Impact of the Learning Curve for Endoscopic Vein Harvest on Conduit Quality and Early Graft Patency

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Background. Recent studies have suggested that endoscopic vein harvest (EVH) compromises graft patency. To test whether the learning curve for EVH alters conduit integrity owing to increased trauma compared with an open harvest, we analyzed the quality and early patency of conduits procured by technicians with varying EVH experience.

Methods. During coronary artery bypass grafting, veins were harvested open (n = 10) or by EVH (n = 85) performed by experienced (>900 cases, >30/month) versus novice <100 cases, <3/month) technicians. Harvested conduits were imaged intraoperatively using optical coherence tomography and on day 5 to assess graft patency using computed tomographic angiography.

Results. Conduits from experienced (n = 55) versus novice (n = 30) harvesters had similar lengths (33 versus 34 cm) and harvest times (32.4 versus 31.8 minutes). Conduit injury was noted in both EVH groups with similar distribution among disruption of the adventitia (62%), intimal tears at branch points (23%), and intimal or medial dissections (15%), but the incidence of these injuries was less with experienced harvesters and rare in veins procured with an open technique. Overall, the rate of graft attrition was similar between the two EVH groups (6.45% versus 4.34% of grafts; $p = 0.552$). However, vein grafts with at least 4 intimal or medial dissections showed significantly worse patency (67% versus 96% patency; $p = 0.05$).

Conclusions. High-resolution imaging confirmed that technicians inexperienced with EVH are more likely to cause intimal and deep vessel injury to the saphenous vein graft, which increases graft failure risk. Endoscopic vein harvest remains the most common technique for conduit harvest, making efforts to better monitor the learning curve an important public health issue.

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In 1997, a technique for harvesting the saphenous vein using endoscopic methods (EVH) was introduced for use during coronary artery bypass grafting (CABG) [1]. During the subsequent decade, EVH was rapidly adopted because of reductions in postoperative pain [2], length of stay [3], and wound-related morbidity [4, 5] compared with the standard open method for vein harvest. Endoscopic vein harvest is now considered the standard of care for conduit procurement in the United States [6] with more than 70% of all CABG procedures using this approach. Recently, retrospective studies of CABG procedures have demonstrated that graft patency and clinical outcomes [7–10] are compromised in patients who undergo EVH in comparison to the open technique. Endoscopic vein harvest has been implicated as a contributing factor to premature graft failure, with endothelial injury and intraluminal thrombus retention within the venous conduit being offered as possible mechanisms.

Endoscopic handling of vascular tissue is inherently less able than open techniques to abide by “no-touch” principles, particularly during the learning curve for EVH [11]. Several authors have demonstrated that the time required to complete the harvest and the need to convert to an open technique or place external repair stitches in the vein are higher during the early adoption of EVH. However, these metrics of the learning curve do not elucidate the more important issue of whether the integrity and thrombogenicity of the procured vein are altered during the learning curve. Our laboratory has established a catheter-based imaging technique, optical

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coherence tomography (OCT), as a method for identifying intimal or deep vessel injury. This technique allows injury to be detected in real time, anywhere within a vein conduit in an operating room setting. The high levels of sensitivity, specificity, and external validity of using catheter-based OCT to identify vascular architecture and pathologic state have been extensively published by our group and others [12–14]. The purpose of this study was to use OCT to determine whether the risk of conduit injury reflects the learning curve of the person performing EVH.

Material and Methods

Subject Enrollment

Institutional Review Board approval was obtained at two institutions (protocols H25350 and H27266) to perform a prospective observational study of patients undergoing isolated CABG (clinicaltrials.gov: NCT00481806). Inclusion criteria for this subset analysis included those patients who underwent EVH during CABG. Exclusion criteria included the inability to obtain follow-up computed tomographic angiography owing to creatinine greater than 2.0 mg/dL or allergy to radiographic contrast, emergency cases, or prior bleeding diathesis. Demographics, preoperative risk factors and medications, and intraoperative and postoperative data were prospectively imported into a relational database. All patients provided prospective informed consent.

