A prospective randomized trial of endoscopic versus conventional harvesting of the saphenous vein in coronary artery bypass surgery

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Objectives: Our objectives were (1) to determine whether minimally invasive endoscopic harvesting of the saphenous vein reduces morbidity due to postoperative wound infection and pain with improved cosmetic results and mobilization as compared with the conventional technique and (2) to compare the histologic properties of the saphenous veins harvested conventionally and endoscopically.

Methods: One hundred forty-four patients undergoing coronary artery bypass grafting were randomized to have vein harvesting performed by either the conventional (n = 72) or an endoscopic (n = 72) minimally invasive technique.

Results: Vein harvest time (open leg wound time) was significantly reduced in the endoscopic group (27.6 vs 64.4 minutes; $P < .0001$). The rate of leg wound infection was significantly reduced in the endoscopic group (4.3%) as compared with the conventional group (24.6%), a relative risk reduction of 83% (95% confidence interval: 36%-129%; $P = .0006$). The majority of infections (84.2%) occurred after hospital discharge. Postoperative leg pain, mobilization, and overall patient satisfaction were also significantly improved in the endoscopic group. Double blinded histologic assessment of harvested vein (n = 28) showed no evidence of any clinically important significant damage to the specimens in either group.

Conclusions: In this prospective randomized trial, endoscopic harvesting of the saphenous vein significantly reduced postoperative leg wound complications, including infection, and improved patient satisfaction as compared with the conventional harvesting technique. There were no significant histologic differences between the conventional and endoscopically harvested saphenous veins.

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Coronary artery bypass surgery is one of the most common elective surgical procedures performed. As coronary artery bypass surgery enters its fourth decade of use, minimally invasive techniques are increasingly being investigated. Although arterial conduits are preferred because of more favorable long-term patency and outcome data, the greater saphenous vein continues to be the most com-

monly used bypass conduit in multivessel coronary artery bypass grafting. Nonetheless, the morbidity associated with conventional vein harvesting potentially includes postoperative pain, leg edema, and wound complications such as wound breakdown, cellulitis, lymphangitis, excessive wound drainage, fat necrosis, and delayed healing. Rates of these complications vary among published reports, with an incidence as high as 24%.¹⁻⁷ More recently, reports have shown a decrease in the morbidity of wound complication by harvesting the saphenous vein endoscopically.⁸⁻¹¹

However, there is no consensus because other studies demonstrating no difference between conventional and endoscopic saphenous harvesting have also been reported.¹²

In the era of fiscal restraint, endoscopic saphenous vein harvesting has been reported to be associated with higher up-front medical costs, and its use, as a result, may be justifiable only among specific and high-risk cases.^{12,13} The short- and long-term benefits of this new technique remain to be established. The goal of this prospective randomized trial is to determine whether minimally invasive endoscopic saphenous vein harvesting is associated with decreased postoperative morbidity while minimizing trauma to the vein harvested.

Methods

Study Conduct

Between May 25, 1998, and October 27, 1999, 145 patients requiring coronary artery bypass grafting were prospectively randomized. One patient withdrew from the study before the operation and was excluded. When designed, the study was intended to be performed at two centers. However, because only 7 patients were enrolled at one center, the decision was made, without looking at the outcome data, to exclude those patients. Therefore, 144 patients were randomly allocated to one of two groups: conventional ($n = 72$), in which the greater saphenous vein was harvested through a conventional longitudinal incision, and endoscopic ($n = 72$), in which the saphenous vein was harvested with the endoscope. The study was approved by the University of Western Ontario Ethics Review Board. Before randomization, written informed consent was obtained from all patients.

Inclusion criteria.

Eligible patients were more than 18 years of age and had coronary artery disease necessitating elective, urgent, or emergency coronary artery revascularization. The intention for all the patients, based on the patient's cardiac catheterization, was to use the saphenous vein for the revascularization.

Exclusion criteria.

Exclusion criteria included the patient's refusal to have surgery, inability to give informed consent, and documented varicosities of the long saphenous vein.

