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Cost analysis and implications of routine deep venous thrombosis duplex ultrasound scanning after endovenous ablation



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ABSTRACT

Background: Duplex ultrasound (DUS) is performed by the majority of physicians after endovenous ablation (EVA) of the great saphenous vein to screen for endovenous heat-induced thrombosis (EHIT) at the saphenofemoral junction extending into the femoral vein. Several factors should be considered in assessing the value and cost of routine DUS after EVA: the natural history of EHIT is poorly defined, the incidence appears low, and the majority are both asymptomatic and Kabnick type 2 (projecting only slightly into the femoral vein). Moreover, routine postoperative DUS screening is not recommended for procedures with higher thromboembolic complication rates, such as joint replacement or bariatric surgery.

Methods: Data on the incidence of death, EHIT, and deep venous thrombosis (DVT) were derived from a systematic review after either radiofrequency or laser ablation of the saphenous vein from two sources: (1) EVA randomized controlled trials (N = 1482) and a (2) large (>150 patients) EVA case series (N = 12,363). The number of tests required to detect one case of EHIT/DVT was calculated from the incidence in the EVA and case series data bases; the cost to detect a case was estimated using the 2013 Medicare global fee schedule for the cost of a unilateral venous DUS study.

Results: This analysis included 13,845 EVA-treated limbs. There were no reported deaths. The incidence of DUS-detected venous thromboembolism after EVA is 0.7%. The cost of unilateral DUS according to the Medicare global reimbursement fee for office-based studies is \$106.71. The total cost of performing DUS in this study population is estimated to be at least \$1,477,399, and the amount of dollars expended per venous thromboembolism detected is \$14,667.

Conclusions: The current Society for Vascular Surgery/American Venous Forum recommendation is to perform screening DUS after EVA within 72 hours postoperatively with a weak level of recommendation (grade 2C). The current analysis demonstrates a low incidence of EHIT/DVT with a corresponding high cost to detect each case with routine DUS screening. These data combined with the unclear clinical significance of EHIT suggest that the policy of universal post-EVA screening should be revised in the near future. (*J Vasc Surg: Venous and Lym Dis* 2017;5:126-33.)

Chronic superficial venous insufficiency is highly prevalent (up to 20%) in the United States¹ and is associated with complications that range from lower extremity pain and swelling to venous ulcers. The Society for Vascular Surgery (SVS) together with the American Venous Forum (AVF) developed practice guidelines for the diagnosis and treatment of lower extremity varicosities and chronic venous insufficiency; the National Institute for Health and Care Excellence guidelines in the United Kingdom produced similar recommendations.^{2,3}

Because of reduced convalescence, less pain, and lower morbidity, these guidelines recommend endovenous thermal ablation of the incompetent saphenous vein over open surgery. Currently, >300,000 endovenous ablations (EVAs) are performed in the United States, a 450% increase in the past decade due to the minimally invasive nature of this procedure.⁴

EVA is associated with less bruising and infection than vein ligation and stripping,⁵ but the potentially more serious thromboembolic complications have become a prominent concern in the EVA era. By contrast, this issue was not commonly discussed in previous ligation and stripping series because postoperative duplex ultrasound (DUS) scans were not routinely performed in these trials. Initially, DUS scans after EVA were performed in the early post-treatment period to assess that the great saphenous vein (GSV) was completely ablated. Hingorani et al, however, described deep venous thrombosis (DVT) in 12 of 73 patients (16%) as extension of the "occlusive clot filling the treated proximal GSV segment, with a floating tail beyond the patent inferior epigastric vein into the common femoral vein."⁶ This and other small case series⁷ prompted most physicians to carry out

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Table I. Comparison between Kabnick⁹ and Lawrence¹⁰ classifications

Kabnick ⁹	EHIT	Lawrence ¹⁰
1	At saphenofemoral junction	Level 3
2	<50% common femoral vein	Level 4-5
3	>50% common femoral vein	
4	Common femoral vein occlusion	Level 6

EHIT, Endovenous heat-induced thrombosis.

routine post-EVA DUS surveillance scans to detect this thrombotic complication.

