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Endoscopic Harvesting Device Type and Outcomes in Patients Undergoing Coronary Artery Bypass Surgery

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Abstract

Objective—To evaluate angiographic and clinical outcomes associated with open and closed tunnel dissection endoscopic vein harvesting (EVH) devices.

Summary Background Data—A previous PREVENT-IV analysis reported that EVH for coronary artery bypass graft (CABG) surgery was associated with worse outcomes compared with traditional vein harvesting; however, outcomes by EVH device type were not available.

Methods—Using data from the PREVENT-IV trial, we compared 1549 patients from 75 surgical sites who underwent EVH with open (n=390) or closed (n=1159) harvest tunnel devices. Outcomes included the incidence of vein graft failure at 12 to 18 months and a composite of death, myocardial infarction, or revascularization through 5 years.

Results—Among patients undergoing open and closed tunnel EVH, no difference in the per-patient incidence of vein graft failure (43.8% vs. 47.1%; adjusted odds ratio [OR], 0.91; 95% confidence interval [CI], 0.53 to 1.55; p=0.724) or per-graft incidence of vein graft failure (25.5% vs. 25.9%; adjusted OR, 0.96; 95% CI, 0.59 to 1.55; p=0.847) was observed. At 5 years, no difference was observed in the primary composite clinical outcome between open and closed system EVH patients (21.5% vs. 23.9%; adjusted hazard ratio, 0.85; 95% CI, 0.66 to 1.10; p=0.221).

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Conclusion—No differences in angiographic or clinical outcomes were observed among patients who underwent open vs. closed tunnel endoscopic harvesting for coronary bypass surgery. These findings suggest that the risks associated with EVH that were reported in a previous PREVENT-IV analysis are not related to a specific EVH device.

Introduction

Saphenous vein grafts are the most commonly used conduit in coronary artery bypass graft (CABG) surgery. [1] Endoscopic vein harvesting (EVH) was introduced as a minimally invasive alternative to traditional open harvesting. Meta-analyses and small randomized studies have shown that endoscopic techniques reduce wound infections, bleeding, post-operative pain, and hospital stay durations. [2–7] Based on these findings, a consensus statement endorsed the use of EVH over traditional harvesting, and by 2008 it was used in approximately 70% of patients undergoing CABG in the United States. [1, 8] In an analysis of the Project of Ex-vivo Vein Graft Engineering via Transfection IV (PREVENT-IV) trial, we previously reported that EVH was associated with a higher rate of vein graft failure at 12 to 18 months and long-term mortality. [9] A secondary analysis of the ROOBY trial similarly reported lower vein graft patency and higher revascularization rates among patients who underwent EVH. [8] However, an analysis of Medicare patients in the Society of Thoracic Surgeons National Database reported no relationship between EVH and mortality, and among patients in the Northern New England Cardiovascular Disease Study, EVH was associated with lower mortality. [10, 11] One possible explanation for these discordant results could be the differential use and outcomes of specific EVH device types, though none of these studies were specifically designed to assess the comparative efficacy and safety of vein harvesting techniques.

There were two commercially available EVH devices used in the PREVENT-IV trial. [12] The *closed tunnel* system occludes the access site with a balloon and insufflates the dissection tunnel with up to 15 mmHg of carbon dioxide, whereas an *open* EVH system does not occlude the access site or pressurize the dissection tunnel. It has been hypothesized that a pressurized closed dissection tunnel could lead to intraluminal clot formation by slowing venous graft blood flow. [13] In addition, in the closed tunnel system the dissector tip is bullet-shaped, allowing for more blunt dissection, vs. the open tunnel system that has a spoon-shaped dissector tip. The lack of EVH device-specific information at the time of the original PREVENT-IV EVH analysis was a recognized limitation insofar as it precluded examining whether the observed vein graft failures were associated with specific EVH devices. [14] Accordingly, after collecting additional device-specific data, we sought to compare rates of vein graft failure and clinical outcomes in patients undergoing closed tunnel vs. open tunnel EVH for CABG.