Obesity was defined as presence of excess body fat, which is correlated by the body mass index (body weight [kilograms]/height [meters squared]). A body mass index greater than 30 kg/m² was defined as obesity on the basis of the World Health Organization criterion. *Peripheral vascular disease* was defined as

a history of intermittent claudication. *Hypercholesterolemia* was defined as total cholesterol or low-density lipoprotein cholesterol greater than the 90th percentile of the general population or use of cholesterol-lowering medications. *Diabetes* was defined as a history of diabetes mellitus or treatment with either oral hypoglycemic agents or insulin. *Chronic renal failure* was defined as a decline in renal function sufficient to cause retention of nitrogenous wastes or requiring hemodialysis or peritoneal dialysis.

Surgical Techniques

Patients in the conventional group had their greater saphenous vein harvested by means of the open technique with a traditional longitudinal incision. This was performed by a physician's assistant preparing the legs circumferentially and making an incision from the groin to the knee and, if necessary, to below the knee, exposing the entire vein by means of a continuous incision. The vein was then dissected with a combination of Metzenbaum scissors and electrocautery. The vein branches were clipped proximally and distally. Once fully dissected, the vein was removed. Hemostasis was achieved with electrocautery and surgical clips. The wound was closed in a one- or two-layer fashion with absorbable sutures. The skin layer was approximated with surgical staples. The leg was then immediately wrapped with a sterile elastic bandage and remained wrapped for 72 hours.

Patients in the endoscopic group underwent endoscopic saphenous vein harvesting. All the endoscopic harvesting was performed by the attending surgeon or surgical assistant, both of whom were experienced with the procedure, having performed over 30 cases before the study. The equipment used included the endoscopic vein harvest system (Ethicon Endo-Surgery, Cincinnati, Ohio) and the 5-mm, 30° angled endoscope (Karl Storz Endoscopy America Inc, Culver City, Calif). The legs were circumferentially prepared. A 2- to 3-cm transverse incision was made on the medial aspect of the leg above the knee. After the saphenous vein was identified with the endoscopic dissector (Ethicon Endo-Surgery), a plane anterior to the saphenous vein was dissected. After the desired length of the saphenous vein was exposed, the vein was circumferentially dissected and isolated from the surrounding tissue with the C-ring dissector (Ethicon Endo-Surgery). Side branches were identified, clipped, and cut with both the endoscopic clip applicator and scissors. In most instances a single incision was sufficient for the length of vein required from the thigh. If more length was required and the dissection had to be extended to the groin, a second incision was then made on the middle aspect of the thigh to allow the endoscopic dissector to reach the groin. On occasion, it was necessary to go below the knee with the endoscopic dissector to harvest an even longer length of vein. One to two incisions were needed on average. When the dissection was completed and the adequate length of vein was obtained, the proximal and distal aspects of the vein were clipped with the endoscopic clip applicator and the vein was removed. After adequate hemostasis had been confirmed, the incisions were immediately closed with absorbable sutures and the skin approximated with surgical staples. The leg was then immediately wrapped with a sterile elastic bandage before protamine was given and occasionally before the patient was systemically heparinized. The leg remained wrapped for 72 hours.

TABLE 1. Patient demographics*

	Conventional method (n = 72)	Endoscopic method (n = 72)
Age†	64.3 ± 9.9	62.5 ± 9.4
Male	61 (85%)	57 (79%)
Arthritis	10 (13.9%)	9 (12.5%)
Hypertension	43 (59.7%)	41 (56.9%)
Hypercholesterolemia	46 (63.9%)	44 (62.5%)
Smoker	13 (18.1%)	17 (23.6%)
Diabetes	18 (25%)	21 (29.2%)
Obesity	14 (19.4%)	14 (19.4%)
Liver failure	0 (0%)	1 (1.4%)
Renal failure	3 (4.2%)	1 (1.4%)
Peripheral vascular disease	5 (6.9%)	6 (8.3%)
Skin disorder	3 (4.2%)	4 (5.6%)
Gout	5 (6.9%)	3 (4.2%)
Triage		
Elective	29 (40.3%)	35 (48.6%)
Urgent	3 (4.2%)	7 (9.7%)
Emergency	33 (45.8%)	27 (37.5%)

*No significant differences between groups.

†Expressed as mean ± SD; all other data are presented as raw counts and percentages (in parentheses).

