Endovascular obliteration of saphenous reflux: A multicenter study

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Objective: **The objective of this study was to assess the differences in clinical outcomes in patients treated with endovenous saphenous vein obliteration with technical outcome of either complete occlusion (CO), near complete occlusion (NCO), defined as ≤5-cm segment of flow in treated vein, or recanalization, defined as >5-cm segment of flow in treated vein.**
Study design: **The study was designed as a prospective registry with follow-up at intervals through 24 months. The subjects were 286 patients from 30 clinical sites with saphenous vein reflux as measured with duplex scanning. A total of 319 limb treatments were performed. Intervention included endovenous catheter obliteration of insufficient saphenous veins with temperature controlled radiofrequency heat, without high ligation of the saphenofemoral junction. The main outcome measures were status of occlusion of treated vein segments, presence of varicose veins and reflux, clinical symptoms scores, physician evaluation of procedure success, and patient satisfaction.**
Results: **At 12 months, 83.6% of treated limbs were classified as CO, 5.6% were categorized as NCO, and 10.8% were recanalized. At 24 months, 85.2% of treated veins were CO, 3.5% were NCO, and 11.3% were recanalized. Varicose veins were present in 95% of limbs before treatment. The presence of varicose veins in limbs with CO was 10.5%, 7.3%, 5.7%, and 8.3% at 1 week, 6 months, 12 months, and 24 months, respectively. The presence of varicose veins in NCO limbs was similar at each interval. Overall, 91.4% of 232 limbs followed to 12 months and 90.1% of 142 limbs at 24 months were free of saphenous vein reflux, regardless of technical outcome. Paresthesia was reported in 3.9% of limbs at 1 year and in 5.6% at 2 years. The pretreatment mean symptom severity score was 2.0. Mean posttreatment symptom scores decreased to 0.07, 0.0, and 0.50 for CO, NCO, and recanalized limbs, respectively, at 6 months. At 12 months, the mean scores were 0.06, 0.0, and 0.32 for CO, NCO, and recanalized limbs, respectively; at 24 months, the scores were at 0.10, 0.40, and 0.63. Patient satisfaction was achieved in 195 of 212 patients (92%) at 1 year and in 121 of 128 (94.5%) at 2 years.**
Conclusion: **Endovenous vein obliteration without high ligation dramatically reduces the presence of varicosities and reflux and, when performed with the prescribed pull-back methodology, is comparable with vein stripping at 1 and 2 years. Patient satisfaction with the procedure is high at 2 years, regardless of technical outcome. At 2 years, the closure procedure is a viable alternative to stripping. (J Vasc Surg 2002;35:1190-6.)**

Greater saphenous vein reflux is an important component of the pathophysiology of primary venous insufficiency and is customarily treated with surgical stripping of the saphenous vein from the groin to just below the knee.[1-5] A new modality, the Closure catheter and procedure (VNUS Medical Technologies, Inc, Sunnyvale, Calif), provides a less invasive alternative to stripping. The device allows controlled radiofrequency endovenous heating to obliterate the refluxing greater saphenous vein in situ. Early reports have established the efficacy of this procedure and have shown that it can be done successfully without high ligation of the saphenofemoral junction.[6-9] Although the procedure results in total occlusion of the vein in almost all of the treated limbs, some procedures result in near complete occlusions in which proximal segments of vein less than or equal to 5 cm remain patent. In a small proportion of cases, recanalization of the vein also occurs. This report assessed the differences in clinical outcomes between patients in whom treatment resulted in complete occlusion (CO), near complete occlusion (NCO), or recanalization of the treated greater saphenous vein segment.