Surgical Technique

All patients underwent off-pump CABG through a median sternotomy by a single surgeon. Open vein harvest procedures (n = 10) were performed at the operative surgeon's discretion. All EVH procedures were performed concurrent to left internal mammary artery harvest by physician assistants (PA) using standardized technique (VasoView 6.0; Maquet Corp, Wayne, NJ) [15]. Heparin bolus was administered before carbon dioxide insufflation at a pressure of 10 to 12 mm Hg within the perivenous tunnel created by the camera dissector. Division of branches was performed with bipolar electrocautery set at 20 W. Proximal saphenous vein ligation was performed through a separate stab incision. After removal from the leg, the saphenous vein was flushed and stored in a Plasma-Lyte solution (Baxter International, Inc, Deerfield, IL) containing heparin, glyceryl trinitrate, and verapamil [16]. After grafting, blood flow was measured in each SVG using transit time ultrasound (Medistim, Inc, Oslo, Norway). Heparin administration was titrated to an activated clotting time greater than 300 seconds. Perioperative aspirin was used in all patients (325 mg by mouth daily). Perioperative coagulation was monitored by thromboelastography (TEG 5000; Haemoscope, Niles, IL) activated by kaolin.

At the study outset, the level of experience of each PA was quantified by the total number of prior EVH cases and ongoing frequency of performing EVH. From previous studies that have monitored the learning curve for EVH [17, 18], we selected 100 cases as the cutoff for defining an experienced versus novice PA.

Intraoperative Image Acquisition and Analysis

After harvest, conduits were cannulated on a sterile back table with a Y-adapter to allow continuous infusion of heparinized glyceryl trinitrate, verapamil, and Plasma-Lyte solution at 100 mm Hg while placing a 1F OCT catheter (Image Wire, Light Lab Imaging, Westford, MA) into the lumen (Fig 1). Images were acquired during a manual pullback at a rate of 1 mm/s. Because the OCT wire emits a red light, wire placement was easily visualized through the vessel wall so that an affected portion of the conduit can be registered to the portion that is selected for grafting. When an abnormality was noted within the discarded portion of the vein, image-guided biopsies were obtained from the affected segments for further histologic and biochemical analysis.

Each OCT image was analyzed independently by 2 separate technicians who were blinded to group assignment. Conduit injury during procurement was categorized as isolated to the intima and minor when the abnormality was restricted to the ostium of branch points or severe when it involved the luminal surface. Deep vessel injury was diagnosed when a separation of the intimal layer from the medial or adventitial layer was noted (with or without an intimal tear) or there was obvious discontinuity in the integrity of the external elastic lamina, suggesting adventitial injury. A composite injury score was created based on the sum total of all discrete injuries noted within each conduit. Residual clot was identified within the saphenous vein lumen by

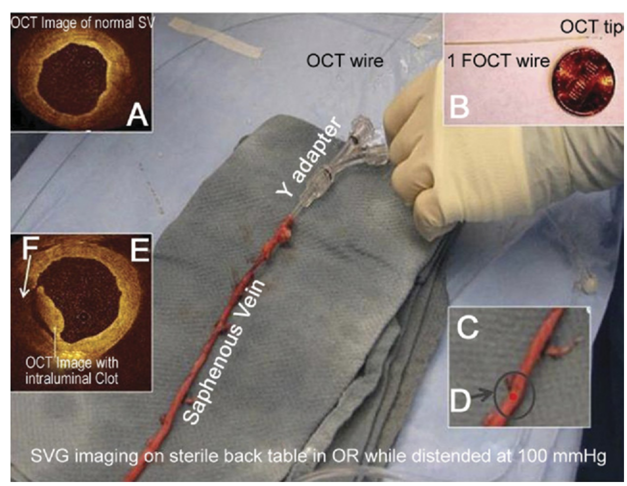

Fig 1. Intraoperative examination of the saphenous vein (SV). On a sterile back table, veins were cannulated with a Y adapter to allow optical coherence tomography (OCT) images (A) to be obtained from an intraluminal 1F OCT wire (B) while gently distending the vein at 100 mm Hg pressure. As the imaging wire is pulled back from within the saphenous vein graft (SVG; C), it is localized by an infrared light emitted from its tip (arrow, D). Any detected abnormalities, such as a retained thrombus (E) with radial signal attenuation suggesting "red clot" (arrow, F), can then be exactly localized within the vein. (OR = operating room.)