Outcome Events and Assessment

All patients received prophylactic perioperative intravenous antibiotic therapy with either cefazolin 1.0 g or vancomycin 500 mg. Leg wounds were assessed daily by a study nurse. At discharge, patients were sent home with a record sheet. They were instructed to record any symptoms of pain, discharge, and cellulitis and told to seek medical attention if symptoms were of concern. Telephone follow-up was made 1 week after discharge by the study nurse. At 6 to 8 weeks, a postoperative clinic assessment was arranged to further evaluate the patients. If necessary, additional reports were obtained from the family physician, referring physician, and other health care workers.

The *primary outcome event* was the rate of leg wound infection at 6 weeks. *Wound infection* was defined by the National Nosocomial Infection Surveillance as (1) evidence of purulent discharge with or without laboratory confirmation; (2) presence of pain, swelling, redness, or heat plus the need to open the superficial incision; (3) dehiscence or the need to open the wound when the patient has a temperature greater than 38.0°C, pain, or tenderness; or (4) abscess on direct examination or by histologic or radiologic examination. In addition, institutional microbiology logs and cardiac surgery ward wound infection logs were reviewed to detect additional potential wound infections. Wound infection was confirmed by bedside examination and review of inpatient and outpatient medical records.

Secondary outcome events included assessment of wound pain, mobilization, patient satisfaction, length of hospitalization, and histologic integrity of harvested saphenous vein. A 10-cm visual analog scale from 0 to 10 was used by the patient to record the

amount of pain experienced at the wound harvest site. The sensitivity of this method of assessment has been previously reported.^{14,15} The scale had reference points on either end of a 10-cm horizontal line with a score of 0 on the left end (representing no pain) and a score of 10 on the right end (representing severe pain). The pain scale was recorded and compared starting on postoperative day 1 and continued on a daily basis until discharge. Pain assessment was continued by the patient as an outpatient on a weekly basis until the time of the final clinic visit at 6 to 8 weeks. The use of analgesics was also recorded and the main reason for drug use, whether for leg or for chest incisional pain.

Mobilization was assessed subjectively by the patient and objectively by the research nurse. A horizontal visual analog scale of 0 to 10 was used (0 for unable to walk and 10 for excellent mobilization). Measurements were made on postoperative days 3 and 4 and at discharge. Assessment of mobilization is difficult on days 1 and 2 after the operation because of the presence of intravenous tubing and chest tubes. Measurements were continued after discharge on a weekly basis by the patient until the final clinic visit at 6 to 8 weeks. The patient's overall satisfaction with the leg incision, including pain and cosmesis, was assessed by having the patient complete a visual analog scale from 0 to 10. A measurement of 0 indicated not satisfied and 10 indicated very satisfied.

Hospital stay was recorded as length of stay in the intensive care unit, on the ward, and total length of time in the hospital from admission to discharge. The number of subsequent hospitalizations due to complications of the leg wound was also recorded.

Pathologic Analysis of the Harvested Vein

A total of 28 specimens were selected from both groups (13 from the conventional group and 15 from the endoscopic group) and were examined histologically. Immediately after removal a 0.5-cm segment of each end and of the center of the vein was cut with a sharp blade and put immediately in a 10% buffered formalin vial. The specimens were labeled proximal, distal, and center and were identified by a number only. All specimens were examined by the same pathologist who was unaware of patient group assignment. The specimens were fixed and sectioned, processed as usual for light microscopy, and stained with Movat's pentachrome.

Statistical Analysis

Statistical analysis was performed with SPSS for Windows version 7.5 (SPSS, Inc, Chicago, Ill). Nominal data were compared by the χ^2 and Fisher exact tests, where appropriate. Parametric tests were used for the comparisons of data. Exact 95% confidence intervals (CI) are provided where appropriate. Analysis was based on the intention-to-treat principle.