Methods

Patient Population

The design and results of the PREVENT-IV ([ClinicalTrials.gov](https://clinicaltrials.gov) number, NCT00042081) trial have been previously described. [12, 15] Briefly, this was a phase III, double blind, multicenter, placebo-controlled, randomized trial designed to assess the effects of

edifoligide, an E2F transcription factor inhibitor, on ex-vivo vein grafts in patients undergoing CABG. A total of 3014 patients were enrolled at 107 sites in the United States between 2002 and 2003, and the first 2400 were scheduled to undergo follow-up angiography 12 to 18 months after surgery. Patients aged 18 to 80 years were eligible if they were scheduled to undergo an isolated, first CABG surgery with two or more vein grafts for atherosclerotic coronary artery disease. Major exclusion criteria included planned valvular surgery, prior cardiac surgery, non-atherosclerotic coronary artery disease, and comorbid illness expected to make 5-year survival unlikely. Each participating site received institutional review board approval, and all patients provided informed written consent.

Endoscopic Vein Harvesting Devices and Identification

The primary analysis compared patients who underwent EVH with a closed tunnel system (Vasoview, MAQUET, Wayne, NJ [formerly Guidant Corporation, Natick, MA]) with patients who underwent EVH with an open tunnel system (Clearglide, Sorin Group, Montvale, NJ [formerly Ethicon Cardioversions, Somerville, NJ, and Datascope INC]). EVH device information was obtained by contacting each PREVENT-IV study site. If a study hospital used both EVH systems, patient-specific harvesting device information was requested. Patients were excluded from this analysis if EVH device information was unavailable.

Outcome Measures

Angiographic endpoints were the per-graft and per-patient incidences of vein graft failure, defined as stenosis $\geq 75\%$ of the vein graft diameter, and vein graft occlusion. All angiograms were interpreted in a central core laboratory blinded to harvesting technique (PERFUSE Angiographic Core Laboratory, Boston, MA). The angiographic outcomes analysis included EVH patients in the aforementioned angiographic cohort who completed the 12- to 18-month angiographic follow-up. Individuals who underwent angiography prior to 12 months for clinical reasons and met an angiographic endpoint were included in this analysis. Patients who died prior to angiographic follow-up were excluded. The primary clinical endpoint was the 5-year composite outcome of death, myocardial infarction (MI), or revascularization. Other clinical endpoints were the individual components of composite outcomes.

Statistical Analysis

The distributions of baseline, peri-operative surgical, and post-operative treatment characteristics were summarized with medians and 25th and 75th percentiles for continuous variables and with percentages for categorical variables. Group differences were assessed with the Wilcoxon rank-sum test (for continuous variables) and the χ^2 test (for categorical variables).

The incidence of vein graft failure was adjusted for predictors previously identified in the PREVENT-IV dataset. [16] Vein graft failure was evaluated both at the patient and graft levels using mixed-effects logistic regression models. The patient-level graft failure model included study site as a random effect and the weight, duration of surgery, graft quality, target artery quality, and use of composite grafts as fixed effects. In the graft-level graft

failure model, both patient and study site were modeled as random effects, while weight, duration of surgery, graft quality, target artery quality, and whether the graft was a composite or non-composite graft were modeled as fixed effects.

Cumulative event rates and survival curves for the clinical outcomes were calculated by the Kaplan-Meier method, and outcome differences were assessed using a Cox proportional hazards model. Covariates associated with the primary clinical endpoint have been previously published. [9, 17] The variables included in the Cox proportional hazards model were age, sex, race, body mass index, hypertension, diabetes, heart failure, New York Heart Association class, recent MI, peripheral vascular disease, smoking, chronic lung disease, creatinine clearance, and poor target artery quality. A frailty model was used to determine whether survival times within study site were correlated and thus required adjustment for study site. [18] In a sensitivity analysis, we assessed whether the subset of patients who underwent EVH in this substudy (i.e., device type was known) was similar to the group of all EVH patients enrolled in PREVENT-IV. We compared the clinical outcome of death, MI, or revascularization between 1) the subset of EVH patients used in this substudy and 2) patients who had open harvesting that were included in our original manuscript that compared EVH with open harvesting.