METHODS

Saphenofemoral, saphenopopliteal, or truncal vein reflux in response to a Valsalva's maneuver in minus 15 degrees reverse Trendelenburg's position or with standing manual compression and release was identified with duplex ultrasound scan. Patients with reflux in nonaneurysmal veins less than 12 mm in lumen diameter as measured with duplex scanning with the patient in a supine position were offered the Closure procedure after informed consent and discussion of alternatives for treatment. Limbs in which saphenous vein tortuosity would impede catheter advancement were excluded. The Closure catheter was used to obliterate the refluxing saphenous vein. Technical details of the procedure and device have been described elsewhere.[6,7] The Closure procedure was performed with general anesthesia at some surgery centers, but most procedures were completed with local anesthesia (tumescent or regional or

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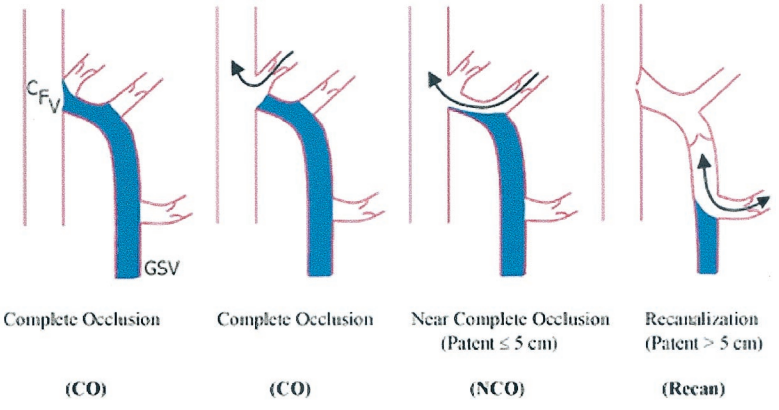

Categorization of vein occlusion status.

both) with or without sedation. In this series, high ligation of the saphenofemoral junction was not done. Adjunctive procedures at the time of treatment included phlebectomy in 187 limbs (58.6%) and sclerotherapy in 11 limbs (3.5%).

Data were collected in an ongoing registry of patients treated from December 1998 to June 2000. This report includes follow-up data through January 2002. The prospective protocol was nonrandomized, and outcome assessments were nonblinded. Color duplex ultrasound scan and physical examination were done before treatment and within 1 week of treatment and were repeated at 6 months, 10 to 14 months (reported as 12-month data), and 2 years after treatment to document the status of the treated vein and limb. *Reflux* was defined as any evidence of reversed flow in any treated vein segment or at the area of saphenofemoral junction. *Varicose vein* was defined as any dilated, tortuous vein. *CO veins* were defined as those with no evidence of flow. *NCO* was defined as less than or equal to 5-cm segment of flow within an otherwise occluded vein. *Recanalization* was defined as greater than 5 cm of flow in any treated vein segment (Fig).

Symptom severity and clinical assessment classification according to CEAP classification were recorded at each visit. A modified symptom severity score on the basis of leg pain, limb fatigue, and edema was calculated before treatment and at each follow-up interval with a score of two for severe symptoms, one for moderate symptoms, and zero for no symptoms.[10] The symptom severity scores ranged from zero for asymptomatic limbs to six for limbs with severe pain, fatigue, and edema. At 6 months and 1 year, treating physicians were asked to assess outcomes as either successful or unsuccessful on the basis of their clinical impression and color duplex ultrasound scan. At each follow-up visit, as a gauge of patient satisfaction, patients were asked by the investigator whether they would recommend the procedure to a friend with similar leg problems. The patient then responded with one of three answers: "yes," "no," or "not sure." If the patient answered "yes," this was scored as patient satisfaction. If the patient answered "no" or "not sure," this was scored as not satisfied.

Table I. Pretreatment distribution of CEAP clinical classification and associated mean duration of reflux

CEAP clinical classification	*Limbs No.*	*Reflux (s)*
0	2 (0.6%)	2.3
1	14 (4.4%)	3.5
2	223 (69.9%)	3.8
3	26 (8.2%)	5.2
4	45 (14.1%)	5.0
5	5 (1.6%)	2.0
6	4 (1.3%)	2.3

Thirty-one sites in the United States, Europe, and Australia participated in the study. These sites comprise the VNUS Closure Treatment Study Group (Appendix), which has been described elsewhere.[7] Only cases from 30 centers that followed the prescribed Closure protocol were included in this report. One center was excluded because the prescribed pull-back technique was not used. Instead, these operators withdrew the catheter on the basis of temperature and regularly exceeded the maximum pull-back rate of 3 cm per minute.