Results

Of the 145 patients initially randomized, 1 patient withdrew before surgery and was excluded from the analysis, leaving a total of 144 patients. The two treatment groups were well matched for important prognostic and surgical variables (Table 1). Patients were middle-aged and the majority were male. Shown in Table 2 are surgical data including mean time intervals for the performance of surgery. The time to harvest

TABLE 2. Operative data*

	Conventional	Endoscopic	P value
No. of bypass grafts	3.3 (1.0)	2.9 (0.7)	.30
LITA used	59 (82%)	62 (86%)	.73
Crossclamp time (min)	62.9 (20.0)	57.1 (23.2)	.51
Cardiopulmonary bypass time (min)	82.9 (27.5)	78.8 (28.5)	.75
Vein - open wound time (min)†	64.4 (29.4)	27.6 (23.7)	<.0001
Total surgical time (min)	184.7 (50.7)	177.2 (41.1)	.69

LITA, left internal thoracic artery.

*Continuous data expressed as means (SD).

†Total time from skin incision to skin closure (including the time to harvest the vein).

the saphenous vein (open leg wound time) was highly significantly shorter among those allocated to the endoscopic group as compared with the conventional method (27.6 vs 64.4 minutes; $P < .0001$). Total surgical time, however, was not different (177.2 vs 184.7 minutes; $P = .69$).

Wound Infection

At the time of hospital discharge 3 leg wound infections had occurred for an overall infection rate of 2.1% (95% CI: 0.4%-6.0%); all developed in the conventional group. Although a difference was emerging with regard to the risk of leg infection favoring the endoscopic group (0% vs 4.2%), the difference was not statistically significant ($P = .12$). After hospital discharge, 16 additional leg wound infections occurred (3 in the endoscopic group and 13 in the conventional group); therefore, 84.2% of the infections occurred late.

Follow-up data on infections was incomplete in 10 patients (7 in the conventional group and 3 in the endoscopic group). These 10 patients did not differ significantly from the remaining patients with complete follow-up data. However, they were not included in the total number of patients in each group for calculating the rate of leg wound infection, changing the total number of patients in the conventional group to 65 and in the endoscopic group to 69. The overall risk of any complication (Table 3) was lower among those in the endoscopic group than in the conventional group ($P = .013$). The difference in the incidence of leg infection between the conventional group and the endoscopic group was highly statistically significant (16/65, 24.6%, vs 3/69, 4.3%; $P = .0006$), resulting in a relative risk reduction of 83% (95% CI: 36%-129%). This 20.3% absolute risk reduction corresponds to a number needed to treat of 5 (95% CI: 3-11); that is, 5 patients would have to have a vein removed endoscopically, rather than by the conventional technique, to prevent 1 infection.

Among the 16 patients in the conventional group with leg infection, none required readmission to the hospital.

TABLE 3. Postoperative complications*

Complications	Conventional	Endoscopic	P value
Non-Q-wave myocardial infarction	0 (0%)	1 (1.4%)	1.0
Atrial fibrillation	2 (2.8%)	1 (1.4%)	1.0
Death	2 (2.8%)	1 (1.4%)	1.0
Leg wound dehiscence	0 (0%)	1 (1.4%)	1.0
Sternal wound infection	1 (1.4%)	2 (2.8%)	1.0
Leg infection at hospital discharge	3 (4.2%)	0 (0%)	.12†
Leg infection at 6 weeks‡	16 (24.6%)	3 (4.3%)	.0006†

*For the overall comparison between groups, the difference in complication rates was statistically significant ($P = .013$).

†The Fisher exact test.

‡This was the primary outcome event. Note that 7 patients in the conventional group and 3 in the endoscopic group were lost to follow-up at 6 weeks. Therefore, the rates are 16/65 and 3/69.

Only 3 patients had their wound infection diagnosed before discharge from the hospital; 13 patients had leg infections diagnosed as outpatients. Thirteen of the patients were treated with oral antibiotics as outpatients with daily visits by the community nurse for dressing changes. One patient visited the emergency department and was discharged receiving oral antibiotics. One further patient required outpatient treatment with intravenous antibiotics. One patient was primarily treated with topical antibiotics. Of the 3 patients with leg wound infection in the endoscopic group, all had their wound infection diagnosed as outpatients. One was treated with oral antibiotics and 2 were treated with topical antibiotics.

One patient in the endoscopic group was readmitted to the hospital with a non-Q-wave myocardial infarction. The 2 deaths in the conventional group resulted from cardiogenic shock. The 1 death in the endoscopic group was due to a combination of septic and cardiogenic shock. No deaths were related to leg wound infection.

