Randomized trial of endoscopic versus open vein harvest for coronary artery bypass grafting: Six-month patency rates

Kwok L. Yun, MD,^a YingXing Wu, MD,^b Vicken Aharonian, MD,^a Prakash Mansukhani, MD,^a Thomas A. Pfeffer, MD,^a Colleen F. Sintek, MD,^a Gary S. Kochamba, MD,^a Gary Grunkemeier, PhD,^b and Siavosh Khonsari, MD^a

See related editorial on page 488.

Objective: We sought to compare the 6-month angiographic patency rates of greater saphenous veins removed during coronary artery bypass grafting with the endoscopic vein harvest or open vein harvest techniques.

Methods: Two hundred patients undergoing nonemergency on-pump coronary artery bypass grafting were prospectively randomized to either endoscopic vein harvest or open vein harvest. Follow-up angiography of all vein grafts was scheduled at 6 months. Graft patency and disease grades were assigned independently by 2 interventional cardiologists. Leg wound healing was evaluated at discharge, 1 month, and 6 months for evidence of complications.

Results: There were 3 conversions from endoscopic vein harvest to open vein harvest because of vein factors. Leg wound complications were significantly lower in the endoscopic vein harvest group (7.4% vs 19.4%, $P = .014$). On multivariable analysis, endoscopic vein harvest emerged as the only factor affecting wound complications (odds ratio, 0.33). Three deaths (2 perioperative and 1 late) occurred in the endoscopic vein harvest group that were unrelated to vein graft closure. Twenty-four and 29 patients in the endoscopic vein harvest and open vein harvest cohorts, respectively, refused the follow-up 6-month angiography. Therefore a total of 144 angiograms (73 endoscopic vein harvests and 71 open vein harvests) and 336 vein grafts (166 endoscopic vein harvests and 170 open vein harvests) were available for analysis. The overall occlusion rates at 6 months were 21.7% for endoscopic vein harvest and 17.6% for open vein harvest. Additionally, there was evidence of significant disease ($>50\%$ stenosis) in 10.2% and 12.4% of endoscopic vein harvest and open vein harvest grafts, respectively. By means of ordinal hierarchic logistic regression, endoscopic vein harvest was not found to be a risk factor for vein graft occlusion or disease (odds ratio, 1.15). Significant predictors were congestive heart failure (odds ratio, 2.87), graft to the diagonal artery territory (odds ratio, 1.76), larger vein conduit size (odds ratio, 1.32), and graft flow (odds ratio, 0.90).

Conclusion: Endoscopic vein harvest reduces leg wound complications compared with open vein harvest without compromising the 6-month patency rate. The overall patency rate depends on target and vein-related variables and patient characteristics rather than the method of vein harvesting.

From the Department of Cardiac Surgery,^a Kaiser Permanente Medical Center, Los Angeles, Calif, and Providence Health System,^b Portland, Ore.

Supported in part by a restricted grant from the Guidant Corporation, Menlo Park, Calif.

Read at the Thirtieth Annual Meeting of The Western Thoracic Surgical Association, Maui, Hawaii, June 23-26, 2004.

Received for publication June 22, 2004; revisions received Aug 19, 2004; accepted for publication Aug 26, 2004.

Address for reprints: Kwok L. Yun, MD, Department of Cardiac Surgery, Southern California Permanente Medical Group, 1526 North Edgemont St, 3rd Floor, Los Angeles, CA 90027 (E-mail: Kwok.L.Yun@kp.org).

J Thorac Cardiovasc Surg 2005;129:496-503

0022-5223/\$30.00

Copyright © 2005 by The American Association for Thoracic Surgery

doi:10.1016/j.jtcvs.2004.08.054

Endoscopic vein harvest (EVH) for coronary bypass grafting (CABG) has been demonstrated to decrease the incidence of leg wound infection and complications¹⁻⁶ compared with the traditional open vein harvest (OVH) technique. However, there continue to be concerns that scope manipulation of the vein might cause trauma to the vessel, which might lead to early stenosis or occlusion. In this regard, EVH has not been shown to compromise the histologic integrity⁷⁻⁹ or functional properties¹⁰⁻¹² of the endothelial, medial, and adventitial layers. Moreover, the short-term 6-month patency rate of EVH veins, as assessed by means of contrast-enhanced electron beam computed tomography,¹³ compares favorably with those historically reported for OVH veins. In a small randomized trial of 35 patients at the University of Montreal,¹⁴ the angiographic 3-month patency rates were similar between the EVH and OVH groups. However, no differences in wound infection rates were observed. In this study we compared the 6-month patency and stenosis rates of vein grafts by using follow-up angiography in patients randomized to either EVH or OVH techniques of saphenous vein harvesting. Multivariable analytic methods were used to determine risk factors for vein graft occlusion and disease, as well as leg wound complications.