At the 30 participating centers, 286 patients were enrolled in the study, 213 women and 73 men, with a mean age of 46.7 years (range, 19 to 78 years). Three hundred and eighteen limbs were treated. One limb was treated twice for a total of 319 treatments. This limb recanalized immediately after the first treatment as a result of treatment of only a 6-cm segment. The pretreatment clinical assessment classifications for the 319 treatments and the associated mean duration of reflux for each classification are shown in Table I. The two limbs classified as CEAP clinical classification 0 both had preoperative leg pain and fatigue. Of the 14 limbs classified as CEAP clinical classification 1, 13 had leg pain and 11 had leg fatigue. The mean duration of reflux for the 319 treatments was 4.0 seconds.

VNUS Medical Technologies, Inc, developed the registry design for the collection of data from multiple study

Table II. Procedural outcomes over time

	Follow-up time period							
	1 week		*6 months*		*12 months*		*24 months*	
Outcome	*n/N*	*%*	*n/N*	*%*	*n/N*	*%*	*n/N*	*%*
CO	267/286	93.4	192/223	86.1	194/232	83.6	121/142	85.2
Varicose veins absent	239/267	89.5	178/192	92.7	183/194	94.3	111/121	91.7
Reflux absent	267/267	100	192/192	100	194/194	100	121/121	100
NCO	14/286	4.9	17/223	7.6	13/232	5.6	5/142	3.5
Varicose veins absent	12/14	85.7	15/17	88.2	11/13	84.6	5/5	100
Reflux absent	10/14	71.4	11/17	64.7	11/13	84.6	5/5	100
Recanalization	5/286	1.7	14/223	6.3	25/232	10.8	16/142	11.3
Varicose veins absent	4/5	80.0	6/14	42.9	15/25	60.0	7/16	43.8
Reflux absent	1/5	20.0	4/14	28.6	7/25	28.0	2/16	12.5

centers. VNUS administered the data collection and analysis and provided limited funding to obtain some follow-up duplex scans on patients 1 and 2 years after treatment. The lead author reviewed all of the data from all involved study centers. Technical assistance in the preparation of this manuscript was provided by VNUS; however, data interpretation, writing of the report, and the decision to submit for publication were under the control of the authors.

RESULTS

Table II shows outcomes of the procedure at follow-up intervals through 24 months for all treated limbs. Follow-up was available on 286, 223, 232, and 142 limbs at 1 week, 6 months, 12 months, and 2 years, respectively. In the remaining 33 limbs, data were not reported at 1 week follow-up. At 1 week, 267 of 286 treated limbs (93.4%) with follow-up were CO, and 14 of 286 (4.9%) had NCO. Only five of 286 (1.7%) had evidence of recanalization. At 6 months, 192 of 223 treated limbs (86.1%) with follow-up were CO, 17 of 223 (7.6%) were categorized as NCO, and 14 of 223 (6.3%) were recanalized. At 12 months, 194 of 232 (83.6%) had CO, 13 of 232 (5.6%) had NCO, and 25 of 232 (10.8%) had recanalized. At 2 years, 121 of 142 (85.2%), five of 142 (3.5%), and 16 of 142 limbs (11.3%) were categorized as CO, NCO, and recanalized, respectively.

An analysis was performed on the outcome data presented in Table II to examine the responses to radiofrequency obliteration of the saphenous vein according to the pretreatment CEAP clinical classification. Pretreatment CEAP clinical classification was not a factor in the rate of CO, NCO, or reflux at 12-month and 24-month follow-up.

Before treatment, 95.0% of the limbs had visible varicosities. Treatment dramatically reduced the prevalence of varicose veins on follow-up examination. The presence of varicose veins in treated limbs with CO was 28 of 267 (10.5%), 14 of 192 (7.3%), 11 of 194 (5.7%), and 10 of 121 (8.3%) at 1 week, 6 months, 12 months, and 24 months, respectively. Truncal reflux was absent in all limbs with complete saphenous occlusion. Junctional tributary reflux also was absent despite the presence in the residual saphenous stump of prograde tributary flow in most cases.