Both the location at or beyond the saphenofemoral junction and the mechanism of this thromboembolic complication after EVA differ from the DVT observed previously with ligation and stripping, and Kabnick has termed this endovenous heat-induced thrombosis (EHIT), characterizing the mechanism of this complication. EHIT is the most common thromboembolic complication observed with EVA⁸ and has been classified anatomically by Kabnick et al⁹ and more recently by Lawrence et al¹⁰ on the basis of the degree of thrombus extension from the saphenous vein up to or beyond the saphenofemoral junction into the femoral vein and in rare instances occluding the femoral vein (Table I).

The true incidence of thromboembolic complications after EVA is difficult to pinpoint accurately because of the heterogeneity of some case series reports and the apparent low incidence of EHIT in these, which generally consist of small numbers. Few prospective studies employ DUS surveillance with the stated purpose of detecting DVT, whereas the timing of scans after EVA varies.¹¹ In addition, the operative techniques used, such as catheter position and amount of thermal energy, vary between institutions. Most important, the statistical phenomenon of a small sample size in these case series combined with a rare event may lead to an underestimation or overestimation of this complication.¹² The report of Mozes et al exemplifies this problem: "During our initial experience with ELT [endovenous laser therapy] in 56 limbs of 41 patients, 39 underwent postoperative DUS scanning. We encountered three cases (7.7%) with thrombus extension into the common femoral vein. All three patients were anticoagulated, and a temporary inferior vena cava filter was placed in one. All remained asymptomatic."⁷ In multiple case series, the incidence of EHIT ranged from 0% to 16%, and this incidence is even lower now with improved technique and newer devices. The incidence of pulmonary embolism (PE) is also extremely low (<0.1%) and is limited to a few cases reported in the literature, none of them fatal.²

Dermody et al published a meta-analysis of randomized controlled trials (RCTs) comparing EVA with ligation and stripping that was combined with case series including reports with >150 cases each for a total of

12,000 limbs. This analysis of a large number of limbs at risk demonstrated a pooled incidence of venous thromboembolism (VTE) complications of <1%.¹¹ Added to the low incidence of VTE complications, the natural history of EHIT, although not well understood, is thought to be less dangerous than that of traditional femoral DVTs. Furthermore, only a minority of thrombi actually project into the common femoral vein (Kabnick 2-3); in the series of Lawrence et al, only 2.6% (13/498) of EHIT cases were this proximal. In Lawrence's more parsed system, he classified these high-risk thrombi as level 4 to level 6.¹⁰ Only for these most proximal thrombi is there a consensus to treat with anticoagulation.

Even with this apparent low incidence and low clinical impact of VTE complications after EVA, the current recommendation from the SVS/AVF guidelines is "to perform DUS within 48-72 hours after EVA to rule out thrombotic complications" (level of evidence 2, grade C).³

The purposes of our study were (1) to analyze the available data on VTE complications from RCTs and case series derived from a large number of limbs at risk, (2) to describe the economic impact of routine DUS after EVA, and (3) to compare the incidence of VTE associated with EVA with other surgical populations that are well known to have higher incidence of VTE complications for which routine DUS is not recommended.

METHODS

Determining the incidence of VTEs. MEDLINE, Embase, Cochrane, and Clinical Trials Registry databases were searched from January 2000 through January 2013 for RCTs and large case series that employed EVA as a single modality for treatment of GSV reflux and had a concomitant postoperative DUS examination. Pooled (stratified) incidence of VTE with 95% confidence intervals was estimated using the DerSimonian-Laird procedure for random-effects meta-analysis. A bootstrap analysis was performed to examine between-modality differences. VTE events were defined as follows: DVT—the presence of acute thrombus within the deep venous system on ultrasound; PE—thrombus within the pulmonary system as detected on an imaging study, such as a spiral computed tomography scan; EHIT diagnosed on DUS—only Kabnick type 2 EHIT and higher (nonocclusive thrombus projecting from the GSV into the deep system at the saphenofemoral junction) to type 4 (total occlusion of the femoral vein that has extended from the GSV) was included.^{9,11}

Overall. Pooled data from RCTs and case series with >150 cases previously described by our group¹¹ were used to define the incidence of VTEs and mortality. In both the RCTs and case series, following current recommendations, all patients had surveillance DUS, so that the number of ultrasound studies needed to yield one positive result could be calculated. Finally, the Medicare