Methods

Protocol

Between November 2000 and October 2002, 236 nonconsecutive patients undergoing isolated CABG at Southern California Kaiser Permanente Medical Center in Los Angeles agreed to be prospectively randomized to either endoscopic or open vein harvesting. Exclusion criteria included less than 2 planned vein graft CABGs, emergency operations, history of greater saphenous vein stripping, and redo CABG with previously harvested greater saphenous vein. Those patients deemed not to be EVH candidates because of insufficient subcutaneous tissue to allow insertion of the endoscopic instruments were also excluded. Of the 236 patients, 21 withdrew voluntarily from the study before the operation. Because of the nonbypassable nature of poor targets during the initial assessment on sternotomy, another 15 patients were excluded from randomization because only one vein graft was required. Standard moderate hypothermia ($\approx 32^{\circ}\text{C}$) cardiopulmonary bypass was used in all participants. Beating-heart surgery was not performed to avoid introducing technical factors that might compromise graft patency. All saphenous vein bypasses were fashioned as single grafts with direct proximal aortic anastomoses. Because of relatively less experience with the EVH technique in the lower leg, only greater saphenous veins from one or both thighs were harvested for the purpose of this study. In most cases a sufficient quantity of vein conduits was obtained from one thigh only.

Intraoperatively, the severity of each target vessel disease (A, minimal disease; B, presence of significant atherosclerotic changes; C, severe calcified disease) was recorded. The caliber of the coronary artery was assessed by means of gentle single passes with smooth probes for a short distance to minimize any potential

endothelial injury. The internal diameter of each vein conduit was also measured directly with varying sized probes, and the number of repairs with fine polypropylene sutures was noted. The presence of significant varicosity or phlebotic changes was also documented. Before sternal closure, vein graft flow rates were obtained by using appropriately sized Doppler flow probes (Transonic Systems, Inc, Ithaca, NY).

Glucose levels were maintained at less than 150 mg/dL both intraoperatively and postoperatively according to a strict protocol. All patients were treated with aspirin and statin drug therapy beginning on the first postoperative day. The study was approved by our institution's investigational review board.

Leg Wound Complications

Leg wound healing was evaluated at discharge, at 1 month, and at the 6-month follow-up coronary angiography session. Patients who subsequently refused to have postoperative angiography were assessed by means of chart review, follow-up with the referring cardiologist, and direct telephone contact. Wound complications were defined as drainage (serous, purulent, or sanguinous), seroma or hematoma formation, positive wound culture for bacterial infection, cellulitis requiring antibiotic treatment, hospital readmission, or documented additional clinic or home health nurse visit for wound care.

Six-month Patency Rates

Follow-up angiography of all vein grafts was scheduled at 6 months after the operation by using the standard percutaneous transfemoral technique. The grafts were selectively catheterized and visualized in 4 projections. A bolus of contrast was injected in the ascending aorta to confirm graft occlusions. All angiograms were reviewed independently by 2 interventional cardiologists who were blinded to the vein-harvesting technique. Graft patency was assigned as patent with unimpaired runoff, patent but with disease producing greater than 50% stenosis of the graft, or occluded. When there was a difference of opinion on patency and disease, the worst-case scenario was used in the analysis. The 2 cardiologists were in agreement 97% of the time.

Surgical Techniques

All patients' legs were circumferentially prepped with povidone iodine solution, and the feet were placed in sterile stockinettes. Before vein harvesting, 5000 units of intravenous heparin was administered. EVH was performed with the Vaso-View system (Guidant Corporation, Menlo Park, Calif), which uses CO_2 insufflation for visualization and dissection. One of 3 physician's assistants, each with approximately 300 EVH case experiences, performed the procedure in every operation. Briefly, a 1.5- to 2.0-cm incision was made medially above or below the knee, depending on the length of vein required. Harvesting was directed toward the groin region for as far proximally as possible. Side branches were divided by using bipolar cauterizing scissors or a bisector. A small puncture was made under endoscopic guidance proximally over the saphenous vein, which was then clamped and divided, and the proximal end was ligated. After removing the vein from the leg, side branches were ligated with 4° silk ties. The incisions were closed with absorbable subcutaneous and subcuticular sutures and then wrapped with an elastic Ace bandage.

TABLE 1. Preoperative patient characteristics according to vein harvest method (intention to treat)

	EVH (n = 100)	OVH (n = 100)	P value
Age (y)	64 ± 9	64 ± 9	.82
Sex (female)	7%	7%	1.00
Smoking	70%	64%	.37
Hypertension	76%	74%	.75
Myocardial infarction	48%	44%	.57
Congestive heart failure	13%	14%	.82
Diabetes mellitus	36%	35%	.93
Peripheral vascular disease	9%	8%	.84
Carotid disease	5%	11%	.11
Stroke	6%	6%	1.00
NYHA class			.51
I	66%	64%	
II	20%	26%	
III	13%	8%	
IV	1%	2%	

Values are presented as means ± 1 SD. EVH, Endoscopic vein harvest; OVH, open vein harvest; NYHA, New York Heart Association.

