One hundred twenty-five concomitant endovascular and open procedures for lower extremity arterial disease

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Objective: **Although the results of staged endovascular and open surgical reconstructions have been well documented, the safety and efficacy of concomitant procedures in the operating room are less well defined. Suboptimal performance of endovascular procedures in an operative setting, or inappropriate reliance on endovascular techniques, might theoretically compromise graft patency. We questioned whether late graft thrombosis is frequently attributable to failure at the endovascularly treated site in this setting.**

Materials and Methods: **Between May 1, 1993, and June 30, 2001, we performed 125 concomitant endovascular and open arterial reconstructions (73 primary reconstructions, 52 graft revisions) in 106 patients. Endovascular techniques were used to treat inflow lesions in 72 cases, outflow lesions in 14 cases, both in four cases, and the graft itself in 35 cases. Fifty-five iliac, 18 femoral, 13 popliteal, six tibial, and 35 graft lesions were treated. For primary bypasses, 33 were to the popliteal level (21 prosthetic, 12 autogenous), 19 were to the tibial or pedal arteries (16 autogenous, three prosthetic or composite), and 12 were to the femoral arteries (one autogenous, 11 prosthetic). Nine patch angioplasties (eight femoral, one popliteal) were performed. For graft revisions, endovascular intervention was for inflow in 13 cases, outflow in three cases, both in one case, and of the graft itself in 35 cases. Surgical revisions involved segmental grafts in 33 cases, patch angioplasty in 18 cases, and both in one case.**

Results: **In the primary group, the initial technical success rate of the endovascular procedure was 93% (68/73), with five patients needing open conversion. The 30-day mortality rate was 1.4%, and the morbidity rate was 11.0%. Of the 19 grafts in the primary group that occluded during the follow-up period (mean, 11.9 months), five thromboses could possibly be attributed to failure at the endovascular site. In the revision group, the initial technical success rate of the endovascular procedure was 88% (46/52), with six patients undergoing conversion to open procedure. The 30-day mortality rate was 0%, and the morbidity rate was 15.4%. Of 22 late graft occlusions in the revision group, only three were attributed to failure at the endovascular site.**

Conclusion: **This largest report to date of concomitant lower extremity endovascular and open revascularization procedures shows the approach to be safe. Few late graft occlusions were attributable to failure at the endovascularly treated site. The concomitant approach offers the efficiency and convenience of single stage therapy and allows immediate treatment for inadequate endovascular results or their complications and potential cost savings.** **(J Vasc Surg 2003;37:316-22.)**

Staged surgical revascularization after initial endovascular treatment has become a well-accepted treatment strategy for more than two decades in patients with multilevel lower extremity occlusive disease.[1-3] However, the durability of angioplasty in a setting where bypass grafts are dependent on the endovascular treatment site remains a reason for concern, as late hemodynamic failure rates of 40% to 65% for angioplasty have been observed in large prospective series.[4-7] As vascular surgeons have embraced the independent performance of endovascular procedures in the operating room over the last decade, the concomitant performance of endovascular and open revascularization as a single procedure has become more attractive. However, the published literature on immediate and late results of combined procedures is somewhat limited (Table I).[3,8-31] Suboptimal performance of endovascular procedures in an operative setting or inappropriate reliance on endovascular techniques might theoretically compromise graft patency. We questioned whether the concomitant approach is safe and whether late graft failure in this setting is frequently related to failure at the endovascular treatment site.

METHODS

Vascular surgeons have independently performed catheter-based procedures at Pennsylvania Hospital in a dedicated endovascular operating room since 1993.[32] A computerized vascular registry was reviewed to identify patients undergoing simultaneous endovascular and open treatment for lower extremity arterial disease between May 1, 1993, and June 30, 2001. All procedures were performed with anesthesia monitoring. Procedures were classified as BYPASS when a new arterial reconstruction was performed with adjunctive angioplasty or as REVISION when a previous reconstruction was treated with combined open and

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Table I. Largest published reports including concomitant open and endovascular lower extremity procedures

Author	*Year*	*Procedures*	*Endo sites*	*Endo success rate*	*Endo patency rate*	*Graft patency rate*
Motarjeme[10]	1981	21	*	90%	*	*
Pfeiffer[12]	1986	70	*	99%	*	*
Spoelstra[14]	1989	79	*	85%	80% at 3 y	*
Weber[15]	1989	78	93	97%	77% at 5 y	*
Chin[16]	1989	48	*	98%	58% to 81% at 2 y	*
Clement[17]	1990	44	*	91%	*	*
AbuRahma[19]	1992	84	85	95%	*	86% at 2 y
Gross[23]	1996	105	*	*	*	*
Schneider[24]	1997	21	28	100%	*	83% at 1 y
Madera[27]	1997	108	150	84% to 92%	58% to 100% at 2 y	*
Melliere[30]	1999	64	64	100%	*	*
Timaran[31]	2001	87	*	97%	79% at 3 y	63% at 3 y
Dougherty	2002	125	130	91%	*	65% at 5 y

Endo success denotes immediate technical success with angioplasty procedure.
*Insufficient data to estimate.

endovascular procedures. Demographic data were tabulated. The two groups were separately analyzed as to outcome events.