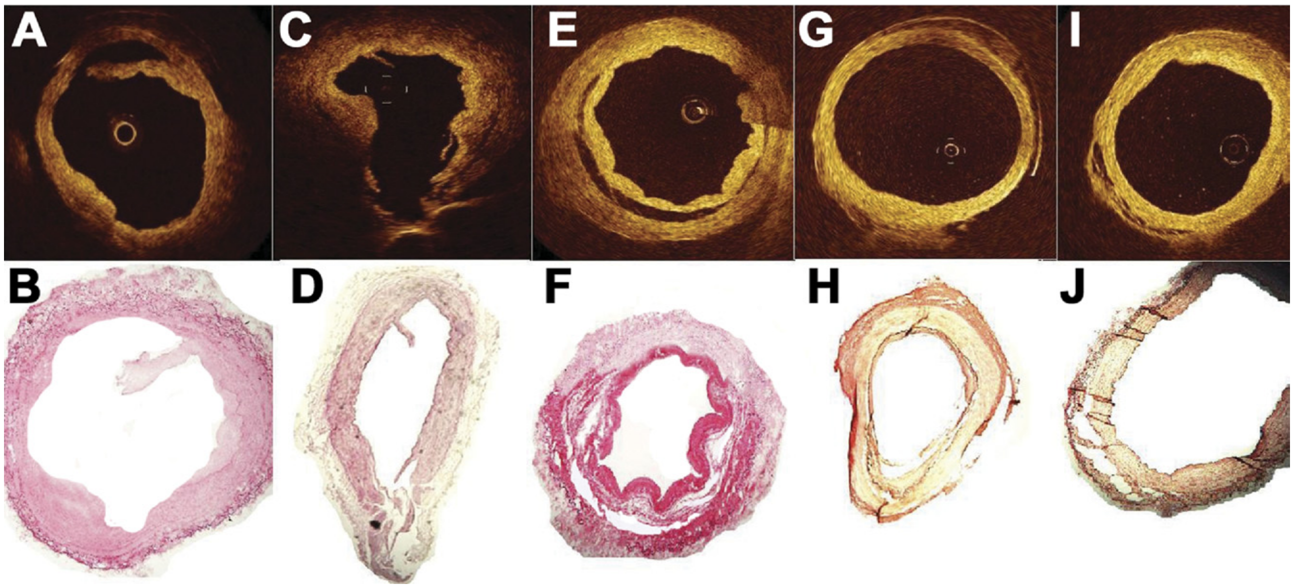

Fig 2. Intimal and deep vessel injury after endoscopic vein harvesting. Evidence of injury noted by optical coherence tomography (A, C, E, G, I) was confirmed with registered histologic sections taken from the abnormal regions (B, D, F, H, J). Injury ranged in severity from being isolated to the intimal layer (A, C) to deeper vessel involvement such as a dissection into the medial layer (E) or disruption of the external elastic lamina (G, I). In each of these representative examples, the corresponding histologic section confirmed the diagnosis suggested by optical coherence tomography. (Hematoxylin and eosin stain; magnification ×10.)

means of cross-sectional OCT images and distinguished by the characteristic radial signal attenuation produced by red thrombi as previously described [19]. Clot distribution within the tract of the vein was documented by externally marking the location of the imaging probe as clot was visualized, and the portion of vein that contains clot relative to the total was calculated (ie, clot fraction).