TABLE 2. Wound complications according to vein harvest method

	EVH (n = 7)	OVH (n = 20)
Drainage		
Purulent	2	6
Serous	1	2
Sanguinous	0	0
Hematoma	2	3
Seroma	0	1
Open wound	1	3
Cellulitis	1	13

EVH, Endoscopic vein harvest; OVH, open vein harvest.

In the OVH group a longitudinal incision was made over the course of the saphenous vein starting at the groin region, with the length of incision dependent on the amount of vein required for the operation. Once exposed, side branches were divided between 4° silk ties. The wound was closed in layers by using absorbable sutures and again wrapped with an Ace bandage.

All veins were gently distended manually with autologous heparinized blood. Any avulsed branches were either repaired by carefully approximating the adventitial layer with 7° polypropylene sutures or excluded if fortuitously located between vein graft segments. The veins were then placed in a heparinized blood solution containing papavarine until ready for use.

Statistical Analysis

Continuous data are expressed as the mean ± SD unless specified otherwise. Demographic characteristics and intraoperative variables of each surgical group were compared by using a contingency table for categorical variables and analysis of variance for

TABLE 3. Conventional logistic regression for leg wound infection

Risk factor	Odds ratio (95% confidence interval)
Age	0.99 (0.95-1.04)
Sex (female)	1.82 (0.47-7.00)
Hypertension	0.77 (0.32-1.90)
Myocardial infarction	0.78 (0.34-1.78)
Congestive heart failure	1.23 (0.39-3.92)
Diabetes mellitus	0.47 (0.18-1.23)
Carotid disease	0.40 (0.05-3.14)
Stroke	0.56 (0.07-4.52)
Peripheral vascular disease	0.82 (0.18-3.81)
Smoking	0.83 (0.36-1.92)
EVH (vs OVH)	0.33 (0.13-0.82)

Two early perioperative deaths were excluded. EVH, Endoscopic vein harvest; OVH, open vein harvest.

continuous variables. The following patient characteristics were entered into a conventional multivariable logistic regression to determine the predictors of leg wound complications: vein harvest method, age, sex, hypertension, history of myocardial infarction, congestive heart failure, diabetes mellitus, peripheral vascular disease, cerebrovascular disease, previous stroke, and tobacco use. In addition, the following target vessel and vein variables, along with the above factors, were entered into an ordinal hierarchical logistic regression (with robust variance estimators to accommodate the lack of statistical independence caused by clustering of grafts within patients) to determine the predictors of graft occlusion and disease: severity of target vessel disease, size of target vessel, territory of target vessel (right, left anterior descending, and circumflex coronary artery systems), vein conduit size, vein quality, graft flow, and vein graft repair. The outcomes in the regression were ordered as patent, patent but significantly diseased, and occluded. Results are presented by using odds ratios (ORs) with 95% confidence intervals (CIs).

Results

Patients undergoing EVH and OVH had very similar clinical profiles (Table 1). Carotid stenosis was more prevalent in the OVH group (11% vs 5%), but this did not achieve statistical significance. Most patients were in New York Heart Association classes I and II with hypertension and smoking history.

There were 2 perioperative deaths, both in the EVH group. One patient died on postoperative day 13 as a result of complications of stroke, and the other died on postoperative day 12 as a result of respiratory failure and sepsis. These 2 patients were excluded from the leg wound complication analysis. One patient in the EVH cohort died of esophageal carcinoma 6 weeks after the operation.

There were 3 conversions from EVH to OVH. The vein was too superficial to allow insertion of the endoscopic dissecting instrument in 2 cases and deemed to be too small

TABLE 4. Coronary artery size and disease, vein conduit diameter and quality, and graft flow according to vein harvest method

	EVH (n = 166)	OVH (n = 170)
Coronary artery size (mm)	1.4 ± 0.3	1.4 ± 0.2
Coronary artery disease grade		
A	60 (36%)	70 (41%)
B	78 (47%)	67 (39%)
C	28 (17%)	33 (19%)
Vein graft internal diameter (mm)	4.0 ± 0.9	3.9 ± 0.9
Vein graft grade		
A	133 (80%)	138 (81%)
B	33 (20%)	32 (19%)
Graft flow (mL/min)	91 ± 47	91 ± 46

Values are presented as means ± SD. EVH, Endoscopic vein harvest; OVH, open vein harvest. Coronary artery disease grade: A, minimal disease; B, atherosclerotic disease; C, severely calcified disease. Vein graft grade: A, good quality conduit; B, presence of significant varicosity or phlebitic changes.

TABLE 5. Graft patency and disease according to vein harvest method

	EVH (n = 166)	OVH (n = 170)
Patent	113 (68%)	119 (70%)
Significant disease	17 (10%)	21 (12%)
Occlusion	36 (22%)	30 (18%)

$P = .584$. EVH, Endoscopic vein harvest; OVH, open vein harvest.

to allow safe endoscopic harvesting in the third. Although the intent-to-treat was EVH, these patients were counted in the OVH group from the leg wound standpoint because of the fact that the actual method of vein harvest required a conventional longitudinal open incision.