At 24 months after treatment, the presence of varicose veins in the CO, NCO, and recanalization groups was 10 of 121 (8.3%), zero of five (0%), and nine of 16 (56.3%), respectively, as shown in Table II. Rates of reflux for the limbs in the CO, NCO, and recanalization groups at 24 months were zero of 121 (0%), zero of five (0%), and 14 of 16 (87.5%), respectively. Significant differences were seen among the three groups as determined with Fisher exact test ($P < .01$).

Paired statistical comparisons of the three groups with Fisher exact test showed significant differences between some groups. The rates of reflux and varicose veins between the CO and recanalization groups were significantly different at each of 6, 12, and 24 months of follow-up ($P < .01$). Comparison of outcomes between the CO and NCO groups showed significant differences in the rate of reflux at 6 and 12 months ($P < .01$) but no differences in the rate of varicose veins at 6, 12, and 24 months of follow-up. The third paired comparison of outcomes between the limbs in the NCO and recanalization groups showed significant differences in the rate of varicose veins at 6 and 24 months ($P < .05$) and in reflux rates at 12 and 24 months ($P < .01$).

Complications occurring during treatment and at short-term follow-up have been previously described.[6-9] Deep vein thrombosis occurred in three of 286 limbs (1.0%), and one of these patients had a pulmonary embolism as described elsewhere.[2] All thrombotic episodes were successfully treated with anticoagulation therapy. Skin burns were observed at an incidence rate of six of 143 (4.2%) in the first 143 of the 286 limbs in which 1-week follow-up was obtained and were observed in zero of 143 (0%) limbs treated in the second half of the study. Clinical phlebitis was observed in six of 286 limbs (2.1%) at 1 week, one of 223 limbs (0.4%) at 6 months, and in no limbs at 12 or 24 months. No limbs showed signs of an infection at any follow-up visit.

Paresthesia, often described as focal hypoesthesia, was the only persistent complication. This was reported in 43 of 286 limbs (15.0%) at 1 week, in 21 of 223 limbs (9.4%) at

Table III. Symptoms (by limb)

	Symptoms									
	Pain		*Fatigue*		*Edema*		*Pigmentation*		*Dermal sclerosis*	
Follow-up time period	*n/N*	*%*	*n/N*	*%*	*n/N*	*%*	*n/N*	*%*	*n/N*	*%*
Pretreatment	265/319	83.1	243/319	76.2	97/319	30.4	69/319	21.6	21/319	6.6
6 months										
CO	9/192	4.7	1/192	0.5	2/192	1.0	15/192	7.8	3/192	1.6
NCO	0/17	0.0	0/17	0.0	0/17	0.0	3/17	17.6	0/17	0.0
Recanalization	4/14	28.6	2/14	14.3	1/14	7.1	1/14	7.1	1/14	7.1
12 months										
CO	6/194	3.1	2/194	1.0	1/194	0.5	18/194	9.3	3/194	1.5
NCO	0/13	0.0	0/13	0.0	0/13	0.0	1/13	7.7	0/13	0.0
Recanalization	3/25	12.0	3/25	12.0	1/25	4.0	4/25	16.0	1/25	4.0
24 months										
CO	4/121	3.3	2/121	1.7	5/121	4.1	9/121	7.4	1/121	0.8
NCO	1/5	20.0	1/5	20.0	0/5	0.0	0/5	0.0	0/5	0.0
Recanalization	4/16	25.0	3/16	18.8	2/16	12.5	3/16	18.8	2/16	12.5

6 months, in nine of 232 limbs (3.9%) at 12 months, and in eight of 142 limbs (5.6%) at 24 months. When the length of endovascular obliteration treatment was limited to the thigh and just below the knee, as is done with limited vein stripping, the paresthesia rates at 12 and 24 months were five of 179 (2.8%) and five of 111 (4.5%) compared with an incidence rate of four of 53 (7.5%) and three of 31 (9.7%), respectively, when treatment extended to the ankle.