Vascular Examination

Specimens from image-guided biopsies were frozen in cutting compound (Tissue-Tek O.C.T., Redding, CA) or embedded in paraffin, sectioned at 5 μm, and stained with CD31 monoclonal antibody (R&D System, Inc, Minneapolis, MN) or hematoxylin and eosin (Fig 2). Microscopic sections were analyzed for the percentage of endothelial integrity on the luminal surface using previously described techniques [20]. Other segments were analyzed for luminal tissue factor activity by incubating the vein within a custom-designed chamber containing Tris buffer pH 7.4, 50 mmol/L $CaC1_2$, 2 U/mL factor VII, and 2 U/mL factor X (American Diagnostica, Stamford, CT). After 60 minutes at 37°C, the reaction was stopped by adding 25 mmol/L EDTA. This incubation solution was combined with Tris buffer pH 8.6 and 5 mmol/L chromogenic FXa substrate Spectrozyme FXa (American Diagnostica) in a 96-well plate, and incubated for 60 minutes at 37°C. The absorption of the reaction buffer was assessed at 405 nm and then compared with a standard curve to determine tissue factor activity.

Computed Tomographic Angiography Analysis

Cardiac computed tomographic angiography (CTA) was acquired by means of a 64-MDCT scanner (Philips Medical Systems, Cleveland, OH) on postoperative day 5 and interpreted by a thoracic radiologist using axial and reconstructed curved planar images. Saphenous vein graft patency was defined as any flow through the length of the graft regardless of the presence of stenosis [21].

Statistics

The primary end point of this trial was to compare the mean composite injury score for conduits procured by technicians who were novice versus experienced at performing EVH. Baseline and perioperative variables for patients assigned to the two groups were compared using Student's t test for continuous variables and χ^2 test for categorical variables. Reproducibility of OCT was determined by defining the intraobserver and interobserver kappa correlation coefficients. The accuracy of OCT-based diagnoses of injury was validated using histopathologic analysis of corresponding regions of interest based on OCT examinations. Statistical analysis was performed with SPSS 17.0 (Chicago, IL); significance was set at a probability value less than 0.05.

Results

Study Groups

Endoscopic vein harvest was completed in all 85 cases without the need for conversion to an open technique. Of 7 different PAs who harvested conduits for this analysis, 5 had fewer than 100 cases of experience at the outset of the study (45, 54, 61, 74, 93 cases), and 2 had significantly greater experience (992, 1,145 cases). Therefore, we analyzed the results from two discrete groups: (1) an expe-

Table 1. Baseline Profile of the Clinical Patient Groups

Variable	Experienced Harvester (n = 55)	Novice Harvester (n = 30)	p Value
Age (y)	64.9 ± 10.4	67.0 ± 11.5	0.39
Male sex	78.8%	90.9%	0.14
Diseased vessels	2.9 ± 0.4	2.9 ± 0.2	0.97
BMI (kg/m^2)	29.7 ± 6.4	30.0 ± 6.1	0.82
Hypertension	86.3%	90.9%	0.52
Diabetes mellitus	41.7%	48.4%	0.56
Dyslipidemia	83.3%	84.4%	0.90
Smoking	33.3%	21.2%	0.23
Renal failure	4.00%	0	0.24
PVD	14.3%	9.1%	0.48
Aspirin use	86.3%	96.7%	0.10
EF (<0.35)	27.8%	25.0%	0.80

BMI = body mass index; EF = ejection fraction; PVD = peripheral vascular disease.

rienced group (n = 55 SVG) that had more than 900 prior cases at the study outset and at a frequency of greater than 30 cases/month, and (2) a novice group (n = 30 SVG) with fewer than 100 prior cases with a frequency of fewer than 3 cases/month. Conduits from the two groups had similar total length (33 versus 34 cm), required similar harvesting times (32.4 versus 31.8 minutes), and needed an equivalent number of repair sutures (0.5 versus 0.7 per vein). Patients who were grafted with the SVG from these two groups had similar baseline characteristics, comorbidities (Table 1), and early and late postoperative outcomes (Table 2).