Length of Stay

Length of stay in the hospital, including time in the intensive care unit, time on the ward, and total time, was similar for both groups (Table 4). The length of stay was slightly shorter, both in the intensive care unit ($P = .05$) and on the ward ($P = 0.04$), for those patients in the endoscopic group who did not have an infection. Among patients who had an infection there were no statistically significant differences between treatment groups. There were also no differences in length of stay when comparing those with and without infections.

Satisfaction and Mobility

Data on satisfaction and mobility were available for about three quarters of the patients at discharge and at 6 weeks,

TABLE 4. Length of postoperative hospital stay

Length of stay (d)	Conventional			Endoscopic			P value
	Median	Mean	SD	Median	Mean	SD	
Intensive care unit	1	1.3	0.9	1	1.4	1	.37
Ward	5	5.5	2.2	5	5	1.9	.78
Total hospital stay	8	9.7	6.2	7	8.5	4.4	.15

TABLE 5. Patient satisfaction

Satisfaction*	Conventional†			Endoscopic‡			P value
	Median	Mean	SD	Median	Mean	SD	
Leg pain at discharge	5	5.3	1.8	10	8.9	2	.05
Leg cosmesis at discharge	5	5.6	2	10	9.3	1	.02
Leg pain at 6 wk	10	8.5	2.6	10	9.1	2.4	.28
Leg cosmesis at 6 wk	9	8.3	2.4	10	9.9	0.4	.08

*Based on 0-10 Likert scale.

†There was an improvement in both scales from discharge to 6 weeks ($P = .001$ for pain and $P = .001$ for cosmesis).

‡From discharge to 6 weeks there was an improvement in pain ($P < .001$), but not in cosmesis.

TABLE 6. Postoperative mobility

Mobility*	Conventional†			Endoscopic‡			P value
	Median	Mean	SD	Median	Mean	SD	
At discharge							
Subjective assessment	7	6.4	1.3	9	8.8	0.8	.02
Nursing assessment	7	7	1.2	9	9	0.7	.09
At 6 weeks' follow-up							
Subjective assessment	8	7	3.5	10	9.8	0.5	.1
Nursing assessment	8	8	1.6	10	9.8	0.5	.11

*Based on 0-10 Likert scale.

†There was an improvement in patient's perception of mobility from discharge to 6 weeks ($P = .03$), but not for the nurse's assessment ($P = .27$).

‡There was an improvement in the patient's perception of mobility from discharge to 6 weeks ($P = .001$), but not conventionally significant for the nurse's assessment ($P = .089$).

with paired data available for analysis for about half the patients.

At hospital discharge there were important differences in the degrees of the patients' pain ($P = .05$) and cosmesis ($P = .02$) favoring endoscopic vein harvesting (Table 5). At 6 weeks the differences were attenuated but still tended to favor endoscopic therapy. When considering both domains and all patients together, the level of satisfaction increased significantly ($P < .001$) from discharge to 6 to 8 weeks' follow-up. For the group assigned conventional vein harvesting, satisfaction improved in terms of pain ($P = .001$) and cosmesis ($P = .001$). For the endoscopic group, there was an

improvement in pain ($P < .001$) but not cosmesis. It should be pointed out that the level of satisfaction was high at the time of discharge for the latter.

At the time of discharge, the patient's subjective ability to mobilize was significantly higher with endoscopic as compared with conventional vein harvesting ($P = .016$). Although slight differences existed for the nursing objective assessment and the perception at 6 weeks' follow-up, all favoring endoscopic harvesting, these differences were not statistically significant. The patient's subjective ability to mobilize improved in both groups over the 6 weeks of follow-up (Table 6).

Sensitivity Analyses

First, 2 patients were randomized to endoscopic therapy but also underwent conventional vein harvesting to the contralateral leg. Neither patient had a primary outcome event. Performing an efficacy analysis (ie, based on treatment actually received and using the leg as the unit of treatment assignment) did not alter the conclusions, and the results remained highly statistically significant ($P = .0013$). Next, 1 patient in the endoscopic group had a wound dehiscence but did not meet the criteria for wound infection based on clinical grounds (or our diagnostic criteria) and so did not receive antibiotics. Including this patient in the infection data, however, did not materially alter the results or the level of statistical significance. Finally, the potential impact of loss to follow-up was assessed by means of a “worst-case scenario” analysis. We assumed that all patients lost to follow-up in the conventional group remained free of infection and those assigned to the endoscopic group had an infection. Even under these extreme, and unlikely, conditions, the direction of benefit favoring endoscopic harvesting remained unchanged and statistically significant ($P = .013$).

