Assessing Outcomes, Costs, and Benefits of Emerging Technology for Minimally Invasive Saphenous Vein In Situ Distal Arterial Bypasses

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Background: Instrumentation for a minimally invasive angioscopic in situ peripheral arterial bypass (MIAB) with catheter-directed side-branch occlusion has recently been approved for use. Despite the attractiveness of this approach (2 short incisions), benefits such as lower morbidity and shorter hospitalizations remain undocumented. To justify wide acceptance, minimally invasive surgical techniques must match conventional procedures in durability and cost while enhancing patient comfort. Often such comparisons are difficult during the implementation phase of a new procedure.

Objective: To compare the outcomes of the MIAB procedures with a concurrent group of patients undergoing conventional in situ bypass procedures.

Design: Retrospective review.

Setting: University medical center.

Patients: The first 20 consecutive MIAB procedures in 19 patients performed between August 1, 1995, and July 31, 1997, were compared with 19 contemporaneous consecutive conventional in situ bypass procedures performed at the same institution.

Main Outcome Measures: Operative time, postoperative length of stay, hospital costs, complications, primary assisted and secondary patency, limb salvage, and survival.

Results: The patient groups were comparable with respect to age, sex, incidence of smoking, coronary artery disease, hypertension, diabetes, renal failure, cerebrovascular disease, indication, and distal anastomosis level. The median operative time was significantly greater for the MIAB group (6.6 hours vs 5.7 hours; \( P = .009 \)), and intraoperative completion arteriography more frequently showed retained arteriovenous fistulas in the MIAB group (53% vs 21%; \( P = .05 \)). The median postoperative length of stay and total cost were 6.5 days and $18,000 for the MIAB group and 8 days and $27,800 for the conventional group (\( P = .05 \)). There were no significant differences in major complications (10% in the MIAB group vs 11% in the conventional group), wound complications (10% vs 11%, respectively), primary assisted patency at 1 year (68%±11% vs 78%±10%, respectively), secondary patency at 1 year (79%±10% vs 88%±8%, respectively), limb salvage at 1 year (85%±10% vs 94%±6%, respectively), or patient survival at 1 year (89%±8% vs 61%±13%, respectively).

Conclusion: Patients undergoing the MIAB procedure avoided lengthy vein exposure incisions without sacrificing short-term results. There was a trend toward decreased hospital stay and cost, which may be further realized as the clinical experience broadens. Although longer follow-up and larger cohorts will always be required to define durability, immediate access to outcomes and costs on small numbers of patients facilitates the early assessment of emerging technology.

Arch Surg. 1998;133:613-618

MORE THAN 100,000 infragingual bypasses are performed annually for the treatment of atherosclerotic peripheral vascular disease of the lower extremities. Approximately one third of these cases are performed with the in situ technique. Traditionally, the operation requires an incision over the entire course of the greater saphenous vein, to facilitate both valve lysis and tributary ligation. Preliminary results with minimally invasive techniques to limit the length of the incision have been favorable.\(^1\)\(^2\) During the past 3 years, the procedure has been simplified and the instrumentation has been refined. Currently, minimally invasive angioscopic in situ bypass (MIAB) is performed with a valvulotome and side branch occlusion system (Baxter Vascular Division, Irvine, Calif) recently approved by the Food and Drug Administration. The purpose of this report is to compare the outcomes of the MIAB procedure with a concurrent
PATIENTS AND METHODS

Data were obtained from a retrospective review of the medical records of consecutive primary in situ saphenous vein bypasses performed at the University of Chicago Hospitals, Chicago, Ill, between August 1, 1995, and July 31, 1997. All MIAB procedures were performed by a single surgeon (G.P.), whereas conventional cases were performed by 1 of 4 other surgeons (L.B.S., H.S.B., J.F.M., and B.L.G.).