Results

A total of 1753 patients in the PREVENT-IV trial underwent EVH, and 1549 patients (88.4%) from 75 of 107 study sites were included in this analysis. A total of 63 sites (n=1153) used only a closed tunnel EVH system, 11 sites (n=210) used only an open tunnel system, and one site (n=215) used both systems. At 8 sites (n=175) device-specific information could not be obtained, and therefore, those patients were excluded from this analysis (Figure 1). From the open EVH group, 180 patients (46%) were from a single surgical site. The mean follow-up time was 5.1 years. The proportion of study patients at each study site undergoing EVH stratified by harvesting system is presented in Figure 2. Baseline differences between the 1159 patients who underwent EVH with a closed system (Guidant) and the 390 patients who underwent EVH with an open system (Datascope) were generally well balanced (Table 1). Closed system harvesting patients had fewer current smokers, a lower prevalence of chronic lung disease, a lower median baseline heart rate, and a higher burden of underlying coronary artery disease. Peri-operative surgical and post-operative treatment variables are presented in Table 2. Open EVH system patients were more likely to undergo urgent surgery, undergo on-pump surgery, have a composite vein graft, have longer surgical times, and have longer lengths of stay. At 30 days, open EVH system patients were more likely to continue aspirin and thienopyridines but were less likely to continue statins.

Angiographic Outcomes

A total of 881 (56.9%) patients in this study had a follow-up angiogram within 18 months. The incidences of vein graft failure and graft occlusion are presented in Table 3. No significant differences were observed in either the per-patient or the per-graft unadjusted

incidence of vein graft failure or occlusion, a finding that persisted after multivariable adjustment.

Clinical Outcomes

The 5-year Kaplan-Meier event rates for the composite outcome of death, MI, or revascularization were 23.9% for closed tunnel and 21.5% for open tunnel EVH patients (Table 4, Figure 3). After multivariable adjustment, the 5-year risk of the primary composite outcome was similar among patients with open harvesting compared with closed harvesting (hazard ratio [HR], 0.85; 95% confidence interval [CI], 0.66 to 1.10; $p=0.221$). Among secondary clinical outcomes, the 5-year Kaplan-Meier event rate for revascularization was numerically lower among patients who underwent open tunnel EVH (12.2% vs. 16.4%); however, the relationship was not statistically significant after multivariable adjustment (HR, 0.73; 95% CI, 0.53 to 1.03; $p=0.072$).

In a sensitivity analysis, we compared the outcomes of patients who underwent EVH that were included in this analysis with the outcomes of patients who underwent open harvesting that were included in our original manuscript. [9] The higher 3-year risk of death, MI, or revascularization for patients who underwent EVH compared with those who underwent open harvesting was similar to our previously published results (adjusted HR, 1.22; 95% CI, 1.01 to 1.47; $p=0.04$).

Discussion

This study, representing the largest device-specific analysis of long-term post-CABG outcomes in patients undergoing EVH, has two important findings. First, no difference was observed in the rates of 12- to 18-month post-operative vein graft failure or occlusion in patients undergoing open or closed tunnel EVH. Second, the 5-year incidences of death, MI, or revascularization were similar between the groups of patients who underwent EVH using open and closed tunnel endoscopic harvesting devices. Thus, no difference in EVH device-specific outcomes could be detected to account for the higher incidence of vein graft failure and adverse clinical events observed in our previous PREVENT-IV analysis. [9]

As previously mentioned, the greater saphenous vein is the most frequently used CABG conduit, and it has traditionally been harvested using a continuous linear skin incision that can extend from below the knee to its junction with the femoral vein just below the inguinal crease. [1] This technique potentially permits clear vein visualization, mobilization, and branch ligation but carries an increased risk of skin wound complications, hematomas, and longer hospital stays. [2–5,19,20] In 1996, an endoscopic vein harvesting procedure was described as an alternative to standard vein procurement. [21] Multiple meta-analyses and small randomized trials subsequently reported advantages of EVH in terms of important short-term outcomes such as surgical site pain, cost, patient satisfaction, and harvest-site-wound complications. [2, 22–24] These analyses were neither powered nor designed to detect long-term differences in vein graft failure rates or major adverse cardiac outcomes. Observational analyses of the long-term safety of EVH are conflicting. Two studies have reported increased harm associated with EVH, including reduced vein graft patency and increased revascularization and death. [8, 9] However, studies by Dacey, et al. and Williams,

et al. reported lower and no difference in long-term mortality, respectively. [10, 11] A limitation of all of the aforementioned analyses is a lack of information about EVH harvesting devices.