Table III summarizes the symptoms reported at 6, 12, and 24 months. Symptoms were determined at each patient visit with a physician examination or a query of the patient and were recorded on case report forms. As such, physicians were not blinded to the status of the patient's condition. Overall pretreatment values are provided for comparative purposes. Whereas 265 of 319 limbs (83.1%) had pain at pretreatment, only nine of 192 (4.7%) and zero of 17 (0%) of CO and NCO limbs, respectively, had pain at 6 months. At 12 months, pain was reported in six of 194 CO limbs (3.1%) and in zero of 13 NCO limbs (0%). At 24 months, pain was reported in the CO and NCO groups at rates of four of 121 (3.3%) and one of five (20%), respectively. In recanalization limbs, pain was reported in four of 14 (28.6%), three of 25 (12.0%), and four of 16 limbs (25%) at 6, 12, and 24 months, respectively.

Table IV summarizes the symptom severity scores reported at 6, 12, and 24 months. Again, overall pretreatment values are provided for comparative purposes. Whereas the pretreatment mean symptom severity score was 2.0, the scores decreased to 0.07 for CO, 0.0 for NCO, and 0.50 for recanalization limbs at 6 months. At 24 months, the mean symptom scores were 0.10, 0.40, and 0.63 for CO, NCO, and recanalization groups, respectively. Absence of the four principal symptoms of venous insufficiency (pain, fatigue, edema, and varicose veins) was determined to learn the number and percent of treated limbs that were asymptomatic at follow-up. Twenty-four months after treatment, 103 of 121 CO limbs (85.1%) were asymptomatic versus four of five NCO limbs (80%) and six of 16 recanalization limbs (37.5%). Significant differences were seen in symptomatic status among the CO, NCO, and recanalization limbs as determined with Fisher exact test ($P < .01$).

Table IV. Mean symptom severity scores

Follow-up time period	*N*	*Mean pretreatment score*	*Mean posttreatment score*
Pretreatment	319	2.00	N/A
6 months			
CO	192	1.93	0.07
NCO	17	1.71	0.00
Recanalization	14	2.14	0.50
12 months			
CO	194	2.02	0.06
NCO	13	1.38	0.00
Recanalization	25	2.20	0.32
24 months			
CO	121	1.85	0.10
NCO	5	1.60	0.40
Recanalization	16	2.31	0.63

N/A, Not applicable.

With Fisher exact test for paired comparisons of the CO and recanalization groups, significant differences were found in asymptomatic status at each of 6, 12, and 24 months follow-up ($P < .01$). However, comparison of the CO and NCO groups showed no difference in rate of asymptomatic status at all follow-up times. Asymptomatic status was different between the NCO and recanalization groups at 6 months ($P < .05$) but not at 12 or 24 months.

Tables V and VI summarize physician and patient assessments of outcomes. Physicians assessed outcome by limb. When limbs were CO, physicians categorized the treatment as successful in 187 of 192 limbs (97.4%) at 6 months, in 192 of 194 limbs (99.0%) at 12 months, and in

Table V. Physician assessment of successful outcome (by limb)

	Follow-up time period					
	6 months		*12 months*		*24 months*	
	n/N	*% successful*	*n/N*	*% successful*	*n/N*	*% successful*
Complete occlusion	187/192	97.4	192/194	99.0	119/121	98.3
Near-complete occlusion	11/17	64.7	12/13	92.3	5/5	100
Recanalization	3/14	21.4	10/25	40.0	6/16	37.5

Table VI. Patient satisfaction assessment (by patient)

	Follow-up time period					
	6 months		*12 months*		*24 months*	
	n/N	*% satisfied*	*n/N*	*% satisfied*	*n/N*	*% satisfied*
Complete occlusion	163/169	96.4	166/175	94.9	104/108	96.3
Near-complete occlusion	14/16	87.5	12/12	100	5/5	100
Recanalization	9/14	64.3	17/25	68.0	12/15	80.0

119 of 121 limbs (98.3%) at 24 months. In contrast, with NCO of the limb, physicians categorized the outcome as successful in only 11 of 17 limbs (64.7%) at 6 months, 12 of 13 limbs (92.3%) at 12 months, and five of five limbs (100%) at 24 months. As expected, when veins had recanalized, physicians categorized the outcomes as successful in only three of 14 limbs (21.4%) at 6 months, 10 of 25 limbs (40%) at 12 months, and six of 16 limbs (37.5%) at 24 months.