SURGICAL TECHNIQUE

The MIAB is performed by means of a component endovascular system. The system consists of an irrigating, retrograde valvulotome and an antegrade angioscopic side-brach occlusion catheter. After proximal and distal dissection of the greater saphenous vein at the inflow and outflow target sites, the vein is transected and heparin is administered systemically. Next, the valvulotome and side-branch occlusion catheter are introduced into the vein. Irrigation fluid (heparin–papaverine–balanced saline solution) is controlled by a foot pedal switch. When a set of valve leaflets is identified, the valvulotome is engaged and valvulotomy of each valve leaflet is performed under direct angioscopic surveillance. Concurrently, the side-branch orifices are identified. A Gianturco occlusion coil is guided through the working channel of the side-branch occlusion catheter and deployed into the venous side branch embolizing the tributary. With the use of this angiography-assisted technique, the greater saphenous vein for in situ bypass is prepared in the majority of cases through 2 small incisions. Proximal and distal anastomoses then proceed in the standard fashion. Completion angiography using cut film or digital subtraction was performed in all cases.

RESULTS

From August 1, 1995, to July 31, 1997, MIAB was performed in 20 limbs in 19 consecutive patients. Nineteen patients underwent consecutive conventional in situ bypass during this interval. Overall, there were 20 men (53%) and 19 women (47%) with a mean age of 68±3 years (range, 37-86 years). There were no significant differences in risk factors or comorbidities between the 2 groups (Table 1).

Thirty-four operations (87%) were performed for limb salvage; an intrapopliteal distal anastomosis was required in 33 operations (85%) (Table 2). There were no significant differences in indication, incidence of re-operation, the presence of contralateral disease, or level of distal anastomosis between groups. The MIAB procedures required significantly more operative time to complete (P=.009). As expected, intraoperative completion arteriography more frequently disclosed the presence of patent retained arteriovenous fistulas in the MIAB group, and additional small incisions were required for ligation in 7 cases.

There were no perioperative deaths. Two major complications occurred in patients undergoing MIAB. One patient sustained a cerebrovascular accident on postoperative day 3, required a brief stay in the intensive care unit, and recovered without sequelae. One patient developed an acute proximal anastomotic pseudoaneurysm that required urgent repair and prolonged the stay. Two major complications occurred in patients undergoing conventional bypass, and both were major groin wound infections. The first patient required extra-anatomic autogenous bypass, which eventually failed, necessitating amputation. The second patient required multiple graft revisions but remained well with a salvaged extremity and secondarily healing wounds.

Completion angiography using cut film or digital subtraction was performed in all cases.

COST ANALYSIS

Cost data were obtained from the University of Chicago Hospitals’ Office of Program Planning by means of the following algorithm. Total costs are all direct and indirect costs and are allocated to the patient encounter level by the Hospitals’ clinical cost accounting system (Transition Systems Inc, Boston, Mass). Direct costs are variable and fixed costs most closely related to patient care. Indirect costs are fixed costs, such as overhead expense, that relate indirectly to patient care. Data reflect all and only costs incurred by the hospital during the entire inpatient stay and do not include physician practice costs. The encounter records used for the cost analysis were those identified by the Office of Program Planning on the basis of patient lists, including medical record number, patient name, bypass procedure date, admission date, and discharge date.

STATISTICAL ANALYSIS

Data are presented as means±SEM or median (range) as noted. Graft patency, limb salvage, and survival were calculated by the life-table method. Statistical comparison between groups was tested by Fisher exact test (discrete variables), Mann-Whitney U test (nonparametric continuous variables), or the log-rank test (patency, limb salvage, and survival). Simple linear regression was performed by the least squares method. A value of P<.05 was considered significant.
After a median follow-up of 9.4 months (range, 1.5-26 months), there were no statistically significant differences in 1-year graft patency (Table 3, Figure 3, and Figure 4), limb salvage (Figure 5), or patient survival (Figure 6).