Wound complications occurred in 7.4% (7/95) of patients having EVH versus 19.4% (20/103) of those having the traditional OVH technique ($P = .014$). The types of wound complications in each group are shown in the Table 2. Most of the wound complications in the EVH cohort resolved with outpatient oral antibiotics. One patient required wound debridement and packing. On the other hand, there were more cases of periwound cellulitis and purulent discharge with 3 open wounds in the OVH group. On multivariable logistic regression (Table 3), EVH (OR, 0.33; 95% CI, 0.13-0.82; $P = .017$) was found to be the only factor (protective vs OVH) affecting wound complications.

Twenty-four and 29 patients in the EVH and OVH groups, respectively, refused the follow-up 6-month vein graft angiography. Therefore a total of 144 angiograms (73 EVH and 71 OVH) and 336 vein grafts (166 EVH and 170

TABLE 6. Graft patency and disease according to territory of revascularization

	Diagonal	Circumflex, PLCX, Ramus, and OM	RCA, PLRCA, and PDA
Patent	40 (59%)	96 (70%)	96 (74%)
Significant disease	10 (15%)	13 (9%)	15 (11%)
Occlusion	18 (26%)	29 (21%)	19 (15%)
Total	68 (100%)	138 (100%)	130 (100%)

$P = .197$. PLCX, Posterolateral circumflex artery; OM, obtuse marginal artery; RCA, right coronary artery; PLRCA, posterolateral right coronary artery; PDA, posterior descending artery.

TABLE 7. Multivariable ordinal hierarchic logistic regression for vein graft occlusion and disease

Risk factor	Odds ratio (95% CI)	P value
Vein graft size	1.32 (0.99-1.77)	.061
Congestive heart failure	2.87 (1.34-6.17)	.007
Vein graft flow	0.90 (0.85-0.97)	.003
Diagonal territory	1.76 (1.06-2.95)	.030
EVH vs OVH	1.15 (0.65-2.05)	.632

CI, Confidence interval; EVH, endoscopic vein harvest; OVH, open vein harvest.

OVH) were available for analysis. Because none of the 3 patients who had conversion from EVH to OVH underwent cardiac catheterization at 6 months, the analyses based on intent-to-treat or actual treatment were the same.

There were more total vein repairs in the EVH group (28 vs 5) involving 24 grafts in 18 patients. The number of vein grafts per patient was similar between the 2 cohorts (2.27 [EVH] vs 2.39 [OVH]). In both groups the distribution of the target vessels was approximately 40% each in the circumflex and right coronary system. About 20% of vein grafts were placed to diagonal arteries. Ninety-nine percent of patients had the left anterior descending artery grafted with the left internal thoracic artery. As shown in Table 4, no significant differences were detected in the severity of target disease and size, vein graft size and quality, and graft flow rates between the 2 groups.

One patient with OVH had recurrent angina at 2 months, requiring percutaneous catheter stenting of a stenosed obtuse marginal vein graft, which subsequently occluded on repeat angiography at 4 months. The overall occlusion rates after 6 months were 21.7% for EVH and 17.6% for OVH (Table 5). However, there was evidence of significant disease (>50% stenosis) in an additional 10.2% of EVH grafts and 12.4% of OVH grafts. There were no differences in the 6-month occlusion and disease rates between EVH and OVH, as determined by means of univariate analysis ($P =$

.584). The distribution of graft occlusion among the 2 cohorts is tabulated in Table 6. By means of multivariable logistic regression, EVH was not found to be a significant risk factor for graft occlusion or disease. The adjusted OR was 1.15 (95% CI, 0.65-2.05; $P = .594$). As shown in Table 7, significant predictors for vein graft occlusion and disease were congestive heart failure (OR, 2.87; 95% CI, 1.34-6.17), vein graft to the diagonal territory (OR, 1.76; 95% CI, 0.85-0.97), and larger vein graft size (OR, 1.32; 95% CI, 0.99-1.77). Conversely, higher vein graft flow had a protective effect (OR, 0.90; 95% CI, 0.85-0.97).

Discussion

Despite the increasing use of arterial grafts for CABG because of more favorable long-term patency, the greater saphenous vein continues to be the most commonly used conduit in multivessel bypass operations. However, the traditional method of vein harvesting with an open longitudinal incision along the course of the greater saphenous vein has been associated with significant complications, including dehiscence, cellulitis, lymphangitis, drainage, edema, pain, hematomas, skin necrosis, and infection. These, in turn, lead to delayed wound healing, increased length of hospital stay, higher cost of postoperative care, and greater patient discomfort. Leg wound complications from OVH have been reported to be as high as 24.3% in a large series of 1047 patients undergoing CABG at the Spartanburg Regional Medical Center in South Carolina.¹⁵ Given the current trend toward less invasive cardiothoracic surgery, minimally invasive methods of vein harvesting have been developed and refined in an attempt to reduce the morbidity associated with OVH. However, endothelial dysfunction has been reported with traction injury during minimally invasive vein harvesting with bridged incisions.¹⁶ Because of concerns of similar possible forces causing vein trauma during EVH that might lead to early occlusion, we compared the angiographic 6-month patency and significant stenosis rates of vein grafts harvested by using open versus endoscopic techniques in a prospective randomized trial.