In contrast, reports of patient satisfaction were similar for patients whose limbs were CO and NCO. At 12 months, 166 of 175 patients (94.9%) with limbs categorized as CO and 12 of 12 patients (100%) with limbs categorized as NCO said they would recommend the procedure to a friend with similar limb problems. Patient satisfaction at 2 years occurred in 104 of 108 patients (96.3%) with limbs with CO and for five of five patients (100%) with limbs categorized as NCO. Patients with at least one recanalized limb were less satisfied with the procedure, with only 68.0% and 80.0% stating that they would recommend the procedure to a friend at 12 and 24 months, respectively.

At 6 months, 11 patients indicated that they would recommend the procedure to a friend, despite their physician's assessment that the procedure was not successful. Five of these patients were assessed as NCO and 6 as recanalization. For the five patients categorized as NCO, the average symptom score was 0.0 at 6 months compared with 2.2 before treatment. The six patients categorized as recanalization had an average score of 0.7 at 6 months, compared with 2.3 before treatment.

At 12 months, nine patients indicated that they would recommend the procedure to a friend, despite their physician's assessment that the procedure was unsuccessful. Only one of these patients was categorized as NCO, and at 12 months, this patient had a symptom score of 0, compared with 2.0 before treatment. The other eight patients were categorized as recanalization. At 12 months, their average score was 0.1, compared with 2.1 before treatment.

At 24 months, five patients indicated they would recommend the procedure, despite an unsuccessful assessment by the physician. All five limbs had recanalization, and the average symptom score was 0.2, compared with 1.8 before treatment.

As of the last follow-up, there were five instances in limbs with CO in which the physician assessed the outcome as successful and the patient's report was different. In three instances, the patients did not answer the question on patient satisfaction, and in the two other instances, the patients had paresthesia in the calf or ankle region.

DISCUSSION

To determine whether the group of limbs with NCO had outcomes that were different than those limbs in the CO group or the recanalization group, statistical comparisons were made with the Fischer exact test. Reflux as determined with duplex ultrasound scan assessment was found to be significantly different among the three data analysis groups and also between each of the paired groups, with the exception of one follow-up time. For example, reflux rates were statistically different between the NCO and CO limbs, between the CO and recanalization limbs, and between the NCO and recanalization groups of limbs at 12 and 24 months.

Significant differences also were found among the CO, NCO, and recanalization groups for the presence of varicose veins and rate of asymptomatic status. However, not all paired statistical comparisons between the groups showed a difference in clinical outcomes. No significant difference was seen in either the presence of varicose veins or asymptomatic status between the group of limbs with

CO versus limbs in the group with NCO. Other paired statistical comparisons, such as the NCO and recanalization groups and the CO and recanalization groups, showed statistically significant differences for the presence of varicose veins at 24 months. These differences show that a population of limbs that maintain an NCO of the saphenous vein at follow-up has clinical outcomes that are no different than a population of limbs that exhibit CO yet are different from those limbs that have recanalization. These results also suggest that, despite the presence of reflux in the group of limbs with NCO, the reflux is often subclinical. Further follow-up is needed to determine whether the subclinical reflux in this group will continue to produce high levels of asymptomatic status.

The results indicate that although physicians were likely to be influenced by the technical outcome of the procedure, patients were more likely to be influenced by how they felt. Patients did not show a difference in satisfaction when the outcome was NCO compared with CO of the vein segment near the saphenofemoral junction (Fig).

Radiofrequency catheter-induced venous closure specifically deals with the problem of truncal saphenous vein reflux. As clinical trial results have accrued, the Closure technique has been modified. The procedure initially was introduced as an adjunct to high saphenous vein ligation. When the success of acute and mid-term obliteration of saphenous vein lumen without ligation became evident, the procedure then was used as a primary treatment.

The Closure technique can be performed with a percutaneous Seldinger method or with a miniphlebectomy incision distally. Groin dissection is not needed. Endovenous obliteration with Closure simulates saphenous stripping. However, all junctional tributaries are not usually obliterated. High ligation alone leaves most of the saphenous trunk patent, leaving the greater saphenous vein to receive tributary flow from distal communicating or perforating veins. Recent studies have shown clearly that stripping of the saphenous vein is superior to ligation alone.[2,5] This suggests that saphenous trunk patency tends to promote recurrent reflux.