EVH does not describe one homogeneous procedure. As previously mentioned, at the time of the PREVENT-IV trial, there were only two commercially available EVH devices in the United States—a closed tunnel system (Vasoview) and an open tunnel system (Clearglide). A closed system uses a balloon to occlude the device entry site and the dissection tunnel is insufflated with carbon dioxide gas at 5–15 mmHg pressure, whereas an open system does not use an occlusive balloon and the dissection tunnel is not pressurized. A small study by Brown and colleagues reporting a lower unadjusted incidence of intraluminal venous clots in patients undergoing EVH with an open tunnel system led to the hypothesis that a pressured dissection tunnel can slow blood flow within a venous graft and lead to increased intraluminal clot; however, the present analysis did not detect a difference in EVH device-specific angiographic or clinical outcomes to support this putative hypothesis. [13] The lack of an observed difference between open vs. closed tunnel harvesting systems suggests the increased risk of vein graft failures and clinical events observed among EVH patients in a previous PREVENT-IV analysis were not device-specific. [9] The hypothesis that EVH may have detrimental effects on vein grafts is supported by a prospective, small study using multiphoton imaging, immunofluorescence, and biochemical techniques that demonstrated increased endothelial damage and reduced viability in EVH vein grafts. [25] This finding, however, has not been supported by all histologic studies. [26] Importantly, EVH techniques continue to evolve, and modern EVH harvesting techniques may be different than those used during PREVENT-IV.

Implications for Current Practice and Future Research

Endoscopic harvesting of saphenous vein grafts clearly has important advantages for short-term outcomes such as wound infections, bleeding, pain, and length of hospitalization. In the context of conflicting outcomes associated with EVH in observational studies, which all have important methodological limitations, the long-term safety of EVH remains unclear. Importantly, we support calls to rigorously evaluate the safety of EVH in angiographic and clinical outcomes in an adequately powered randomized trial. [3, 8, 9]

Limitations

This study has several limitations that merit consideration. First, this study did not record measures of operator volume, which may be an important determinant of intimal and deep-vessel-harvesting-related injuries. [27] Second, there was no protocol requirement for pre-harvest use of heparin, which may reduce vein graft clot burden. [13] Third, although the multivariable analysis adjusted for variables known to be associated with vein graft failure, the patients included in this analysis were not randomized. Fourth, more than 40% of patients undergoing EVH with a Datascope device were from one study site, and no study center information was available in our dataset. We attempted to reduce the potential study center bias by modeling study center as a random effect when assessing vein graft failure. Study center was found to be nonsignificant as a random effect in the frailty model ($p=0.96$). Therefore the Cox proportional hazards models used to assess clinical outcomes did not

include the random effect for study center. Fifth, the site of vein graft harvesting (thigh versus calf) was not available in our dataset. Finally, the 5-year vein graft patency rate in this study was lower than in some reports, but is consistent with other published patency rates. [8, 28]

Conclusion

In a large cohort of patients undergoing CABG with EVH, no difference was detected in the incidence of vein graft failure or occlusion between patients undergoing open or closed system EVH. Additionally, no difference was detected in the 5-year incidence of death, MI, or revascularization. This analysis suggests that the higher incidences of vein graft failures and clinical events observed among EVH patients in the PREVENT-IV population were not related to a specific EVH device or system.

