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Influence of Endoscopic versus Traditional Saphenectomy on Event-Free Survival: Five-Year Follow-up of a Prospective Randomized Trial

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ABSTRACT

Background: Endoscopic harvesting of the greater saphenous vein is increasingly used during cardiac surgery to improve patient satisfaction and reduce the wound complications associated with traditional open techniques. Although histologic studies suggest no significant difference in vein quality between these two techniques, long-term follow-up is lacking to address whether graft patency and event-free survival are influenced by the harvest method.

Methods: A total of 112 isolated coronary artery bypass patients were prospectively randomized to have veins harvested using either an endoscopic (n = 54) or traditional (n = 58) technique. Groups were demographically similar with regard to preoperative risk stratification and coronary procedures performed. Event-free survival (freedom from death, myocardial infarction, or recurrent angina) and use of outpatient resources for resolution of wound complications were determined. Follow-up was 100% at 5 years.

Results: Five-year actual event-free survival was similar in patients with endoscopic versus traditionally harvested veins (75% versus 74%, $P = .85$). The number of outpatient office visits required to manage each wound complication to complete resolution was significantly less following endoscopic versus traditional vein harvest (1.5 versus 6 visits, $P = .001$).

Conclusions: Wound complication management following endoscopic versus traditional vein harvest requires less resource utilization. Five-year follow-up of a prospective randomized trial demonstrates that use of endoscopic versus traditionally harvested saphenous veins does not influence event-free survival.

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BACKGROUND

The greater saphenous vein (SV) remains the most commonly used conduit for coronary artery bypass grafting (CABG), yet reports of vein harvest complications have been neglected in the surgical literature. When prospectively evaluated and consistently defined, leg wound complications following longitudinal saphenectomy have been found to occur in 19% to 24% of patients [Allen 1998, Utley 1989]. A reduction in leg wound complications following endoscopic vein harvest (EVH) has been reported for both cardiac [Allen 1997, Cable 1997, Allen 1998, Davis 1998] and peripheral vascular [Lumsden 1996] procedures. In a prospective, randomized study we reported that EVH, when compared to the traditional longitudinal technique, reduced leg wound complications from 19% to 4% [Allen 1998]. Furthermore, in a larger retrospective review we determined that traditional saphenectomy, along with obesity and diabetes, were multivariable predictors for development of a harvest-site complication [Allen 2000a]. Although short-term patient benefit is apparent, a lack of long-term follow-up to determine if endoscopic saphenectomy adversely influences patient outcomes has dampened a broader adoption of this technique. This report summarizes 5-year clinical follow-up of patients prospectively randomized to either endoscopic or traditional saphenectomy.

METHODS

Between October 1996 and February 1997, 112 patients scheduled for elective coronary artery bypass grafting were prospectively randomized to undergo endoscopic (n = 54) or traditional (n = 58) longitudinal saphenectomy. The SV was harvested either endoscopically (Ethicon Endo-Surgery, Cincinnati, OH, USA) according to a previously described technique [Allen 1997, Allen 1998] or traditionally using a longitudinal fillet incision without skin bridges. Conversion from EVH to traditional harvest occurred in 3 of 54 (5.6%) of patients. Details of this study and the results of 6-week follow-up regarding leg wound complications have been previously published [Allen 1998]. In summary, study participants had isolated coronary artery disease that required the use of the greater SV for some of their revascularization. Exclusion

criteria were history of emergent surgery or the presence of leg ulcerations or an active bacterial infection. Patients in each group had similar preoperative demographics, operative risk stratification (Parsonnet and Cleveland Clinic scores), risk factors for leg wound complications (sex, diabetes mellitus, obesity, hypoalbuminemia, anemia, peripheral vascular disease), and operative demographics (number of bypass grafts, time on bypass, and number of arterial grafts). Similar antibiotic prophylaxis and postoperative wound care were provided to both groups. A wound complication was defined as inflammation, dehiscence, cellulitis, lymphangitis, drainage, necrosis, or abscess necessitating dressing, antibiotics, or debridement before complete healing without eschar [Utley 1989, Allen 1998].