Diagnosis of Conduit Injury and Clot Burden

Intraoperative acquisition of OCT data was successfully completed within times of 2.9 ± 0.4 minutes per examination. The composite injury score for the portion of SVG that was actually grafted was significantly greater for the novice versus experienced group (Table 3). Plotting the average injury score for each harvester during the study

Table 2. Clinical Outcomes

Variable	Experienced Harvester (n = 55)	Novice Harvester (n = 30)	p Value
Day 5 SVG failure	6.4%	4.3%	0.55
30-day major morbidity[a] and mortality	9.6%	9.3%	0.82
1-year MACCE[b]	12.2%	7.7%	0.43

[a] Major morbidity according to The Society of Thoracic Surgeons definition. [b] Major adverse cardiac and cerebrovascular events (MACCE) defined as composite at 1 year of cardiac-related death, readmission for myocardial infarction or need for revascularization, or stroke.

SVG = saphenous vein graft.

Table 3. Harvest-Related Trauma in Clinical Saphenous Vein Graft Harvested by Two Different Groups of Harvesters[a]

Injuries	Experienced Harvester (n = 55)	Novice Harvester (n = 30)	p Value
Harvester	2	5	. . .
Ostial branch tear	1.11 ± 1.05	1.72 ± 1.79	0.05
Intimal injuries	0.65 ± 1.2	0.76 ± 1.09	0.69
Deep vessel injuries	3.42 ± 3.19	5.24 ± 4.34	0.03
Composite injury score	5.18 ± 3.71	7.72 ± 5.37	0.01

[a] All data are mean ± standard deviation.

against their baseline number of cases of experience revealed a strong and statistically significant correlation ($R = -0.83$; $p = 0.01$). The difference between groups was largely attributable to intimal injuries around the ostia of branch points (1.72 versus 1.11 injuries/conduit) and deep vessel injury evidenced by disruption of the external elastic lamina (Table 3). There was no difference in the in the clot burden of the veins between the experienced and novice harvester (24% versus 27% clot fraction; $p = 0.3$) or the risk of severe intimal injury. The results from a third open harvest group (n = 10) showed that clot retention (3%) and conduit injury (composite score 2.9 ± 3.5) were all less common using the open harvesting technique.

Validation of Optical Coherence Tomography Findings

There were strong interobserver correlation coefficients noted for the diagnosis of ostial branch injuries ($\kappa = 0.81$), intimal injuries ($\kappa = 0.89$), and deep vessel injuries ($\kappa = 0.82$). When analyzing surplus segments of the SVG, we noted a significant correlation between the number of intimal abnormalities detected by OCT and percent endothelial integrity on histochemical analysis of an image-guided biopsy ($R = -0.5$; $p = 0.02$). There was no difference in the degree of endothelial disruption found on histology in areas diagnosed by OCT as having either minor versus severe intimal abnormalities. Furthermore, an imaging diagnosis of deep vessel injury showed a significant relationship to the expression of tissue factor activity on the luminal surface ($R = 0.4$; $p = 0.03$).

Graft Outcomes

The rate of attrition was similar for SVG in the two EVH harvesting groups (6.45% versus 4.34% vein graft attrition at 5 days; $p = 0.552$). Saphenous vein grafts that had at least four major injuries evident on OCT showed significantly worse graft patency at day 5 (67% versus 96% patency; $p = 0.05$). There was no significant difference noted in the clot fraction within the veins that failed versus those that remained patent on analysis at day 5 (32% versus 26% clot fraction; $p = 0.34$).

Comment

In this prospective pilot study, we noted that veins procured from novice EVH harvesters had nearly 50% more discrete injuries than veins procured by harvesters with more EVH experience. The diagnosis of conduit injury was made by OCT imaging and confirmed on registered biopsies that showed denuded endothelium and heightened activity of tissue factor. Given that these intimal abnormalities are well known drivers of thrombogenicity, it was not surprising that the rate of attrition increased by 45% when the composite injury score surpassed a threshold of 4 in the portion of conduit used for grafting. The relationship of conduit quality to experience with EVH may reflect a tendency among harvesters who are less experienced with this technique to more forcefully manipulate the vein in an effort to gain better endoscopic vision or exposure. Importantly, most of the recent CABG studies that reported adverse outcomes after EVH were enrolling patients during a time frame in which this technique was being rapidly adopted [7–10]. Although not reported in these studies, it is likely that many of their harvesters had a level of experience similar to that of our novice group. Although our study is underpowered to demonstrate a direct link to patency, we provide strong circumstantial evidence that PA inexperience may have played an underappreciated role in the results of these well-publicized EVH studies.