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References

1. Allen K, Cheng D, Cohn W, et al. Endoscopic Vascular Harvest in Coronary Artery Bypass Grafting Surgery: A Consensus Statement of the International Society of Minimally Invasive Cardiothoracic Surgery (ISMICS) 2005. *Innovations*. 2005; 1:51–60. [PubMed: 22436545]
2. Cheng D, Allen K, Cohn W, et al. Endoscopic Vascular Harvest in Coronary Artery Bypass Grafting Surgery: A Meta-Analysis of Randomized Trials and Controlled Trials. *Innovations*. 2005; 1:61–74. [PubMed: 22436546]
3. Markar SR, Kutty R, Edmonds L, Sadat U, Nair S. A meta-analysis of minimally invasive versus traditional open vein harvest technique for coronary artery bypass graft surgery. *Interact Cardiovasc Thorac Surg*. 2010; 10:266–270. [PubMed: 19942633]
4. Kiaii B, Moon BC, Massel D, et al. A prospective randomized trial of endoscopic versus conventional harvesting of the saphenous vein in coronary artery bypass surgery. *J Thorac Cardiovasc Surg*. 2002; 123:204–212. [PubMed: 11828277]
5. Yun KL, Wu Y, Aharonian V, et al. Randomized trial of endoscopic versus open vein harvest for coronary artery bypass grafting: Six-month patency rates. *J Thorac Cardiovasc Surg*. 2005; 129:496–503. [PubMed: 15746730]
6. Allen KB, Heimansohn DA, Robison RJ, Schier JJ, Griffith GL, Fitzgerald EB. Influence of endoscopic versus traditional saphenectomy on event-free survival: five-year follow-up of a prospective randomized trial. *Heart Surg Forum*. 2003; 6:E143–E145. [PubMed: 14722001]
7. Allen KB, Griffith GL, Heimansohn DA, et al. Endoscopic versus traditional saphenous vein harvesting: a prospective, randomized trial. *Ann Thorac Surg*. 1998; 66:26–31. [PubMed: 9692434]
8. Zenati MA, Shroyer AL, Collins JF, et al. Impact of endoscopic versus open saphenous vein harvest technique on late coronary artery bypass grafting patient outcomes in the ROOBY (Randomized On/Off Bypass) Trial. *J Thorac Cardiovasc Surg*. 2011; 141:338–344. [PubMed: 21130476]
9. Lopes RD, Hafley GE, Allen KB, et al. Endoscopic versus open vein-graft harvesting in coronary-artery bypass surgery. *N Engl J Med*. 2009; 361:235–244. [PubMed: 19605828]
10. Williams JB, Peterson ED, Brennan JM. Association between endoscopic vs open vein-graft harvesting and mortality, wound complications, and cardiovascular events in patients undergoing CABG surgery. *JAMA*. 2012; 308:475–484. [PubMed: 22851114]
11. Dacey LJ, Braxton JH, Kramer RS, et al. Long-term outcomes of endoscopic vein harvesting after coronary artery bypass grafting. *Circulation*. 2011; 123:147–153. [PubMed: 21200010]