**COMMENT**

Lower-extremity peripheral vascular disease is an important cause of morbidity and disability in the elderly. For many of these patients, bypass procedures are the only available alternative to major limb amputation. Approximately one third of these bypass procedures are performed by the in situ technique. First performed by Robb and Hall in 1959 at St Mary’s Hospital in London, England, and reported by Hall in 1962, surgeons have strived to simplify valve lysis, the most unique component of the procedure. Notably, Leather et al emphasized the importance of meticulous surgical technique and the use of the Mills valvulotome; they reported excellent graft patency rates in more than 1000 patients. Unfortunately, to accomplish their technique, it is necessary to make a long incision over the full length of the greater saphenous vein. Such long incisions can be troublesome, especially in diabetic patients in whom complications can be devastating. Wound complications after in situ saphenous bypass procedures are common and have been reported in up to one third of cases. When these complications occur, they result in painful and prolonged hospitalizations. Moreover, in extreme cases, both life and limb can be jeopardized. Therefore, the ability...
to reduce or avoid lengthy vein exposure incisions would be a major advance in the care of these patients. A variety of systems have been developed to lyse venous valves endovascularly.\textsuperscript{7-9} Although these approaches have largely been successful, the need for additional incisions to ligate venous branches has remained. To circumvent this problem, an endovascular side-branch occlusion system was developed and investigated by Rosenthal et al.\textsuperscript{1,2} They used a nitinol alloy catheter that was inserted antegrade and articulated under retrograde angioscopic control to occlude side branches with platinum coils. This initial approach has been simplified by the development of a multichannel angioscope, which enables side branches to be visualized and occluded under direct vision by means of a single angioscopic catheter.

Development of this new procedure was dependent on a collegial relationship with the producers of this angioscope and related equipment (Baxter Vascular Division). During the first 12 months of use, 4 alterations were made in the process by which side-branch occlusion was effected. This was facilitated by the attendance of company specialists in the operating room, as well as complete and detailed compliance with the routine reporting standards for investigational device development by the Food and Drug Administration.

The surgical technique reported herein uses a combination of retrograde catheter valvulotomy and angioscopic side-branch occlusion. Although small additional incisions were necessary in 7 patients to ligate missed side branches, conversion to a totally open procedure did not occur. There were no cases of residual fistula patency after successful coil deployment. Completion angiography and follow-up duplex scans more frequently identified patent arteriovenous fistulas in the MIAB group, although they did not appear to affect long-
term patency. Operative time was statistically significantly longer in the MIAB group, although the actual difference was less than 1 hour. This analysis included cases on the steep portion of the “learning curve,” as the institution’s total experience with this new procedure was reported.

Despite avoiding lengthy leg incisions, the MIAB group did not demonstrate a reduction in the incidence of postoperative wound complications. Two patients in each group sustained wound infections, all of which were located in the incisions over the proximal or distal dissection fields. As expected, MIAB did not prevent complications involved with target vessel exposure. No patient in the conventional group sustained vein exposure wound infections, although their prevalence is well documented in larger series.6 Both postoperative length of stay and total hospital costs were reduced in the MIAB group, although the differences did not reach statistical significance with the appropriate nonparametric tests (Table 3). A trend toward decreased resource utilization was clearly evident, however, as the average total cost of MIAB was approximately $10 000 less per case.

These observations illustrate several concepts relevant to the development of emerging technologies in clinical practice. From an economic perspective, satisfactory costs (equal to or lower than conventional) must be demonstrated during the initiation phase that accompanies every new procedure. While the utility of any operation is invariably defined with time, it is often difficult to determine the value of a new approach early in its history. Initial reports by originators or enthusiasts are predictably positive, but subsequent results may not be as good in the hands of others. This may reflect true limitations of the procedure or merely the fact that extensive experience is needed for proper application of the techniques.

Early in our application of MIAB we were confronted with a number of difficult questions that related directly to the above issues. How could we expect enhanced efficiency and lower costs so early in a new surgical experience? If, in the initial cases, costs were not substantially lower or, worse yet, increased, what expense was tolerable if patient satisfaction and/or outcomes from the new procedure were measurably better? Finally, how could we assess trends in outcome or costs in a dynamic practice setting in which operative performance and expertise in patient selection were both actively changing?