This report shows that endovenous obliteration eliminated truncal saphenous continuity in 83.6% of 232 treated limbs at 12-month follow-up and in 85.2% of limbs at 24 months. Jones et al[2] reported that the incidence rate of reflux and recurrent varicose veins 12 months after stripping and ligation of the greater saphenous vein was 9.1% and 14.5%, respectively. Jones et al[2] also reported reflux and varicose vein rates of 13% and 25%, respectively, at 2-year follow-up. Similar results were reported by Rutgers and Kitslaar[11] who showed a 9% incidence rate of reflux at 1 year and a 12% rate 2 years after vein stripping and ligation. With the Closure procedure in this study, reflux and persistent varicose veins were noted in 20 of 232 limbs (8.6%) and 23 of 232 limbs (9.9%), respectively, at 12 months. At 24-month follow-up, the Closure procedure resulted in a reflux and varicose vein rate of 14 of 142 (9.9%) and 19 of 142 (13.4%), respectively. One hundred eleven of the 142 limbs with 24-month duplex scans also were scanned at 12 months. Of these, only two (1.8%) changed from reflux free at 12 months to duplex scan evidence of reflux at 24 months.

In the authors' experience, this less invasive technique is well accepted by patients. Several exceptions to this were observed in patients with complete obliteration (CO) of the treated vein, in which the treatments included either the lesser saphenous vein or the below-knee segment of the greater saphenous vein. With cases of incomplete obliteration (NCO and recanalization), results were better when judged by patients than by physicians. The reasons for this remain unclear, but the improvement in reported patient symptom severity score was definite. A placebo effect might possibly exist.

With recanalization, as expected, the results are not as good as with CO and NCO. The persistence of tributary flow in the region of the saphenofemoral junction, found on duplex scan imaging, is prograde in nearly all limbs categorized as CO and NCO. Tributary patency did not appear to relate to symptoms reported at 1-year and 2-year follow-up.

With respect to complications, the use of tumescent and local anesthesia, in our opinion, reduces thermal injury to surrounding tissue, which in turn reduces the risk of skin burns and should add to further patient satisfaction. However, with endovenous obliteration, the nerve injury improves with time, and anatomic nerve disruption during stripping is unlikely to resolve.

The clinical outcomes associated with CO and NCO with endovenous Closure appear to be similar. However, because of the relatively small number of limbs in the NCO group, these data must be considered with caution. Overall, the incidence rate of varicose veins and reflux for the population of limbs examined up to 2 years is comparable with published results from vein stripping studies.[2,11] Patient satisfaction is more than 95% at 1 and 2 years in the CO and NCO groups and also is present in more than two thirds of patients with recanalization. Compared with traditional stripping and ligation surgery, the Closure technique is relatively atraumatic. Recurrent varicose veins after vein stripping or ligation surgery are common, costly, and complex problems. Their frequency ranges from 20% to 80% depending on the definition of recurrence.[12] At 1 and 2 years, the evidence from this nonrandomized registry shows that radiofrequency endovenous obliteration, when performed with the prescribed pull-back methodology, appears to be a viable alternative to conventional stripping. Long-term studies on the durability of the Closure technique, including evidence of neovascularization, will continue, with results being reported as they become available. Future studies ideally will follow recommendations from the Recurrent Varices after Surgery consensus document, such as randomized studies, to compare long-term results of varying approaches.[12] A randomized prospective study comparing the Closure technique with conventional stripping is currently underway.

The limitations of this report, as with many reports of registry data, include lack of conventionally treated control

subjects, absence of blinded assessment of outcomes, and variability of follow-up compliance amongst the participating centers. In addition, data from some patients were excluded because of a lack of follow-up data at each follow-up opportunity, and data from one center were excluded because they did not conform to the prescribed catheter pull-back technique. Nevertheless, no attempt was made to exclude the earliest procedures that may have been susceptible to "learning curve" pitfalls. Therefore, we believe that this registry analysis supplies meaningful and encouraging outcome data on this minimally invasive approach to treatment of symptomatic saphenous reflux.

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Please see the related commentary by Dr E. John Harris, Jr, on pages 1292-4.

Appendix.

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