Postoperative duplex ultrasound scan surveillance was routinely used for all reconstructions. Causes and timing of graft failure were recorded; although causes of occlusion were not always certain, the status of the endovascular treatment site was assessed in all cases with operation, angiography, or noninvasive studies. For nominal variables, χ^2 analysis was used. Graft patency and limb salvage calculations were estimated with the Kaplan-Meier life-table method and compared with the log-rank test. Graft patency was defined with Society for Vascular Surgery/International Society for Cardiovascular Surgery consensus standards[33,34] and, for the purpose of this analysis, referred to the status of the operative reconstruction. Technical failure of concomitant angioplasty procedures was separately analyzed and reported, but these procedures were not censored from late patency analysis.

RESULTS

There were 73 procedures in the BYPASS group and 52 in the REVISION group. The total cohort was 106 patients, with some undergoing bilateral procedures or secondary reconstructions and some BYPASS patients later undergoing combined treatment and thus being separately analyzed as REVISION procedures. Thus, no combined procedures were excluded from analysis.

No differences were seen between the BYPASS and REVISION groups in age (mean, 69.3 years), gender (54.4% male), race (75.2% white), or prevalence of diabetes mellitus (52.8%), tobacco use (78.4%), hypertension (76.0%), or hyperlipidemia (47.2%). End stage renal disease was more common for BYPASS procedures than for REVISION procedures (17.8% versus 5.7%; $P < .05$).

Patients with combined inflow and outflow disease in whom an inflow procedure alone might have been sufficient were treated with a single or sequential procedure and therefore excluded from this analysis. During the time period reflected in this report, isolated inflow procedures were performed with an open (n = 147) or endovascular treatment (n = 107) approach. The indication for surgery in the BYPASS group was for limb salvage in 65 procedures, disabling claudication in six procedures, and popliteal aneurysm in two procedures. The open procedure was a secondary revascularization in 28 of 73 cases (38.3%). For REVISION procedures, surgical indication was a patent but failing graft in 34 cases and an acutely thrombosed graft in 18 cases.

In the BYPASS group, 77 lesions were treated in 73 procedures. The endovascular portion of the procedure was for inflow in 58 cases, outflow in 11 cases, and both inflow and outflow lesions in four cases. The angioplasty sites were the common iliac artery (n = 29), external iliac artery (n = 16), superficial femoral artery (n = 19), popliteal artery (n = 11), and tibial vessels (n = 2). Stents were deployed in 16 of 29 common iliac lesions and 13 of 16 external iliac lesions. The surgical revascularization was most frequently femoropopliteal (n = 33; 12 vein, 21 prosthetic) or infrapopliteal (n = 19; 16 vein, three prosthetic) bypass.

For the REVISION group, all procedures involved treatment of at least one lesion surgically and one endovascularly. In many cases, a more severe, longer lesion was treated surgically and a focal, less severe lesion was treated endovascularly. Fifty-three lesions were treated with balloon angioplasty in 52 procedures. Grafts were to pedal or crural arteries (n = 27; 22 autogenous, five prosthetic), popliteal arteries (n = 18; 12 autogenous, six prosthetic), aortofemoral (n = 4), femorofemoral (n = 2), and iliofemoral (n = 1). Lesions were in previously placed bypass grafts in 35 cases (distal anastomosis, 23; proximalanastomosis, 8; midgraft, 4), inflow arteries in 13 cases, outflow vessels in three cases, and both inflow and outflow arteries in one case. Stents were placed in 10 cases (iliac, 8; superficial femoral, 2). The open surgical procedure was a segmental bypass graft in 20 procedures, patch angioplasty in 18 procedures, interposition graft in 13 procedures, and both patch and interposition in one procedure.