Traditional surgical principles for handling vascular tissue emphasize a no-touch approach during dissection to minimize the risk of intimal damage. Endoscopic vein harvest inherently requires forces to be applied to the vein that are usually avoided in open harvest, including traction, adventitial stripping, and venous compression. Despite obvious differences in vein handling compared with open methods, multiple prior comparisons of techniques have failed to demonstrate measurable differences in endothelial integrity or other markers of conduit integrity [16, 22, 23]. However, these investigations of conduit quality have been limited to discarded specimens of the vein with the assumption that intimal loss observed histochemically from these graft segments closely reflects the overall status of the endothelium within the graft proper. Because of an inherent sampling error, this type of analysis has limited utility for detecting focal injury within the SVG. This error creates a substantial limitation for testing our hypothesis because trauma during EVH most likely presents as focal disruption of the vein. Focal injury is critically important to diagnose because it can provoke an occlusive thrombus and loss of the graft even when the remainder of the vessel is pristine. Optical coherence tomography provides a high-resolution assessment of vessel integrity throughout the entire harvested SVG. Therefore, our study has adequate sensitivity to be able to answer the critical question about the safety of this technique.

Admittedly, there is a lack of unanimity on the role of EVH on premature graft loss [24]; this type of ongoing debate is not surprising given the variability of techniques and level of experience among centers. It is important to remember that utilization of EVH exceeds 100,000 cases/year in the United States alone, largely because of patient demands for less-invasive techniques. It was reassuring that risk of secondary vein injury from EVH decreases to a level similar to that for open harvest as harvesters become highly experienced. However, efforts to mitigate the effect of the learning curve would become an important public health issue if the results of our pilot study are ultimately confirmed. Prior studies have suggested that as few as 20 cases of experience are required to complete the learning curve of EVH [16]. In contrast, we found that learning was not complete with even close to 100 cases of experience when using conduit injury on OCT imaging as a more a sensitive metric for learning. This revised estimate suggests that acquiring EVH experience and maintaining this skill presents a more complex quality improvement challenge than previously assumed. Dedicating specific staff to learn and perfect their EVH technique is necessary but not sufficient. The centerpiece of most effective quality improvement efforts is a precise measurement of performance. Optical coherence tomography imaging of bypass conduits provides invaluable feedback to technicians during their learning curve for EVH. Although OCT imaging would add additional time (approximately 3 minutes per examination) and cost ($300 per disposable probe) to each case, this type of activity is consistent with the growing mandate to provide rigorous quality assurance and transparency of results in medicine and surgery [25]. Using OCT guidance to select the optimal portion of the conduit and to avoid grafting damaged portions could result in substantial downstream cost savings if it improves the longevity of revascularization.

Our study was underpowered to answer the question whether EVH inexperience compromises graft patency. Without these data, it is possible that we may be overstating the pathophysiologic importance of the abnormalities we detected within the SVG. We do not believe this is the case for several reasons. We ruled out imperfect anastomotic technique and poor outflow as confounding causes of graft failure using intraoperative measurements of flow within each completed SVG. Prior studies using intraoperative angiography corroborate that defects in the body of the SVG are more frequent than problems within the proximal or distal anastomoses [26]. The stark contrast in the rate of the early graft failure between SVG and internal thoracic artery placed on either dominant (eg, left anterior descending coronary artery) [27] or nondominant (eg, circumflex artery and right coronary artery) [28] vascular beds strongly implicates characteristics unique to the vein conduit rather than anastomotic technique or graft outflow as a primary cause of the failure. Compromised endothelial integrity is the primary determinant in the interrelated pathogenesis of thrombosis, intimal hyperplasia, and arteriosclerosis within the SVG [29]. Endothelial cell disruption hinders the natural anticoagulant properties of a normal vessel [30, 31]. Animal models corroborate our finding that deendothelializing injury stimulates mural tissue factor activity within vessels [32]. Evidence of an intimal tear or dissection within a coronary artery similar to what we identified in some of our SVGs has been shown to be one of the most dominant predictors for acute vessel closure after percutaneous transluminal coronary angioplasty (odds ratio, 5.19; $p < 0.001$) [33]. Until available evidence proves otherwise, the goal of harvesting SVG with as close to perfect intima as possible seems prudent considering all these basic science and clinical arguments together with the increased risk of adverse events that inevitably follow acute graft failure [7–10].