In this study leg wound-related complications were significantly reduced with EVH (7.4% vs 19.4%), which is consistent with previous reports.¹⁻⁶ Furthermore, most of the complications within the EVH group were relatively minor compared with those in the OVH cohort. By means of multivariable analysis, EVH was found to be the only significant predictor of leg wound complications, with a relative risk reduction of 67% (OR, 0.33). This is in concordance with findings of other investigators.^{2,5,6} In a meta-analysis of 14 randomized trials comparing minimally invasive vein harvest techniques with the conventional open technique with regard to leg wound infection, Athanasiou and associates¹⁷ reported a significantly lower rate in the minimally invasive vein harvest group (OR, 0.22; 95% CI,

0.14-0.34). In a subgroup analysis of the minimally invasive cohort with EVH, the OR of leg wound infections versus OVH was almost identical to that of the minimally invasive group as a whole. Surprisingly, diabetes did not emerge as a significant risk factor in this study. The fact that only thigh veins were harvested might have reduced the number of wound complications because diabetic vasculopathy is largely a small-vessel disease affecting wound healing more below the knees.

In the present trial the overall 6-month vein graft occlusion rate was 20%, with an additional 11.5% demonstrating stenotic regions of greater than 50%. No significant patency differences were noted between EVH and OVH veins. These figures are similar to those reported by Perrault and coworkers¹⁴ in a smaller prospective randomized trial during the same time period. In that study the occlusion rates at 3 months were slightly lower at 14.8% and 15.6% in the OVH and EVH groups, respectively. However, only 59 vein grafts were examined versus 336 in this study. This might be an insufficient sample size because no differences in wound complications were ascertained. Furthermore, occlusion data from angiography at 3 months might not be representative of that obtained at 6 months. This is supported by the fact that an additional 35.5% of grafts showed the presence of greater than 25% stenosis.

The reported 1-year vein graft occlusion rate with the OVH technique ranges from approximately 5% to 30%,¹⁸⁻²³ with multiple determining factors. In the most contemporary comprehensive series from the National Defence Medical Centre and University of Ottawa Heart Institute,²¹ the angiographic vein graft occlusion rate was 12% early and 19% (of 3706 grafts examined) at 1 year. Of the patent grafts, an additional 6% (5% of all grafts) had significant stenosis, reducing the caliber of the graft to less than 50% of the grafted coronary artery. This is consistent with our finding of a 20% occlusion rate at 6 months. Nevertheless, these figures were rather disappointing and might reflect the results of bypassing smaller vessels with more distal disease because of the advent of aggressive multivessel stenting. This is supported by the fact that the number of percutaneous catheter-based interventions during the study period at our institution increased by 22% per year, whereas isolated CABG decreased by 15% per year.

In this study multivariable ordinal hierarchic logistic regression was used to model not only the variation at both the patient and graft level but also the outcome of multiple categories. By means of this analysis, significant predictors of vein graft occlusion and disease were congestive heart failure, grafting to diagonal arteries, larger vein graft size, and lower graft flow. In agreement with other reports,^{18,22,24,25} traditional cardiovascular risk factors, such as hypertension, sex, diabetes mellitus, and previous myocardial infarction, did not affect graft patency and disease.

Congestive heart failure might indicate large areas of infarcted myocardium with poor distal runoff. Concordantly, Shah and colleagues²⁴ found that ejection fraction significantly reduced vein graft patency in 1402 symptomatic patients operated on between 1977 and 1999 at the Austin Hospital in Melbourne, Victoria, Australia. Similar to other studies,^{18,22} higher graft flows conferred a protective effect against graft occlusion and might reflect a combination of larger target diameter, less distal coronary disease, and greater number of runoff branches. This is supported by the fact that the severity of target disease becomes a significant predictor for graft occlusion, with an OR of 1.9 if flow is eliminated from the multivariable analysis. Independently, patency is inversely related to vein conduit diameter, as published previously.²⁴ The reason for this is not clear but might be related to lower velocity flow and greater graft-to-target mismatch with larger and thicker vein grafts. Because there is a preferential harvesting of thigh veins over calf veins with EVH because of its relatively greater ease, this might be one of the drawbacks of the technique.

Whether target territory is an important determinant of vein graft patency is controversial. Although Shah and coworkers²⁴ reported vein graft bypasses to the diagonal artery had the best long-term patency after those to the left anterior descending artery, Bjork and associates¹⁸ did not find differences in the early or 1-year patency of vein grafts to the various territories being revascularized. In this study grafting of the diagonal artery was associated with higher occlusion and disease development at 6 months. The reason for these different findings is unclear. However, diagonal artery targets are usually smaller and supply a smaller area of myocardium compared with other vessels in the circumflex and right coronary systems.