Table II. Additional costs created by a positive duplex ultrasound (DUS) result (direct cost)

Intervention	Cost
Cost of LMWH for 10 days	\$626
Cost of second scan	\$106.71
Total	\$732.71

LMWH, Low-molecular-weight heparin.

global reimbursement fee of \$106.71 for performing a DUS examination (Current Procedural Terminology code 93971G) was used to calculate the cost of routine surveillance DUS. Other direct cost factors in the total cost estimate are displayed in Table II. The incidence of major bleed while receiving low-molecular-weight heparin (LMWH) was 1% with its attendant cost of \$7673 per bleeding episode; the incidence of heparin-induced thrombocytopenia and thrombosis (thrombotic complication, not thrombocytopenia alone) was 0.174%, and the cost of admission for that complication was \$34,155¹³ (Table III).

RESULTS

Incidence of VTE. Pooled (study-stratified) proportions derived from the meta-analysis for DVT, PE, and EHIT as well as for combined DVT and PE for each set of studies are shown in Table IV. These are presented separately for the RCTs and case series and also for the RCTs and case series combined. The pooled proportions for each VTE category for all modalities and study types are all 1% or less, with the exception of EHIT in the radiofrequency ablation (RFA) case series group, with an incidence of 1.4%. Table IV also shows that the number of limbs treated with endovenous laser ablation (EVLA) was much larger than with the other modalities (12,095 EVLA vs 1750 RFA). For each form of treatment, the number of limbs in the case series analysis was greater than that reported in the RCT analysis (for EVLA, there was a nearly 10-fold difference).

Of note, the pooled proportions of VTE (0.7%) as well as the incidence of DVT alone (0.2%) in the combined ligation and stripping arms of the analyzed RCTs were also low and comparable to those seen with the endovenous techniques.

In this large compilation of 13,845 cases, the number of postoperative DUS studies performed to yield a positive study was 138.45. Because the cost of a unilateral DUS examination (according to the Medicare global reimbursement fee for office-based studies) is \$106.71 and the total cost of performing the DUS examination in our study population is estimated to be at least \$1,477,399, the dollars expended per VTE detected is \$14,667 (138.45 × \$106.71).

Following the current recommendations of routine postoperative DUS for all EVAs, if we use a modest estimate of 300,000 EVAs performed in the United States

Table III. Cost of treating anticoagulation complications¹³

Complication	Cost
Major bleed (1% incidence)	\$7673
Heparin-induced thrombocytopenia and thrombosis (0.174% incidence)	\$34,155

per year,⁴ with (100/13,845) 0.7% having a clinically significant DVT/EHIT, we estimate only 2100 clinically significant positive ultrasound results per year. This results in an overall cost of screening of \$32,013,000 (300,000 × \$106.71) per year, which leads to a cost of \$15,244 per positive study.

DISCUSSION

The current recommended approach for management of patients after EVA is to perform a DUS scan within a week to detect VTE and to a lesser extent to document target vein closure. DUS is used as a *screening test* in this instance to identify undiagnosed DVT/EHIT in individuals without signs or symptoms (as opposed to a *diagnostic test*, in which DUS is employed to detect disease in patients with symptoms). Screening with DUS is advocated in the SVS/AVF guidelines: "Although the risk of DVT, heat-induced thrombus extension, or PE is rare and therefore the yield is low, we suggest postprocedural DUS scanning within 24 to 72 hours to exclude any thrombotic complication. Evidence to support this recommendation is of low quality (grade 2C)." The characteristics of an ideal situation for a screening test are (1) the condition has serious consequences, (2) treatment of the asymptomatic condition is better than in the symptomatic patient, and most important, (3) the prevalence of the condition is moderately high.

Examining these criteria

Does the condition have serious consequences? It is difficult to state unequivocally that EHIT Kabnick type 2, the preponderance of cases with EVA, has serious consequences, such as a PE or death, because of a paucity of natural history studies of this condition. Although this condition is typically treated with anticoagulation, anecdotal evidence from untreated patients with EHIT 2 suggests a low morbidity. PEs are rare and reported fatalities are even rarer, with none described in our systematic review of 13,845 cases.