Patient Follow-up

Wound complications were followed in all patients until complete resolution. The number of office visits required to manage each wound complication was used as a surrogate to determine outpatient resource utilization for wound management. Long-term follow-up was conducted by telephone interview and letters to determine each patient's current cardiac and leg-wound status. Information collected included cardiac history (evidence of myocardial infarction, recurrence of angina, or congestive heart failure) and information regarding any leg wound complications requiring inpatient or outpatient treatment. If queries elicited a positive response these were verified by obtaining office or hospital records. Follow-up was 100% at 5 years.

Statistical Analysis

Statistical analyses were done using the methodology of the PC JMP Statistical Discovery Software (SAS Institute, Cary, NC, USA). Categorical variables were analyzed using χ^2 or Fisher exact test where appropriate. Treatment groups were compared with respect to actual event-free survival (freedom from death, myocardial infarction, or recurrence of angina) using an intention-to-treat analysis. A probability of $\leq .05$ using 2-tailed testing was considered statistically significant.

RESULTS

Actual 5-year event-free survival (freedom from death, myocardial infarction, recurrent angina, or congestive heart failure) was similar for the endoscopic and traditional harvest groups (75% versus 74%, $P = .85$). Five patients in each group underwent angiography during follow-up. One patient in each group had a normal angiogram, and SV graft closures were noted in 4 patients in the traditional group and 4 patients in the EVH group. Vein graft stenosis less than 50% was seen in 2 EVH grafts versus 3 traditional grafts, and SV graft stenosis greater than 50% was seen in 3 EVH grafts versus 2 traditional grafts.

Postoperative leg wound complications at 6 weeks were previously reported in 2 of 51 (4%) of patients who underwent EVH versus 11 of 58 (19%) of patients who underwent the traditional longitudinal incision ($P \leq .02$) [Allen 1998]. The number of outpatient office visits required to manage each wound complication to complete resolution was significantly less following endoscopic vein harvest (1.5 versus 6 visits, $P = .001$).

DISCUSSION

Although the advantages of endoscopic versus traditional saphenectomy have been demonstrated in both randomized [Allen 1998, Davis 1998] and nonrandomized studies [Allen 1997], criticisms that have impeded the broader adoption of endoscopic saphenectomy by cardiac surgeons have included: (1) the potential for conduit trauma during endoscopic harvest, which may result in premature graft failure, (2) additional operative time, and (3) increased cost due to disposable instruments. The potential for increased SV trauma during endoscopic harvest compared to the traditional longitudinal technique is an important issue. Complications related to premature graft failure, which might be attributed to EVH, have not been addressed with long-term follow-up. As previously reported, acute perioperative events that might be associated with gross conduit trauma occurred with similar frequency for endoscopic and traditional harvest techniques [Allen 1998]. In a subsequent blinded histologic comparison of endoscopically and traditionally harvested SV, minor histologic alterations were observed with both harvest techniques; however, no significant differences were noted between groups [Griffith 2000]. Even though endoscopically and traditionally harvested SV appear histologically similar, no long-term clinical follow-up, until now, has been available to address whether EVH adversely influences long-term event-free survival compared to a traditional harvest technique. Similar 5-year event-free survival rates reported from this prospective randomized trial should assuage the criticism that EVH may result in increased conduit trauma and detrimental long-term results.

Additional criticisms of EVH such as increased operative time and the higher expense for endoscopic instrumentation can be balanced against a reduction in patient morbidity and improvement in patient satisfaction. Although an economic analysis was beyond the scope of this trial, outpatient resource use for the care of leg wound complications following traditional longitudinal saphenectomy was significantly reduced with EVH. In addition, refinements in endoscopic equipment, harvest technique [Allen 2000b], and postoperative care [Allen 2000c] continue to improve operative times and the care of wound complications that are occasionally seen with EVH. Although wound complications are not eliminated with EVH, when they do occur, their management is simplified compared to traditional harvest-site complications.

A limitation of this study is that a clinical endpoint (event-free survival) rather than angiography was used as a surrogate to reflect vein graft longevity. This study's prospective randomized design in demographically similar groups deflects this criticism to a degree. Although postoperative angiographic studies would ideally be used to evaluate the long-term influence of vein harvest technique on graft patency, the practicality and cost of such studies were considered prohibitive.

CONCLUSION

In a prospective, randomized trial, endoscopic compared to traditional longitudinal saphenectomy significantly reduced perioperative leg wound complications and outpatient resource use without adversely influencing 5-year event-free survival. Endoscopic saphenectomy should be the standard of care for patients who require greater SV grafts during coronary revascularization.

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