = .464$) and number scale (CAE: median, 3 (IQR, 1-5); MOCA: median, 3 (IQR, 2-5); $P = .333$). Average pain score was also similar between treatment groups. Eighty-three percent (70 patients) of the population attended the 2-week follow-up. Postprocedure ecchymosis score, recovery time, and clinical and quality of life scores were similar between groups.

Conclusions: The early results of this trial showed that pain score is comparable between CAE and MOCA endovenous ablation. The results also indicated similar improvement in quality of life, clinical improvement, and recovery time. Recruitment of patients is ongoing, and longer term follow-up data are currently being collected.

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Diagnosis of and Therapy for Vein Insufficiency in Children

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Objective: Venous insufficiency of the lower extremities is usually considered to be a genetically determined, long-term acquired disease. Children have rarely been examined.

Methods: In an ongoing study, until May 2018, a total of 170 legs in 85 children of Angioclinic vein patients aged 6 to 18 years (38 male; 47 female) were examined with high-frequency ultrasound (Siemens X700 [Siemens Healthcare, Hoffman Estates, Ill]; Mindray M9, 14-16 MHz [Mindray, Mahwah, NJ]; Vevo MD, 16-32 MHz [SonoSite, Bothell, Wash]). Investigation time was limited to 15 minutes. In case of visible vein changes (protruding, more intense color, increased diameter), ultrasound started here. Otherwise, systematic screening of saphenous veins and medial perforators was performed.

Results: In 47 of 85 children (55.3%), relevant venous disease was found in 59 of 170 legs (34.7%), as follows: focal valvular defects of the great saphenous vein (GSV; 14/170 [8.2%]), segmental GSV reflux without varices (15/170 [8.8%]), segmental GSV reflux with varices (11/170 [6.5%]), GSV side branch reflux only (13/170 [7.6%]), total GSV reflux (3/170 [1.8%]), focal small saphenous vein valve lesion (2/170 [1.2%]), segmental small saphenous vein reflux (1/170 [0.6%]), and medial perforator reflux (none). In the subgroup of 6- to 8-year-old children, 9 of 30 legs (30.0%) already showed pathologic changes. Among the cases allowing diagnosis of lesion type (n = 53), unilateral commissural mismatch was the most frequent pattern (24/53 [45.3%]). Whereas some findings may be treated at a suitable age (14-18 years) with today's methods (side branches: microfoam; saphenous: thermal, MOCA, biomatrix foam), vein-saving methods are still missing for single-valve insufficiency and stages before clinical reflux.