Histopathologic Examination

A total of 39 random specimens from the conventional group and 45 specimens from the endoscopic group were analyzed histologically. The proximal, center, and distal aspects of the veins harvested by both methods were found to have normal changes in the intima, media, and adventitia. The differences noticed were minimal and not significant.

Discussion

The morbidity related to saphenous vein harvesting by conventional methods can be debilitating for some patients. Over the several decades that coronary artery bypass surgery has been performed, this morbidity has become an acceptable postoperative complication with rates ranging from as low as 1% to as high as 24%.¹⁻⁷ With the evolution of minimally invasive surgical techniques, less invasive methods of harvesting the saphenous vein have been developed with the goal of reducing postoperative wound morbidity.^{8,9,16-20} However, the benefits remain inconsistent according to some published reports.¹²

Benefits of Endoscopic Method

The main result of our trial is that endoscopic harvesting of the saphenous vein results in a significant decrease in the rate of wound infections from 24.6% to 4.3% (conventional vs endoscopic groups; $P = .0006$). The low rate of wound complications in the minimally invasive group is in accord with Allen and Shaar,⁹ the other randomized prospective trial of endoscopic saphenous vein harvesting. Although the rate of infection in the conventional group seems high, the majority of infections (84.2%) occurred after hospital dis-

charge. All patients with infections were treated as outpatients. As a result, we were unable to show any important differences in length of stay between vein harvesting methods or between patients with and without infections. To determine which factors are associated with the increase in wound infection, we performed a stepwise multiple logistic regression analysis. Randomization to endoscopic harvesting was the only independent variable associated with reduced wound infection.

Previous reports have indicated that endoscopic vein harvesting reduces postoperative pain, decreases length of stay in the hospital, and improves mobility.^{8,19-22} Others, however, were unable to detect differences in postoperative pain and mobility between the traditional and endoscopic methods.^{12,13} A secondary finding in our trial was that patients who had their vein harvested endoscopically had significantly reduced postoperative leg pain at the time of discharge and, to a lesser extent, at 6 weeks' follow-up. At 6 weeks both groups had improved to such an extent that the differences in perceived pain were minimal. In addition, we found a difference in postoperative ambulation favoring endoscopic harvesting when assessment was made by the patient. In terms of patients' satisfaction with cosmesis, there was a significant difference at discharge between the two groups, but not at the 6-week follow-up period. After 6 weeks the patients in the conventional group had undergone the healing process and their leg wounds had improved cosmetically. Hence, when compared with endoscopic harvesting (patients were already satisfied at the time of discharge), no significant differences were seen.

Potential Concerns Allayed

Several potential drawbacks of endoscopic harvesting include an increased vein harvest time and the possibility of vein trauma during vein preparation.^{8,13} The prolonged harvest time with the endoscopic technique observed in previous studies was a result of differences in definitions. Whereas previous studies looked at the time to harvest the vein only (whether conventionally or endoscopically), we believe that the time from incision until the skin is closed is more important in terms of potential infection. In our study, endoscopic harvesting was performed by a staff surgeon or surgical assistants who had already progressed through their learning curves. As a result, the mean vein harvest time (open leg wound time) for the endoscopic group was significantly shorter than the open conventional technique (27.6 vs 64.4 minutes; $P < .0001$). The concern that endoscopic saphenous vein harvesting might increase the incidence of saphenous vein trauma is valid given the potentially detrimental effect on short- and long-term vein graft patency. However, in our experience and that of others who have compared endoscopic saphenous vein harvesting

with conventional methods,^{8,11,19,22} there was no apparent increase in acute graft closure nor increased rate of perioperative myocardial infarction in the endoscopic harvest group. This suggests that a gross loss of endothelial integrity is not likely, although the possibility of minor injury to the vein could still exist. Moreover, in our study we did not find any histologic difference between the segments of vein harvested conventionally and endoscopically. A similar finding has been reported previously.¹⁹