12. Alexander JH, Hafley G, Harrington RA, et al. Efficacy and safety of edifoligide, an E2F transcription factor decoy, for prevention of vein graft failure following coronary artery bypass graft surgery: PREVENT IV: a randomized controlled trial. *JAMA*. 2005; 294:2446–2454. [PubMed: 16287955]
13. Brown EN, Kon ZN, Tran R, et al. Strategies to reduce intraluminal clot formation in endoscopically harvested saphenous veins. *J Thorac Cardiovasc Surg*. 2007; 134:1259–1265. [PubMed: 17976458]
14. Patel NN, Angelini GD. Surgery: Open or endoscopic vein graft harvesting - this is the question! *Nat Rev Cardiol*. 2009; 6:738–740. [PubMed: 19935681]
15. Alexander JH, Ferguson TB Jr, Joseph DM, et al. The PROject of Ex-vivo Vein graft ENgineering via Transfection IV (PREVENT IV) trial: Study rationale, design, and baseline patient characteristics. *Am Heart J*. 2005; 150:643–649. [PubMed: 16209958]
16. Magee MJ, Alexander JH, Hafley G, et al. Coronary artery bypass graft failure after on-pump and off-pump coronary artery bypass: findings from PREVENT IV. *Ann Thorac Surg*. 2008; 85:494–500. [PubMed: 18222251]
17. Lopes RD, Williams JB, Mehta RH, et al. Edifoligide and long-term outcomes after coronary artery bypass grafting: PROject of Ex-vivo Vein graft ENgineering via Transfection IV (PREVENT IV) 5-year results. *Am Heart J*. 2012; 164:379–386. [PubMed: 22980305]
18. Vu HTV, Knuiman MW. A hybrid ML-EM algorithm for calculation of maximum likelihood estimates in semiparametric shared frailty models. *Comput Stat Data Anal*. 2002; 40:173–187.
19. Schurr UP, Lachat ML, Reuthebuch O, et al. Endoscopic saphenous vein harvesting for CABG - a randomized, prospective trial. *Thorac Cardiovasc Surg*. 2002; 50:160–163. [PubMed: 12077689]
20. Ouzounian M, Hassan A, Buth KJ, et al. Impact of endoscopic versus open saphenous vein harvest techniques on outcomes after coronary artery bypass grafting. *Ann Thorac Surg*. 2010; 89:403–408. [PubMed: 20103309]
21. Lumsden AB, Eaves FF Iii, Ofenloch JC, Jordan WD. Subcutaneous, video-assisted saphenous vein harvest: report of the first 30 cases. *Cardiovasc Surg*. 1996; 4:771–776. [PubMed: 9013008]
22. Athanasiou T, Aziz O, Skapinakis P, et al. Leg wound infection after coronary artery bypass grafting: a meta-analysis comparing minimally invasive versus conventional vein harvesting. *Ann Thorac Surg*. 2003; 76:2141–2146. [PubMed: 14667670]
23. Athanasiou T, Aziz O, Al-Ruzzeh S, et al. Are wound healing disturbances and length of hospital stay reduced with minimally invasive vein harvest? A meta-analysis. *Eur J Cardiothorac Surg*. 2004; 26:1015–1026. [PubMed: 15519197]
24. García-Altés A, Peiró S. A systematic review of cost-effectiveness evidence of endoscopic saphenous vein harvesting: is it efficient? *Eur J Vasc Endovasc Surg*. 2011; 41:831–836. [PubMed: 21411346]
25. Rousou LJ, Taylor KB, Lu X-G, et al. Saphenous vein conduits harvested by endoscopic technique exhibit structural and functional damage. *Ann Thorac Surg*. 2009; 87:62–70. [PubMed: 19101270]
26. Griffith GL, Allen KB, Waller BF, et al. Endoscopic and traditional saphenous vein harvest: a histologic comparison. *Ann Thorac Surg*. 2000; 69:520–523. [PubMed: 10735691]
27. Desai P, Kiani S, Thiruvanthan N, et al. Impact of the Learning curve for endoscopic vein harvest on conduit quality and early graft patency. *Ann Thorac Surg*. 2011; 91:1385–1392. [PubMed: 21524447]
28. Hayward PA, Gordon IR, Hare DL, et al. Comparable patencies of the radial artery and right internal thoracic artery or saphenous vein beyond 5 years: results from the Radial Artery Patency and Clinical Outcomes trial. *J Thorac Cardiovasc Surg*. 2010; 139:60–70. [PubMed: 20106358]

Figure 1.
Endoscopic vein harvesting device use
Abbreviations: EVH, endoscopic vein harvesting.

Figure 2.
Endoscopic vein harvesting device use across study sites

Figure 3.
Kaplan-Meier curve for death, myocardial infarction, or revascularization for patients undergoing open and closed system endoscopic vein harvesting
Abbreviations: CI, confidence interval; HR, hazard ratio.