One method for determining the impact of EHIT is to assess the consequences from contemporary prospective RCTs, in which routine postoperative DUS was *not performed*. The recent Comparison of Laser, Surgery and foam Sclerotherapy (CLASS) study¹⁴ had a trial design in which no postoperative DUS scan was performed until 6 weeks after the procedure. None of the 210 patients undergoing endovenous laser therapy (EVLT) developed a VTE. Because the study design

Table IV. Incidence of endovenous heat-induced thrombosis (EHIT) and deep venous thrombosis (DVT) in randomized controlled trials (RCTs) and large case series¹¹

Study	No. of limbs	Mortality	Incidence of PE, %	Incidence of DVT, No. (%)	Incidence of EHIT, No. (%)
RCTs					
RFA	371	0	1	1 (0.3)	1 (0.3)
EVLA	1111	0	0.7	4 (0.4)	8 (0.7)
Case series					
RFA	1379	0	0.2	1 (0.1)	19 (1.4)
EVLA	10,984	0	0.3	22 (0.2)	44 (0.4)
Total	13,845			28 (0.2)	72 (0.5)

EVLA, Endovenous laser ablation; PE, pulmonary embolism; RFA, radiofrequency ablation.

required a report of a symptomatic event and no early DUS scan was performed, this does not rule out an asymptomatic VTE of no apparent clinical consequence. Perhaps the best data on the natural history of EHIT are provided by the prospective study of Sufian et al of 4906 patients.¹⁵ In this large number of patients who underwent RFA of the GSV, DUS was performed at 2 to 3 days after the procedure and subsequently in those patients who had a positive study result for EHIT, as follows, by Kabnick classification: EHIT 1, 100 limbs (2.0%; not usually treated); EHIT 2, 61 limbs (1.2%); and EHIT 3, 12 limbs (0.24%). In Sufian's study protocol, patients with EHIT 2 received antiplatelet therapy, whereas patients with EHIT 3 were treated with heparin. This study provides the best prospective information on EHIT 2 patients. As shown in Table V, 3 patients with EHIT 1 progressed to EHIT 2 and 3 more with EHIT 1 progressed to EHIT 3, whereas only 3 of the 61 patients (4.9%) with EHIT 2 progressed to EHIT 3. Serial DUS examinations showed resolution of EHIT within 4 weeks in 74% of patients. Two patients (0.04%) developed a PE.

Does treatment of the asymptomatic condition result in better outcome than treatment in symptomatic patients only? The rationale for routine DUS screening after EVA is based on the premise that if EHIT is detected early in asymptomatic patients, earlier treatment may lead to prevention of PE and death. Although the concept of achieving early therapeutic anticoagulation levels in conventional DVT is well validated, extending the premise to EHIT is currently lacking in objective evidence.

Table V. Incidence of endovenous heat-induced thrombosis (EHIT) ≥2 after endovenous ablation (EVA)

Series	No.	EHIT 2	EHIT 3
Sadek ¹⁸	4223	2.1%	0
Lawrence ¹⁰	500	2.6%	0
Sufian ¹⁵	6707	1.1%	0.09%
1 to 3	EHIT 1 = 173		3 (1.7%)
2 to 3	EHIT 2 = 61		3 (4.9%)

Is the incidence of the condition high? The incidence of VTE greatly affects the value of a screening test. In our systematic review and meta-analysis, a total of 37 (2.1%) VTEs occurred in the 1750 limbs undergoing RFA, 33 (89%) of which were EHIT; in the EVLT group, there were 11 VTEs in the 1111 RCT procedures and 82 VTEs. In the 10,984 case series procedures, again the majority (60%) were EHIT for an overall 0.7% incidence (Table IV). The overall incidence of 28 DVTs (0.2%) and 72 EHITs (0.5%) resulted in a 0.7% incidence for the combined RFA and EVLT series. Thus, the incidence of VTE is low, which makes the value of a routine screening DUS scan less justifiable.