Issues of Cost

The cost of the disposable vein harvest system (Ethicon Endo-Surgery, Cincinnati, Ohio) used in our study is approximately \$400 CDN (\$270 US). With the development of nondisposable vein harvesting systems, this cost may decrease. Once the system has been purchased (estimated cost \$600 CDN), the only ongoing costs include disposables such as surgical clips. We estimate that the cost of treating a postoperative leg wound infection could range from \$200 CDN for an emergency room visit to \$1000 CDN per day for admission to the hospital. We showed that endoscopic harvesting resulted in a 20% absolute reduction in the risk of leg infection and this corresponds to a number to treat of 5. That is, by removing veins from 5 patients by this technique, one could prevent 1 leg wound infection and the resultant subsequent costs. Therefore, one could postulate that use of the endoscopic method might potentially result in cost savings (that is, eventually pay for itself) or at least result in an acceptable cost-effectiveness ratio, such as cost per leg infection averted. A formal economic evaluation is necessary to test this hypothesis.

Study Limitations

We acknowledge some limitations of our trial. First, our study was necessarily unblinded. As such, this could possibly lead to outcome ascertainment bias for the “soft” outcomes of patient satisfaction and mobility. For the outcome of infection we used recognized strict diagnostic criteria (National Nosocomial Infection Surveillance). Second, there were incomplete data on ascertainment of patient satisfaction, pain, and mobility, and as a result these should be interpreted with caution. In addition, since it was not possible to make the study blinded to the patients, the secondary outcome events could have easily been affected by the patient’s subjectivity and desire to please. To avoid the secondary outcomes being influenced by these factors, before enrolling the patients we explained to them that the primary purpose of the study was to see whether the new method of vein harvesting decreased the rate of leg wound infection. Not much emphasis was placed on the secondary outcomes. Also, the patients were asked to provide their true and genuine subjective assessment when filling out the visual analog scales for the secondary outcome events. Third, 10 patients were lost to follow-up with regard to the primary outcome event.

Notwithstanding, we performed a number of sensitivity analyses showing that our conclusions are robust under many assumptions, including those of a “worst case” scenario. Despite these extreme assumptions, the difference in the rate of leg infection between the two groups still remained statistically significant in favor of the endoscopic group. Finally, our study was performed in one center with a surgeon and assistants who had considerable experience with this technique and, as a result, may not be generalizable to other centers or to less experienced surgeons.

Conclusion

Endoscopic saphenous vein harvesting reduces the incidence of postoperative leg wound complications, especially leg wound infections, in patients undergoing coronary artery bypass graft surgery. The saphenous vein harvested endoscopically is histologically intact with no evidence of additional injury when compared with the conventional method of harvesting. Moreover, we found significant differences, favoring the endoscopic method, in the patients’ postoperative mobility, leg pain, and satisfaction. Therefore, we recommend the routine use of minimally invasive saphenous vein harvesting in coronary artery bypass surgery.

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Discussion

Dr Forrest Junod (Sacramento, Calif). Dr Kiaii's study draws several conclusions about the benefits of endoscopic vein harvest. Decreased infection and pain allow patients more comfort, early ambulation, and early satisfaction with wound appearance. My comments will be limited to infection, technique, and cost.

Although the Sacramento Cardiovascular Surgeons Group evaluated Ethicon, Origen, and Genzyme systems for limited incision harvest, we have chosen not to use them routinely because of additional cost and unproven benefit over either open or bridging techniques in our hands. In fact, one of our harvesters is aptly titled "Charlie-scope" for his adept retrieval of veins through very small longitudinal bridging incisions. The study addresses cost for the system and compares the treatment for wound infection. Equipment costs in Canada appear much less than in California. In fact, in the United States we are paid for 90 days of care including office visits. Therefore, aside from patient and physician discomfort the only additional expenses are for antibiotics, emergency department and hospital admissions, and operative intervention. One significant infection may well pay for many endoscopes if the savings are real. There is a need for a cost study based on comparable patients. For cosmesis there is no question that patients appreciate the small scars. However, in the absence of longitudinal scars demarcating the length of vein removed, venous mapping may be an additional cost for patients requiring second procedures. With regard to technique, many of our initial vein harvests are from the lower leg beginning at the ankle and avoiding the groin areas. Thigh vein is harvested in patients with peripheral vascular disease, previous vein harvest, and unsuitable lower saphenous veins. Other important surgical tactics to decrease infection in addition to sterile technique are circumferential preparation of the entire leg, limited incisional beveling, avoidance of skin flaps, meticulous hemostasis, and subcuticular closure. We also use closed drainage systems for obese thighs with difficult or cavernous excavations. Endoscopic vein harvest in our experience seemed most suited to upper leg and thigh veins where there is