Table 1

Baseline characteristics stratified by endoscopic harvesting device

Characteristic	All EVH Patients (n=1549)	EVH System		PValue
		Closed Tunnel (n=1159)	Open Tunnel (n=390)	
Demographics				
Age, yr	64.0 (56.0, 70.0)	64.0 (56.0, 71.0)	62.0 (55.0, 69.0)	0.051
Male	1232 (79.5)	920 (79.4)	312 (80.0)	0.793
White	1412 (91.2)	1048 (90.4)	364 (93.3)	0.080
BMI, kg/m ²	29.0 (26.0, 32.8)	29.0 (26.1, 32.8)	29.3 (25.8, 32.8)	0.848
Medical history				
Hypertension	1182 (76.3)	882 (76.1)	300 (76.9)	0.741
Dyslipidemia	1196 (77.3)	898 (77.5)	298 (76.4)	0.643
Diabetes	574 (37.1)	424 (36.6)	150 (38.5)	0.506
MI	664 (42.9)	496 (42.8)	168 (43.1)	0.923
PCI	369 (23.8)	274 (23.6)	95 (24.4)	0.773
Heart failure	140 (9.0)	107 (9.2)	33 (8.5)	0.646
NYHA class III/IV	350 (22.8)	261 (22.8)	89 (23.0)	0.922
Atrial fibrillation or flutter	108 (7.0)	76 (6.6)	32 (8.2)	0.269
Stroke	89 (5.7)	68 (5.9)	21 (5.4)	0.723
Peripheral vascular disease	189 (12.2)	147 (12.7)	42 (10.8)	0.318
Current smoker	362 (23.4)	249 (21.5)	113 (29.0)	0.002
Chronic lung disease	243 (15.7)	169 (14.6)	74 (19.0)	0.039
Systolic blood pressure, mmHg	135 (120, 150)	135 (120, 150)	134 (120, 148)	0.768
Diastolic blood pressure, mmHg	75 (68, 82)	75 (68, 82)	76 (68, 84)	0.298
Heart rate, bpm	70 (62, 80)	70 (62, 79)	71 (63, 80)	0.030
Left ventricular ejection fraction, %	50.0 (40.0, 60.0)	50.0 (40.0, 60.0)	50.0 (40.0, 60.0)	0.247
Number of coronary artery stenosis (≥ 75%)				
0	75 (4.9)	48 (4.2)	27 (6.9)	0.001
1	302 (19.5)	205 (17.7)	97 (24.9)	
2	588 (38.0)	448 (38.8)	140(35.9)	
3	581 (37.6)	455 (39.4)	126 (32.3)	
Left main	133 (8.6)	97 (8.4)	36 (9.2)	0.599
Hemoglobin, g/L	13.9 (12.7, 14.9)	13.9 (12.7, 14.9)	13.9 (12.7, 14.9)	0.957
Creatinine clearance, mL/min	89.1 (69.7, 112.2)	88.5 (69.4, 111.5)	90.4 (71.1, 114.1)	0.632

Data are presented as median (25th, 75th percentile) or n (%).

Abbreviations: BMI, body mass index; EVH, endoscopic vein harvesting; NYHA, New York Heart Association; MI, myocardial infarction; PCI, percutaneous coronary intervention.

Table 2

Peri-operative and post-operative treatment stratified by type of endoscopic harvesting device

Characteristic	All EVH Patients (n=1549)	EVH System		PValue
		Closed Tunnel (n=1159)	Open Tunnel (n=390)	
Urgent surgery	815 (52.7)	543 (46.9)	272 (69.7)	<0.001
Internal thoracic artery graft	1420 (91.7)	1066 (92.0)	354 (90.8)	0.456
Number of vein grafts				0.065
1	37 (2.4)	28 (2.4)	9 (2.3)	
2	950 (61.3)	732 (63.2)	218 (55.9)	
3	486 (31.4)	343 (29.6)	143 (36.7)	
4	76 (4.9)	56 (4.8)	20 (5.1)	
Any composite graft	588 (38.0)	408 (35.2)	180(46.2)	<0.001
Worst graft quality				0.589
Good	1136 (73.4)	847 (73.1)	289 (74.3)	
Fair	333 (21.5)	249 (21.5)	84 (21.6)	
Poor	79 (5.1)	63 (5.4)	16 (4.1)	
Worst target artery quality				0.085
Good	719 (46.5)	529 (45.7)	190 (49.0)	
Fair	507 (32.8)	374 (32.3)	133 (34.3)	
Poor	320 (20.7)	255 (22.0)	65 (16.8)	
Surgery duration, min	235 (195, 277)	232 (192, 273)	245 (207, 285)	<0.001
Cardiopulmonary bypass	1118 (72.2)	763 (65.8)	355 (91.0)	<0.001
Cardiopulmonary bypass duration, min	98 (77, 121)	97 (75, 122)	98 (80, 120)	0.680
Intra-operative intraaortic balloon pump	85 (5.6)	55 (4.8)	30 (7.7)	0.042
Post-operative ICU duration, hr	25 (21, 48)	26 (21, 48)	25(22, 46)	0.555
Post-operative hospital duration, d	6.0 (5.0, 8.0)	6.0 (5.0, 8.0)	7.0 (5.0, 8.0)	<0.001
Medications within 24 hr of surgery				
Internal mammary graft used	1420/1549 (91.7)	1066 (92.0)	354 (90.8)	0.456
Medications continued at 30 d				
Aspirin	1392 (90.8)	1031 (89.7)	361 (94.0)	0.012
Thienopyridine	415 (27.1)	285 (24.8)	130 (33.9)	0.001
β -blocker	1224 (79.8)	907 (78.9)	317 (82.3)	0.151
Statins	1147 (74.8)	875 (76.2)	272 (70.6)	0.031
ACEIs or ARBs	657 (42.8)	482 (41.9)	175 (45.5)	0.229