Whereas it is true that the majority of EHIT patients are asymptomatic and thus it is reasonable to consider screening, it is likely that some of the reported VTE cases in the compiled series were symptomatic, particularly those with DVT (28% of the cases in our review) rather than EHIT (72% of the cases in this review), and would have been subjected to symptom-directed DUS in the absence of routine screening DUS. Although the frequency of symptomatic thrombotic events cannot be estimated from the reported series, the effect, which was certainly present to some extent, would further reduce the reported yield of the screening studies and would increase the cost of the program in terms of expense per VTE identified.

A recent presentation by Mo et al at the 2016 American Venous Forum meeting, based on the largest compilation (30,007 studies) of post-EVA VTEs yet reported, showed an overall incidence of 1.1%, a number close to ours. The majority were EHIT 2 (1%), whereas the remainder were EHIT 3 (0.1%) or EHIT 4 (0.013%).¹⁶

Validity is an important attribute of a screening test and indicates the ability of a test to determine which patients have the disease (EHIT) and which do not, whereby the ideal test has both a high sensitivity and specificity. There are no specific studies that compare DUS to another "gold standard" test such as phlebography for the diagnosis of EHIT, as there are for the diagnosis of DVT in general. A detailed systematic review and meta-analysis of DUS in asymptomatic patients by Kassai et al with an analysis by the summary receiver operating

Table VI. Comparison of the incidence of deep venous thrombosis (DVT) or endovenous heat-induced thrombosis (EHIT) after surgical procedures

Procedure	No.	Incidence, %
Ligation and stripping ¹¹	975	0.7
EVA ⁵ RCTs	1482	0.06
Case series	12,363	0.756
THR ¹⁹	200	20
Gastric bypass ²⁰	106	0.8
Prostatectomy ²¹	1300	2.6

EVA, Endovenous ablation; RCTs, randomized controlled trials; THR, total hip replacement.

characteristic method showed a sensitivity of 0.82 with a specificity of 0.98 for proximal DVT but a positive predictive value of ~0.90 (0.10 false-positive rate).¹⁷ The distinction on DUS scan between a type 1 EHIT (normal, not requiring treatment) and a type 2 EHIT (abnormal for purposes of possible treatment), however, may be subtle. This diagnosis is usually based on image analysis of thrombus projecting from the proximal GSV into the femoral vein, not compression. In this report, we note 72 patients diagnosed with EHIT by DUS examination. Assuming the preceding sensitivity and specificity estimates are correct, 7 of the positive studies could have been falsely positive, whereas the DUS could have missed 14 cases of EHIT. If we were to assume a more conservative false-positive rate of 3% for the diagnosis of EHIT in the 72 patients, 2 patients would undergo unnecessary treatment.

Table V displays the specific incidence of EHIT 2 as well as the proportion of EHIT 2 cases that progress to a higher EHIT category from several case series. All cases of EHIT in the individual series of Sadek et al¹⁸ and Lawrence et al¹⁰ (Lawrence levels 4 and 5 are equivalent to Kabnick class 2, occupying <50% of the femoral vein lumen), which total 5228 limbs at risk, were EHIT 2; no EHIT type 3 or 4 occurred.

How does the incidence of VTE after EVA compare with other surgical procedures, and what is the policy toward screening DUS scans with these procedures?

Table VI compares the incidence of VTE with EVA in the RCT or case series analysis with that with total hip replacement,¹⁹ gastric bypass,²⁰ and prostatectomy,²¹ in which no prophylaxis was given (natural history studies). As with EVA, in which the overall incidence of VTE is much lower, symptomatic DVT is also lower after these three procedures. There was a 5.8% incidence of proximal DVT in the Kim study of DVT after total hip replacement. Despite the higher incidence of DVT with joint replacement compared with EVA, both the American College of Chest Physicians (ACCP) and the American Academy of Orthopaedic Surgeons guidelines recommend against routine DUS screening after total joint replacement (grade 1B).²² For patients undergoing

general, gastrointestinal, urologic, gynecologic, bariatric, vascular, plastic, or reconstructive surgery, the ACCP guidelines recommend that periodic surveillance should not be performed (grade 2C).

On the other hand, the same guidelines also recommend pharmacologic prophylaxis against DVT for patients undergoing joint replacement (grade 1B-1C) and a risk-based approach for patients undergoing abdominal and pelvic surgery with recommendations for pharmacologic prophylaxis to those patients with a Caprini score >3.