This preliminary study addresses some of these questions. By design, the analysis encompassed all consecutive cases of the experimental procedure, thus including the initial learning curve. As expected, the operating time was slightly longer and residual arteriovenous fistulas were more frequently missed. However, long-term patency was not affected, and patient satisfaction was clearly enhanced. It is hoped that the initial trend in reduced hospital cost and reduced postoperative length of stay will be more fully realized as the experience grows. Given these salutary features of the MIAB procedure, it recently has been adopted by the additional surgeons in our group.

Presented at the 105th Scientific Session of the Western Surgical Association, Colorado Springs, Colo, November 18, 1997.

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REFERENCES


DISCUSSION

Jonathan B. Towne, MD, Milwaukee, Wis: I was surprised that there was no difference in incidence of wound complications between the 2 groups. Certainly as the series increases, the incidence of wound complications should decrease in the minimally invasive group. There also is no statistically significant difference in 1-year patency, although the primary assisted patency was 10% less and the secondary patency 9% less in the minimally invasive series. This corresponds to other series in the literature where early patency, in my judgment, is approxi-
The basic question is, what decrease in early graft function are you willing to pay for shortened length of stay and the resulting cost savings? I would like to ask the authors the size criteria of the saphenous veins to use this technology. Also, how did the authors choose the branch of the saphenous vein to use with the known high incidence of thigh, calf, and total duplications of the saphenous vein? Likewise, how many of those little "fuzz balls" did they leave in the lumen of the vein, and how difficult were they to remove?

This technique is the wave of the future. I salute the authors for doing a comparative study. Personally, I am awaiting further technical refinements, since so many of my patients have veins in the 2- to 3.5-mm range.

John L. Glover, MD, Royal Oak, Mich: If there was no difference in the wound complications, why is there such a significant difference in the length of stay?

Wayne M. Swenson, MD, Bismarck, ND: I am wondering whether the authors have tried, instead of the long incision, the little transverse incisions over the venous branches that you can find with the light from your scope instead of the "fuzz balls."

Harlan D. Root, MD, San Antonio, Tex: This innovative approach is interesting. In using the endoscopic approach, if you mark the tributaries as the light shows up, you can then go back and double-team the leg, so to speak, and have the junior resident cut down on the sites where the tributaries are and save some time that way.

Judging from your slide, you were only going to the proximal third of the calf. Have you gone to the posterior tibial, dorsalis pedis level? There may be limitations in your technique in that regard. Finally, have you missed any valves and had to go back and cut down and redo any valve site, either endoscopically or through an open technique?

Dr Gewertz: Dr Towne raises a few points that are, I think, very pertinent. One is that by happenstance or, hopefully, by technique, wound complications were infrequent in both groups. Although the national average may be somewhat higher, we were fortunate that in the 19 patients who were studied in either group, wound complications were less than 15%.

We do not believe that graft patency will be different. There is no statistical difference at this time. Of course, that confidence is limited by the relatively small cohorts that were studied in both groups. There really is no conceptual reason why the patency should be different, particularly when better equipment is developed and patient selection is refined.

We are currently limited to 3-mm veins in this technique. The device itself is currently constituted as 2.8 mm, and we are told by the engineers that it may be a while until a device smaller than 2.8 mm is produced. In answer to your specific question about the coils, there were 3 events in which coils were misplaced in a way that was significant, and all were recovered with endoluminal "basket" techniques.

In view of some of the other questions, the reason the "conventional" patients stayed in the hospital longer was more for pain and ambulation than for wound complications. We would also agree that minimal incisions are useful in patients treated with conventional in situ bypass. Sometimes, unfortunately, those minimal incisions become so plentiful to afford adequate visualization that, before you are done, you have quite a few of them.

We have taken a number of these bypasses to the ankle level. On several occasions we did note inadequate valve lysis that needed to be treated either endoluminally or by cutdown, but the number of incisions was less than 3 in those patients.

In short, we had some trepidation in presenting these data because we are in a "learning curve." The very first case that was done by Dr Piano was included in this group, and we anticipate that, with additional surgical experience, the lengths of stay will come down even more.