An additional limitation of our study was that it was not a randomized comparison of the two harvesting groups, and thus the possibility of bias exists. We attempted to minimize this possibility in several ways. First, we included consecutive patients in the study, rather than targeting certain patients for a given harvesting method. Second, abnormalities on OCT were confirmed in each case by histologic findings performed by reviewers who were unaware of the harvesting method. Third, we accounted for baseline clinical and demographic characteristics to identify variables that might have confounded the analysis. Because of these limitations, the results of this study are most appropriately interpreted as preliminary data to inform the design of an appropriately powered multicenter trial that will provide more definitive conclusions on these issues.

In summary, we used high-resolution OCT imaging to confirm that technicians inexperienced with EVH are more likely to provoke deep vessel injury to the SVG compared with those with more than 900 cases of experience. When the number of discrete injuries within the portion of SVG that ends up being grafted exceeds a threshold of four, the risk of early graft failure rises by almost 50%. Continued analysis of conduit quality using OCT will determine whether improvements defined by this high-resolution imaging modality translate into grafts with better short-term and long-term patency. Regardless, our study provides further evidence supporting OCT as an important quality-assurance tool useful for optimizing harvesting techniques during CABG.

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DISCUSSION

DR MICHAEL MACK (Dallas, TX): Rob, congratulations on a great study, you have been a leader in this field, and thank you for forwarding me the manuscript ahead of time.

People come to medical meetings to learn what they are doing right, what they are doing wrong, and go home and change or continue what they are doing based on what they learned. So I would like to ask a number of questions in that context about your study.

First, you showed that OCT (optical coherence tomography) is a valid tool for demonstrating decreased graft patency in 6 out of 9 patients if you have greater than four areas of injury. Is this a validated tool for long-term patency of saphenous vein grafts and should we all be using it at home and discard veins that have four injuries or greater that have intimal dissection?

DR POSTON: The cohort now is 85 patients. We have had about 2 years of follow-up. So the ability to answer that question is fairly limited based on the data set. I will say, and this is data that we are going to be presenting at STS (The Society of Thoracic Surgeons), that the adventitial injury linked to EVH (endoscopic vein harvesting) does seem to be related to an abnormal remodeling effect. Veins seem to develop a stricture in the long term at a higher rate when there is a significant amount of perioperative adventitial injury. I do think that EVH has adverse implications based on a mechanism of a fixed higher rate of adventitial injury that might influence long-term patency. But, again, this speaks to the need to investigate clinical events based on the underlying mechanism as opposed to just doing a large randomized trial.

DR MACK: Do you view OCT as a research tool or would you like to see it more broadly used to make clinical decisions?

DR POSTON: I would say if you have PAs (physician assistants) at your center that are new at endoharvesting conduits, then OCT adds a tremendous value, because if you see an injury it gives real-time feedback to that PA, and also identifies an area where you can excise the damaged portion of the conduit. In every one of the conduits that I analyzed, we thought clinically that they were fine. It is not like you can see a severe intimal dissection externally. It is just not there. So given that OCT imaging gives your PAs feedback and its information is easily treatable by not using that portion of the conduit, then I believe that it should be used. It is currently FDA (Food and Drug Administration) approved for intracoronary use. It would require some additional investigation to get this FDA approved for conduit evaluation.

DR MACK: Next, all these post hoc analyses in other series show that EVH has a lower graft patency. Do you believe that is true? Does EVH have a lower great patency across the United States?