Per society consensus, the SVS/AVF guidelines suggest treatment with anticoagulation (LMWH) only in those cases of EHIT that extend into the common femoral vein.³ Sufian's prospective study suggests that most cases of untreated EHIT 2 (~75%) resolve by the second week,¹⁵ whereas cases of spontaneous regression or resolution of thrombus especially in the intermediate-risk EHIT group (Lawrence 3-4, Kabnick 2) have been reported.^{14,23} There are no specific guidelines for prophylaxis for patients undergoing EVA. Of interest is that the 0.7% incidence of VTE in the ligation and stripping arm of RCTs is no different from the incidence with EVA (Table IV), but in the past, we have not routinely screened patients after ligation and stripping.

Risk factors for VTE with EVA

Multiple risk factors for VTE complications with EVA have been described in the literature to identify potential candidates for prophylaxis. The most consistent is previous history of DVT.^{14,24,25} Lawrence et al and Sufian et al also identified a large-diameter (Lawrence et al, >8 mm; Sufian et al, 10 mm) GSV below the saphenofemoral junction as a risk factor for EHIT.^{10,15} Finally, Benarroch-Gampel et al found that patients with lower extremity ulceration have a significantly higher risk for DVT.²⁶

Rhee et al found a statistically significant increased risk for EHIT in patients with higher Caprini scores.²⁴ This combined with the approach of the ACCP guidelines to general surgery procedures could justify the use of the Caprini score preoperatively to identify the high-risk EVA patients who will benefit from DUS screening and possible treatment. The use of LMWH does come with an associated cost of \$40 to \$50/day and a risk of major spontaneous bleeding of about 2% to 3%.²⁷

When the current available literature is examined, it is difficult to justify routine DUS screening for all patients undergoing EVA. This screening could lead to overdiagnosis and overtreatment of a poorly understood clinical entity like EHIT, which appears to have a low morbidity and sparsely documented mortality. Such a strategy places an added economic burden on the U.S. health care system of >30 million dollars. Furthermore, because GSV closure rates approach 100%, early postoperative DUS does not seem necessary.

Table VII. Sensitivity analysis: Actual cost of screening for deep venous thrombosis (DVT) or endovenous heat-induced thrombosis (EHIT) based on 300,000 endovenous ablation (EVA) procedures

EHIT/DVT incidence, %	No. of cases per population (13,845)	No. of positive test results for Kabnick type 2 or higher (300,000)	Total cost of screening (300,000)	Cost/positive study
1	138	3000	\$32,013,000	\$10,671
1.5	207	4500	\$32,013,000	\$7114
2	277	6000	\$32,013,000	\$5350
5	692	15,000	\$32,013,000	\$2134
10	1384	30,000	\$32,013,000	\$1067

Economic implications

With an incidence of 0.7% for DVT/EHIT in 13,845 procedures, 137 studies must be performed for each study positive for VTE at a cost of \$14,667 per VTE detected. Assuming that 300,000 EVAs are performed each year in the United States, a major direct cost for DUS screening alone is approximately \$32,100,000. Most physicians treat EHIT 2 or higher with LMWH on an outpatient basis. The cost of LMWH, such as enoxaparin (Lovenox), averages \$62.60 for daily treatment and ~\$626 for 10 days of outpatient treatment of EHIT 2 or higher. Whereas this cost would seem modest if we assume EHIT to be dangerous, perfectly diagnosed, and safely treated, these assumptions must be tempered. If we conservatively assume a false-positive rate of 3%, then 90 patients in our series would have been incorrectly identified and subjected to treatment with LMWH at a cost of \$56,340 for the drug as well as an additional follow-up scan at \$9540 ($\106×90). This expense of \$65,880 for treatment and follow-up of false-positive DUS studies would thus provide no value to the patients. Worse is that complications in the false-positive group—the cost of a major bleed, estimated at 2% for two patients at \$15,346 ($2 \times \7673), and the complication of heparin-induced thrombosis (not the laboratory finding of a reduced platelet count), which is estimated at 0.6% (0.54 patients)—would add an additional \$7300 ($13,560 \times 0.54$) for a total cost of treatment for the 90 patients with false-positive results of \$88,526.