Technical success, defined as <30% residual stenosis and no pressure gradient across the treated lesion, was

Table II. Angioplasty failure in BYPASS and REVISION groups

Location	*Graft type*	*Failure reason*	*Treatment*
BYPASS			
Common iliac	Prosthetic femoral-popliteal	Extravasation	Prosthetic ilio-femoral
External iliac	Vein femoral-popliteal	Nondilatable	Prosthetic ilio-femoral
External iliac	Prosthetic femoral-popliteal	Dissection	Prosthetic ilio-femoral
Superficial femoral artery	Vein popliteal-tibial	Embolization	Thrombectomy/vein patch
Popliteal	Vein popliteal-tibial	Nondilatable	Vein jump graft
REVISION			
Graft-proximal (superficial femoral artery; n = 2)	Vein	Nondilatable	Vein patch
Graft-distal (tibial)	Vein	Nondilatable	Vein patch
Graft-distal (tibial)	Prosthetic	Dissection	Prosthetic interposition
Graft-distal (peroneal)	Vein	Rupture	Vein interposition
External Iliac artery	Vein	Dissection	Prosthetic interposition

Table III. Perioperative morbidity for concomitant procedures

	BYPASS group (n = 73)	*REVISION group (n = 52)*
Death	1	0
Myocardial infarction	2	1
Wound infection	2	2
Hematoma	1	2
Lymphatic fistula	1	0
Graft infection/erosion	1	1
Pneumonia	1	1
Deep vein thrombosis	0	1
Total moribidity	8 (11.0%)	8 (15.4%)

achieved for the angioplasty procedure in 114 of 125 cases overall (91.2%). Angioplasty failure was treated with open conversion in five BYPASS and six REVISION procedures (Table II); graft placement was used in seven cases, and patch repair in four.

One cardiac death occurred in the series as whole, for a mortality rate of 0.8% (1.4% for BYPASS group, 0 for REVISION group). Morbidity was observed in 16 of the 125 procedures (12.8%), and complications are listed in Table III. In addition, early graft occlusion (<30 days) occurred in four BYPASS and two REVISION procedures and is reflected in patency calculations.

In a follow-up period that averaged 27.6 months (range, 2 to 75 months), graft occlusions occurred in 19 BYPASS patients and 22 REVISION patients. Life-table survival analysis is shown for the BYPASS group for end-points of primary patency, assisted primary patency, secondary patency, and limb salvage (Fig). Subgroup analysis for patency was limited by sample size but was compared for stent utilization (n = 29 with stent versus 44 without stent) and iliac angioplasty site (n = 45 iliac versus 28 infrainguinal). In comparison of assisted primary patency for patients with stent placement versus no stent and for iliac versus infrainguinal angioplasty site, no statistically significant differences were observed. We also were unable to discern a difference for inflow versus outflow angioplasty, but because the outflow group had only 13 patients, a type II error was possible.

Twenty-three revisions were performed on patent grafts in the BYPASS group, in most cases for duplex scan-diagnosed lesions. Of the 23, seven (30.4%) were for restenosis at the angioplasty site. These revisions account for the marked difference in primary and assisted primary patency survival curves.

For the 19 graft thromboses after BYPASS procedures (mean, 11.9 months after surgery), restenosis at the angioplasty site was noted in five cases and therefore possibly contributed to graft failure. Angioplasty sites for these occlusions were the common iliac artery in one case, the external iliac in one case, and the popliteal in three cases. There was a statistically significant higher risk of angioplasty site failure causing graft thrombosis for popliteal or tibial lesions (n = 11) than for more proximal lesions (n = 62; $P = .011$). Treatment for these failures was repeat angioplasty and new graft in three cases, patch revision and thrombectomy in one case, and no procedure in one case.

For REVISION procedures, patency analysis could not be performed with the life-table method because of the variable ages and patency history of the revascularization procedures revised, but apparent causes of graft failure were identified. Graft occlusion in the REVISION group occurred at a mean of 7.5 months in 22 grafts. In only three of these 22 was restenosis noted at the endovascular treatment site (external iliac, 1; popliteal, 1; tibial, 1). New grafts were constructed in two cases and a secondary revision was done in one case, and all have remained patent through a mean follow-up period of 12.5 months.

For 11 of the 19 thrombosed BYPASS procedures (57.9%), patients were delinquent for duplex scan surveillance (n = 9) or had duplex scan lesions that were being followed conservatively (n = 2) at the time of graft thrombosis. This included three of the five procedures where angioplasty site stenosis contributed to graft occlusion. Likewise for REVISION procedures, 15 of 22 procedures (68.2%) in which later thrombosis developed were for patients who had missed duplex scan surveillance (n = 10) or had abnormalities being followed conservatively (n = 5). Two of these were among the three procedures where angioplasty site restenosis was found to be the cause of graft occlusion.