There are several limitations to the study that should be addressed. First, because the current method of EVH requires dissection close to the adventitial layer, the surrounding tissue was removed in both groups. The preservation of this fatty pedicle might be important as a natural external support, thereby protecting the vein against the effects of aortic shear stress,²⁶ and has been associated with improved graft patency at 18 months.²² Whether EVH techniques need to be modified to incorporate this no-touch component remains to be defined by future prospective randomized studies.

Second, the list of potential factors contributing to vein graft occlusion or disease was far from exhaustive because our focus was on the most relevant clinical variables. Additionally, several risk factors, such as renal insufficiency and chronic obstructive pulmonary disease, were not included in the analysis because of the small number of patients possessing these characteristics.

Third, the results of EVH in this study are based on more than 300 case experiences for each physician's assistant and

might not reflect that during the learning phase of this technique. Therefore generalization of the findings to other institutions might not be applicable.

Finally, despite the fact that this is the largest prospective randomized angiographic trial comparing EVH with OVH, the sample size might not be adequate because of incomplete angiographic follow-up to detect differences in the patency rates between the 2 methods of vein harvesting. However, an OR of 1.15 (closed to unity) with a relatively small 95% CI supports the reliability of the results.

In summary, EVH reduces the leg wound complications associated with the traditional open harvesting technique without compromising vein graft patency. The overall patency rate depends on target and vein-related variables and patient characteristics rather than the method of vein harvesting.

References

- Kiai B, Moon BC, Massel D, Langlois Y, Austin TW, Willoughby A, 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;123:204-12.
- Bitondo JM, Daggett WM, Torchiana DF, Akins CW, Hilgenberg AD, Vlahakes GJ, et al. Endoscopic versus open saphenous vein harvest: a comparison of postoperative wound complications. *Ann Thorac Surg.* 2002;73:523-8.
- Carpino PA, Khabbaz KR, Bojar RM, Rastegar H, Warner KG, Murphy RE, et al. Clinical benefits of endoscopic vein harvesting in patients with risk factors for saphenectomy wound infections undergoing coronary artery bypass grafting. *J Thorac Cardiovasc Surg.* 2002;119:69-76.
- Puskas JD, Wright CE, Miller PK, Anderson TE, Gott JP, Brown WM III, et al. A randomized trial of endoscopic versus open saphenous vein harvest in coronary bypass surgery. *Ann Thorac Surg.* 1999;68:1509-12.
- Crouch JD, O'Hair DP, Keuler JP, Barragry TP, Werner PH, Kleinman LH. Open versus endoscopic saphenous vein harvesting: wound complications and vein quality. *Ann Thorac Surg.* 1999;68:1513-6.
- Allen KB, Griffith GL, Heimansohn DA, Robison RJ, Matheny RG, Schier JJ, et al. Endoscopic versus traditional saphenous vein harvesting: a prospective, randomized trial. *Ann Thorac Surg.* 1998;66:26-32.
- Meyer DM, Rogers TE, Jessen ME, Estrera AS, Chin AK. Histologic evidence of the safety of endoscopic saphenous vein graft preparation. *Ann Thorac Surg.* 2000;70:487-91.
- Griffith GL, Allen KB, Waller BF, Heimansohn DA, Robison RJ, Schier JJ, et al. Endoscopic and traditional saphenous vein harvest: a histologic comparison. *Ann Thorac Surg.* 2000;69:520-3.
- Fabricius AM, Diegeler A, Doll N, Weidenbach H, Mohr FW. Minimally invasive saphenous vein harvesting techniques: morphology and postoperative outcome. *Ann Thorac Surg.* 2000;70:473-8.
- Rinia-Feenstra M, Stooker W, de Graaf R, Kloeck JJ, Pfaffendorf M, de Mol BAJM, et al. Functional properties of the saphenous vein harvested by minimally invasive techniques. *Ann Thorac Surg.* 2000;69:1116-20.
- Cable DG, Dearani JA, Pfeifer EA, Daly RC, Schaff HV. Minimally invasive saphenous vein harvesting: endothelial integrity and early clinical results. *Ann Thorac Surg.* 1998;66:139-43.
- Black EA, Guzik TJ, West NEJ, Campbell K, Pillai R, Ratnatunga C, et al. Minimally invasive saphenous vein harvesting: effects on endothelial and smooth muscle function. *Ann Thorac Surg.* 2001;71:1503-7.
- Davis Z, Gaber D, Clark S, Roth H, Bufalino V, Budoff MJ, et al. Long-term patency of coronary grafts with endoscopically harvested saphenous veins determined by contrast-enhanced electron beam computed tomography. *J Thorac Cardiovasc Surg.* 2004;127:823-8.
- Perrault LP, Jeanmart H, Bilodeau L, Lesperance J, Tanguay JF, Bouchard D, et al. Early quantitative coronary angiography of saphenous