DR POSTON: Well, I am aware that there have been groups that have shown that EVH at their centers don't affect patency, yet this remains consistent with the idea that EVH results are heavily technician-dependent. So I think if you have PAs that are experienced, and we happen to have 2 that had over 1,000 cases of experience, and you use preheparin and you do all the other things that are important for preserving conduit quality, then I think you will find that EVH doesn't increase your graft failure rate. The particular caveat about the adventitial injury from EVH remains given its potential to affect long-term patency.

DR MACK: The third question is, you have clearly shown there is a relationship to the learning curve. The question is, everybody at some point that is starting has to start at zero. How do you get these people safely over the learning curve?

DR POSTON: Well, step one is to monitor. We can't just say that our PAs can have somebody else scrub in with them and help them and they will take longer in the beginning and then after 20 are 30 cases it will get better. You have to monitor that and find out. I did not do a longitudinal study here where I analyzed the PAs and saw exactly when it is that their numbers of venous injuries went down. But we had PAs that had close to 100 cases of experience and still were developing more injuries.

DR MACK: But do you need a second PA with the first PA? Are the company representatives monitoring and coaching from the sidelines? Is that sufficient? How exactly do you get people trained?

DR POSTON: It is a good question. Based on what I have done, I can't give any definitive answers, but I think the way we come up with those answers is we start monitoring what we are doing and not just assume that everything is okay because the harvesting times are coming down.

DR MACK: The next question is, you yourself need a CABG (coronary artery bypass graft) and the only person available to harvest your vein has 20 cases under their belt. Do you want your vein harvested endoscopically or open?

DR POSTON: Well, I don't want a vein graft.

DR MACK: That is the only option. You are stuck, you are in a corner, 20 cases.

DR POSTON: Do I have to have a vein?

DR MACK: And you have to have a vein.

DR POSTON: I think that is an excellent question.
(Laughter).

DR MACK: What is the excellent answer? All right, I will let you off the hook.

The last question is, do we need a national randomized study of best practice, endoscopic vein harvest versus open?

DR POSTON: Well, like I tried to get at in the talk, I think that this suggestion is the conventional wisdom, but I believe that we ought to also design a trial, maybe perhaps as a subgroup of that RCT (randomized controlled trial), and look at the mechanism of the relationship. Without this, you could end up after completing a large randomized trial showing only modest patency difference in endoscopic- versus open-harvested veins and not really understand why it was that way and what we could improve about endoscopic technique. If the difference was dramatically worse with EVH, then we would say "throw out endoscopic harvest." If the difference was subtle, then we would want to find a way to improve it. And so I think imaging or some technique to investigate the mechanism is very critical.

DR KEVIN D. ACCOLA (Orlando, FL): The question I have and the statement is, saphenous vein graft patency, the equation is so complicated. You can take a beautiful vein that looks good and passes all of your studies—and this is an important study, because we have to continue to evaluate these things with new technologies. But the equation is so variable, because if you sew that to a bad coronary that is diffusely diseased with poor runoff, I think all bets are off. The question I have for you and maybe to follow-up with Mike's suggestion of a study of randomizing this with conventional vein harvest techniques is, have you looked at the quality of vessels that these are being sewn to? Because most of these are thigh veins, and oftentimes you take a bigger thigh vein, sew it to a small interior marginal or a small marginal or a small PDA (posterior descending artery), and your long-term results are not going to be as good. Have you looked at that or considered that in your analysis?

DR POSTON: Sure, and that is one of the challenges of trying to investigate conduit outcomes and perhaps patency, because there are a tremendous amount of variables. But Virchow told us that they boil down to three points: flow, coagulation, endothelium. And so we looked at these variables from the outset. I have been analyzing these results for 5 years, the last 2 years with the OCT, and we found that conduit quality seems to be the key. And this is the same thing the PREVENT 4 trial investigators showed, the ROOBY trial investigators, and others. They have analyzed graft patency in a more thoughtful way and found that conduit quality is a very important variable. Yes, target quality, runoff, those variables play a role, but I think the key trigger and an explanation of why a mammary does better than a vein is the intimal quality, and I think we can't overlook that compared to the other variables just because it is more difficult to be able to assess.