Data are presented as median (25th, 75th percentile) or n (%).

Abbreviations: ACE, angiotensin-converting enzyme inhibitor; ARB, angiotensin-receptor blocker; EVH, endoscopic vein harvesting; ICU, intensive care unit.

Table 3

Per-patient and per-graft angiographic outcomes

Outcome	Unadjusted		Adjusted ^{a,b}	
	Closed Tunnel	Open Tunnel	OR ^c (95% CI)	P Value
Per-patient outcomes				
Total patients	678	203		
Vein graft failure	319 (47.1%)	89 (43.8%)	0.91 (0.53–1.55)	0.724
Vein graft occlusion	293 (43.3%)	80 (39.6%)	0.92 (0.53–1.60)	0.763
Per-graft outcomes				
Total grafts	2301	674		
Vein graft failure	596 (25.9%)	172 (25.5%)	0.96 (0.59–1.55)	0.847
Vein graft occlusion	535 (23.3%)	150 (22.3%)	0.94 (0.57–1.54)	0.791

^aPer-patient outcomes adjusted for weight, length of surgery, poor graft quality, poor target artery quality, composite grafts, and site.

^bPer-graft outcomes adjusted for weight, length of surgery, graft quality, target artery quality, composite graft, and site.

^cOR for open tunnel compared with closed tunnel devices.

Abbreviation: CI, confidence interval; OR, odds ratio.

Table 4

Adjusted 5-year major adverse cardiac events

Event	Closed Tunnel	Open Tunnel	HR ^a (95% CI)	P Value
Death, MI, revascularization			0.85 (0.66–1.10)	0.221
Number of events	271	83		
KM estimate of 5-yr event rate (%)	23.9	21.5		
Death			1.01 (0.72–1.42)	0.953
Number of events	134	49		
KM estimate of 5-yr event rate (%)	11.9	12.7		
MI			0.89 (0.39–2.00)	0.771
Number of events	30	9		
KM estimate of 5-yr event rate (%)	2.8	2.4		
Revascularization			0.73 (0.53–1.03)	0.072
Number of events	179	45		
KM estimate of 5-yr event rate (%)	16.4	12.2		
Death or MI			0.96 (0.70–1.32)	0.799
Number of events	163	56		
KM estimate of 5-yr event rate (%)	14.4	14.5		
MI or revascularization			0.78 (0.57–1.08)	0.136
Number of events	185	51		
KM estimate of 5-yr event rate (%)	17.0	13.7		

^aHR for open tunnel compared with closed tunnel devices, adjusted for age, sex, race, body mass index, hypertension, diabetes, heart failure, New York Heart Association class, MI (within 30 days of enrollment), peripheral vascular disease, smoking, chronic lung disease, creatinine, clearance, and poor target artery quality.

Abbreviations: CI, confidence interval; HR, hazard ratio; MI, myocardial infarction; KM, Kaplan-Meier.