- nous vein grafts for coronary artery bypass grafting harvested by means of open versus endoscopic saphenectomy: a prospective randomized trial. *J Thorac Cardiovasc Surg.* 2004;127:1402-7.
15. Utley JR, Thomason ME, Wallace DJ, Mutch DW, Staton L, Brown V, et al. Preoperative correlates of impaired wound healing after saphenous vein excision. *J Thorac Cardiovasc Surg.* 1989;98:147-9.
 16. Cook RC, Crowley CM, Hayden R, Gao M, Fedoruk L, Lichtenstein SV, et al. Traction injury during minimally invasive harvesting of the saphenous vein is associated with impaired endothelial function. *J Thorac Cardiovasc Surg.* 2004;127:65-71.
 17. Athanasiou T, Aziz O, Skapinakis P, Perunovic B, Hart J, Crossman MC, et al. Leg wound infection after coronary artery bypass grafting: a meta-analysis comparing minimally invasive versus conventional vein harvesting. *Ann Thorac Surg.* 2003;76:2141-6.
 18. Bjork VO, Ekestrom S, Henze A, Ivert T, Landou C. Early and late patency of aortocoronary vein grafts. *Scand J Thorac Cardiovasc Surg.* 1981;15:11-21.
 19. Goldman S, Copeland J, Moritz T, Henderson W, Zadina K, Ovitt T, et al. Saphenous vein graft patency 1 year after coronary artery bypass surgery and effects of antiplatelet therapy: results of a Veterans Administration Cooperative Study. *Circulation.* 1989;80:1990-7.
 20. FitzGibbon GM, Leach AJ, Keon WJ, Burton JR, Kafka HP. Coronary bypass graft fate: angiographic study of 1,179 vein grafts early, one year, and five years after operation. *J Thorac Cardiovasc Surg.* 1986;91:773-8.
 21. Fitzgibbon GM, Kafka HP, Leach AJ, Keon WJ, Hooper GD, Burton JR. Coronary bypass graft fate and patient outcome: angiographic follow-up of 5,065 grafts related to survival and reoperation in 1,388 patients during 25 years. *J Am Coll Cardiol.* 1996;28:616-26.
 22. Souza DSR, Dashwood MR, Tsui JCS, Filbey D, Bodin L, Johansson B, et al. Improved patency in vein grafts harvested with surrounding tissue: results of a randomized study using three harvesting techniques. *Ann Thorac Surg.* 2002;73:1189-95.
 23. Puskas JD, Williams WH, Mahoney EM, Huber PR, Block PC, Duke PG, et al. Off-pump vs. conventional coronary artery bypass grafting: early and 1-year graft patency, cost, and quality-of-life outcomes. A randomized trial. *JAMA.* 2004;291:1841-9.
 24. Shah PJ, Gordon I, Fuller J, Seevanayagam S, Rosalion A, Tatoulis J, et al. Factors affecting saphenous vein graft patency: clinical and angiographic study in 1402 symptomatic patients operated on between 1977 and 1999. *J Thorac Cardiovasc Surg.* 2003;126:1972-7.
 25. Korpilahti K, Engblom E, Syvanne M, Hamalainen H, Puukka P, Vantinen E, et al. Angiographic changes in saphenous vein grafts and atherosclerosis risk factors. A 5-year study with serial measurements of serum lipids and lipoproteins. *Scand Cardiovasc J.* 1998;32:343-51.
 26. Tsui JCS, Souza DR, Filbey D, Bomfim V, Dashwood MR. Preserved endothelial integrity and nitric oxide synthase in saphenous vein graft harvested by a "no-touch" technique. *Br J Surg.* 2001;88:1209-15.

Discussion

Dr James Fann (Stanford, Calif). The use of EVH has become more prevalent, mainly as a result of reports of decreased wound infections and improved wound healing, with consequent financial implications. As you point out, one is always concerned about the trauma to the vein from this procedure. Notwithstanding histologic reports, patency rates on the basis of follow-up coronary angiography are what we as surgeons have always wanted to process and consider to be the gold standard. Therefore, I congratulate you and your colleagues on this intriguing prospective randomized trial with 6-month patency data of those undergoing EVH versus OVH.

I have some specific questions the data presented. In the exclusion criteria, what would you consider to be insufficient subcutaneous tissue to allow for insertion of endoscopic instruments, especially because thigh veins were preferentially used in your report, and how do you evaluate these patients preoperatively? I ask this because there were 3 conversions from endoscopic tech-

nique to that of the open or conventional approach as a result of overly superficial location of the vein.

Also, I worry about vein repairs in terms of patency, and it must be emphasized that the number of vein repairs in the endoscopic group is substantially higher than that in the open group.

As much as we hate to admit it, early graft occlusion occurs, and on the basis of this and other recent studies, it appears to happen more often than we wish. I think this finding is another important piece of information from your study. Given that the patency rate in the endoscopic group appeared worse, do you think the difference in the occlusion rates at 6 months reflects a β error, and had there been more patients, would the endoscopic approach have been statistically worse?

Finally, what was the outcome of patients who had graft stenosis or occlusions? Were these patients readmitted to the hospital? Did they sustain myocardial infarctions?

Again, this article answers some highly relevant issues in coronary artery surgery, and I thank the Association for the opportunity to discuss it.