enough subcutaneous tissue to allow easy passage of the scope. Conversion to the open method in the lower leg occurred when the scopes could not be passed, when expedient harvest was necessary for the waiting surgeon, and when bleeding obscured the view through the scope.

What technical limitations did you experience in the ability to harvest the entire saphenous vein, particularly from the lower leg?

Dr Kiaii. Dr Junod, thank you for your comments. Those are all concerns that we considered when we started to perform this procedure.

In terms of cost analysis, one of our objectives was definitely to try to determine whether endoscopic harvesting is more cost effective than the conventional method. When we first started doing this procedure we used a disposable system from Ethicon, but since then nondisposable systems have been used. Now the cost of endoscopic saphenous vein harvesting at our institution is just the cost of surgical clips, because the system is a nondisposable system that we can use for several procedures.

We had a long learning curve of at least 30 or 40 patients before we were familiar with the technique. Initially we did not go below the knee because the system we used could not easily be used there. Once we had gained experience with actually manipulating the instrument within that small space, then we actually were able to go below the knee.

Dr Junod. In the past 5 years with 5000 cases requiring coronary artery bypass and saphenous vein harvesting by any method, an annual leg infection rate of 0.5% to 2.2% was recorded in our group. Unlike the procedure in this report, incisional redness treated after discharge with antibiotics or areas of skin necrosis allowed to granulate were not included. Lymphedema causing persistent swelling in the leg and undrained hematomas were also not categorized. Your study and others cited high infection rates for open methods. However, some have cumulative figures for poor wound healing, as well as infection yielding higher morbidity rates for open, presumably long longitudinal incisions. What definitions did you use for infection? Did you include cultures to prove that there was infection rather than just an inflammatory response, or was operative debridement necessary?

Dr Kiaii. At our institution we follow the criteria set by the National Nosocomial Infection Surveillance, and the criteria include primary evidence of purulent discharge, evidence of redness, pain, evidence of dehiscence or a wound having to be opened because of the patient having an elevated temperature, pain at the incision site, or clinical evidence of abscess. Interestingly, the majority of the patients in whom leg wound infection was diagnosed were all treated on an outpatient basis. When we originally started the study, we did a literature review. It was hard for us to believe that such a high wound infection rate existed in the literature. When we gathered the data and were confronted with the same result, we discussed our result with our infectious disease department. Their data are composed primarily of patients who were inpatients before leaving the hospital. Today most patients are being discharged from the hospital within 4 to 5 days postoperatively, so it is difficult for leg infections to be diagnosed. However, in patients in whom infection was diagnosed, we had definite evidence from cultures that were taken from the patients while in the hospital.

Dr Junod. Were cultures not obtained from outpatients?

Dr Kiaii. It was very difficult to obtain cultures from outpatients because most had already been seen by the family physician and were receiving antibiotics. Cultures from such patients did not yield a positive result.

Dr Junod. How have you treated infected hematomas from endoscopic vein harvest? That is one of the complications that occurred early in our series of patients.

Dr Kiaii. We found that wrapping the legs immediately after the operation and then leaving them wrapped for 72 hours decreased the incidence of hematuria.

Dr Junod. How have you treated infections in the areas in which hematomas developed even though the leg had been wrapped?

Dr Kiaii. If a hematoma was present and we thought the site was infected, then we surgically opened the wound.

Dr Junod. Did you irrigate from end to end, and did you do any other things to drain the hematoma? Did you open all of the narrowest sources or just the ends?

Dr Kiaii. We opened it right at the site where we thought the hematoma was present.

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