Our previously published meta-analysis of VTEs occurring in RCTs and case series^{5,11} showed that the lowest incidence of DVT/EHIT reported was 0.3% and the highest 1%. Table VII demonstrates a sensitivity analysis of how the cost per positive study will vary with the incidence of DVT or heparin-induced thrombocytopenia and thrombosis, being lower with a higher incidence. An incidence of 2% (the high range in our analysis of studies) results in a cost per positive study of \$5350, which is high in comparison to the cost of screening mammography for breast cancer, which averaged \$63 per positive test result with an overall positive test result incidence of 3.3% to 5.0%.²⁸ The standard metric for evaluating the economic benefit of a screening test beyond the cost per positive study is to determine the cost per

year of life saved. Our systematic review of 13,845 procedures yielded no mortalities, so that cost/year of life saved with routine DUS screening after EVA cannot be readily calculated. The projected cost per year of life saved, however, given an extremely low mortality rate with EVA, would be extremely high and prohibitive.

Similar concerns about the performance of routine DUS after EVA have been raised recently in a publication by Jones and Kabnick,²⁹ in which the authors suggested that DUS after ablation should not be performed and should be removed from future guidelines. They used a few selected studies from the literature to describe the incidence of EHIT with EVA, as opposed to a systematic review/meta-analysis of multiple series as was used in the current study. They posited an incidence for symptomatic PE of 0.01%, based on their impression, which led to an incidence of 30 patients per year (based on 300,000 EVAs/year) with a symptomatic PE. We believe that the data presented here by us, which are based on a meta-analysis of RCTs and large case series with >13,000 limbs at risk, support the belief that routine post-EVA DUS is not justified on the basis of the low incidence VTE, uncertain clinical significance, and high diagnostic and treatment costs. However, a more conservative selective approach would be to increase the yield of the test by screening high-risk patients (using risk assessment tools) to identify VTE. This approach will result in a program with a better diagnostic yield, decreased cost, and decreased risk of inappropriate treatment of patients with false-negative scans. Use of risk assessment tools such as the Caprini score might also support selective use of VTE prophylaxis in selected EVA patients as well.

Our study has the inherent limitations of using meta-analysis, but we restricted inclusion to either RCTs or case series with >150 cases. Indeed, the latter cohort (*pragmatic trials*) comprised 12,363 limbs (89%). This shifts the population to reflect more closely a “real-world” experience with the incidence of DVT/EHIT.

Because of the low incidence of VTE complications after EVA, it is probably impossible to power an appropriate RCT to address the concerns raised in this report, but analysis of a large, prospectively gathered registry might prove useful. Earlier this year, the AVF and the SVS Patient Safety Organization collaborated to launch

a new Varicose Vein Registry for the Vascular Quality Initiative. The Vascular Quality Initiative now includes 320 centers in 46 states, organized into 18 regional quality groups, and will provide data that will allow comparison of venous treatment outcomes and complications. We might consider incorporating a preprocedure risk assessment tool, like the Caprini score, to this registry to help us identify the relationship between this risk factors and possible complications. The sensitivity analysis in Table VII shows the marked decrease in cost per positive study that a higher incidence of positive studies (10%) produces, as would occur in a "high-risk" population.

CONCLUSIONS

The current SVS/AVF recommendation is to perform screening DUS after EVA within 72 hours postoperatively, but with a weak level of recommendation (grade 2C). The current analysis demonstrates a very low incidence of EHIT/DVT with a corresponding high cost to detect each case with routine DUS screening. These data combined with the unclear clinical significance of EHIT suggest that the policy of universal post-EVA screening should be revised in the near future. We propose limiting postoperative DUS to patients at high risk for VTE and those with postoperative symptoms suggestive of VTE.

AUTHOR CONTRIBUTIONS

Conception and design: LS, TO, MI

Analysis and interpretation: LS, TO, ET, MI

Data collection: LS, TO, ET

Writing the article: LS, TO, ET

Critical revision of the article: LS, TO, ET, MI

Final approval of the article: LS, TO, ET, MI

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