Dr Yun. Thank you, Dr Fann, for your kind comments and insightful critique.

To answer your first question, there are some rare patients who have basically no subcutaneous tissue between the vein and the dermis layer of the skin. This makes the vein relatively adherent, and we do not try to introduce the endoscopic instruments in these patients. Having said that, it takes very little subcutaneous tissue to dissect the veins with the nose cone of the endoscope. Our physician's assistants are now very efficient at harvesting the vein from the lower leg, meaning the calf. However, we usually do not know whether there is adequate subcutaneous tissue until the skin incision is made and the vein is isolated. Because we randomized patients before skin incision in this study, there were 2 patients who had their legs opened and were considered conversions, although the endoscopic instruments were never opened. Preoperatively, it is rare in this subset of patients to have the vein visible around the knee, which tells us that the vein is superficial, but these are the only patients who were excluded preoperatively on the basis of this criterion.

Regarding the vein repairs, it is always a concern. Although there were more total vein repairs in the endoscopic vein-harvesting group, 28 versus 5, this was still only 1 repair for every 8 graft segments. Most of these were avulsions of small adventitial branches and were eliminated whenever possible.

In terms of graft patency, the study was originally designed to have a statistical power of 80% at an α level of .05 to detect a difference as small as 5% between the 2 groups in either direction. Unfortunately, we were not able to achieve this goal because approximately 30% of patients refused follow-up angiography. Whether we have committed a β error in this situation is unclear, but my biostatistician tells me that performing a post hoc power calculation on the basis of observed effects is pointless because it has a 1:1 relationship with the P value. In other words, a clinical study with negative findings will always result in a low post hoc statistical power.

The differences between the 2 groups that you alluded to became even less if patent, but stenotic vein grafts were also included in our analysis. Furthermore, because we obtained, on multivariable analysis, an OR of only 1.15, being very close to 1,

with a relatively small 95% CI as opposed to a high OR with a large CI, we are reasonably sure of the reliability of our data.

In answer to your last question regarding what happened to these patients, only one patient in the open group had angina 2 months after the operation. This patient underwent stenting of a stenosed obtuse marginal graft, which subsequently occluded at 4 months. The rest of the patients who were found to have either occlusion or stenotic grafts at the time of follow-up angiography were asymptomatic. Of these patients, most were treated medically. Four underwent stenting of a stenotic graft, and 4 had percutaneous catheter-based interventions to the native vessels.

Dr Vaughn Starnes (*Los Angeles, Calif*). Just a couple of quick technical questions, Kwok, if you could. First, do you heparinize your patients before beginning the endoscopic vein harvesting?

Dr Yun. Yes.

Dr Starnes. What do you do if the segment looks burned but does not leak? Do you resect that? We found that some of our pulmonary arteries are excellent, with no burn on the vein. Occasionally, we get a vein brought up, and it does not leak, but there is obviously a burned area where there is a large branch where they tried to bovie it off.

Dr Yun. In terms of the anticoagulation, initially, before this study, we were concerned because sometimes we would see little strands of fibrin in the vein, and that was what prompted our study.

Since that time, we have given about 5000 units of heparin before the endoscopic instruments are introduced, and that is what we did for this study.

In terms of burn marks, those are concerns, and we do try to eliminate them as much as possible, especially at big branches, where it looks like it is burned right down to the base.

Dr Thomas Burden (*Stanford, Calif*). Any flow-probe information on any of these patients? Flow probes are being more widely used by more of us as time goes by, especially if we are using beating-heart technologies. Have any of these patients had flow-probe analysis along with your angiography?

Dr Yun. Yes, all of them have flow-probe measurements, and we found that the high flow-probe rate had an independent protective effect on vein graft closure.

Dr Burden. Do you know what that number is? Do you depict that as greater than a 30-, 40-, 50-, or 70 mL flow?

Dr Yun. It was done in increments of 10 mL/min. I do not know whether there was an exact cutoff point at which it became significantly better.

Dr Burden. And there was no correlation between flow and patency at 6 months?

Dr Yun. There was.

Dr Burden. There was?

Dr Yun. Yes, on multivariable analysis, the higher the flow rate, the higher the patency rate.

The Journal of Thoracic and Cardiovascular Surgery Conflict of Interest Policy

To assure fairness to authors submitting work for consideration in *The Journal of Thoracic and Cardiovascular Surgery*, a mechanism exists for managing conflicts of interest. The editor and each of the section editors complete a "Conflict of Interest" form that identifies any and all relationships with commercial and other academic entities. When the editor has a potential conflict because of a relationship with another entity or author, the editor appoints an alternate editor from among the section editors or editorial board members who assumes the entire responsibility for final decisions on the manuscript in question. The editor does not read the reviews that are submitted nor engage in discussing the manuscript prior to the final decision. When the conflict of interest involves a section editor, a "guest section editor" is appointed who fills the role normally played by the conflicted section editor. All members of the editorial board and reviewers are asked to indicate any conflict of interest when they agree to review a manuscript.