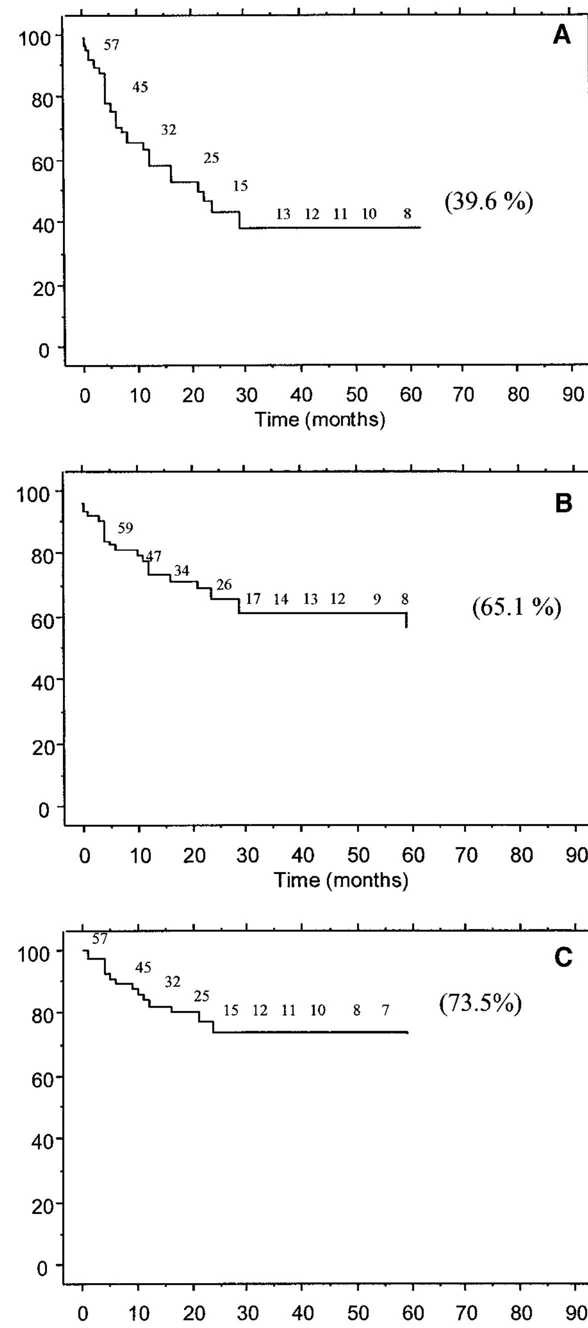
DISCUSSION

Over the last decade, vascular surgeons have assumed an increasing role in the performance of endovascular procedures. The development of new technologies, such as intravascular stents and stent grafts, has increased the pool of patients who can be treated with transluminal therapy. Increasing age and comorbidities in the population needing lower extremity revascularization has also made the less invasive approach more attractive.

The complementary use of endovascular procedures and subsequent surgical revascularization has been validated in a number of reports.[1,2,35-37] Brewster et al[1] reported a favorable 76% 5-year graft patency rate in 79 patients treated with preliminary iliac artery angioplasty followed by interim femorofemoral or femorodistal bypass. More recently, Faries et al[36] observed a 3-year graft patency rate of 71% in 126 patients treated sequentially with iliac artery angioplasty followed by infrainguinal bypass. Despite earlier concerns about the durability and reliability of angioplasty in the setting of downstream bypass grafts, the approach is now well accepted and often preferred in the setting of multilevel disease and limb-threatening ischemia.

The concept of combining angioplasty and surgery as a single procedure is not new. There are at least 25 published reports of combined procedures for lower extremity indications.[8-31] Table I summarizes the larger series where concomitant procedures were performed. In 1981, Fogarty et al,[8] Lowman et al,[9] and Motarjeme, Keifer, and Zuska[10] separately reported the earliest series of such concomitant procedures for lower extremity ischemia. Within the combined series of 55 patients, two angioplasty failures, one embolization, and three hematomas were the only reported complications. Despite these favorable early results, there was little enthusiasm for combining the procedures in the operating room for more than a decade. Putative advantages of separating the procedures have been cited, such as better imaging in the radiology suite, the ability to assess hemodynamic results of the angioplasty before more distal surgery, and (not the least) lack of catheter skills possessed by vascular surgeons.[1,14,18,35,38]

In the last decade, vascular surgeons have become increasingly interested in and experienced with performance of transluminal angioplasty and stent procedures. Numerous reports have documented the safety of performance of endovascular procedures by vascular surgeons in the operating room setting.[16,19,22,23,27-30,32,39,40] In the largest published series to date of comcomitant procedures, the report of Madera and colleagues[27] on angioplasty in the operating room included 108 combined open and endovascular procedures among 239 endovascular procedures performed by vascular surgeons on 200 patients. The immediate technical success rate of the angioplasty procedure was 90%, the highest for proximal lesions. The late patency



Kaplan-Meier plots of estimated primary patency rate (**A**), assisted primary patency rate (**B**), and secondary patency rate (**C**) for BYPASS group surgical reconstructions. Grafts or limbs at risk depicted. Note limb salvage plot includes eight of 73 procedures done for indications other than limb salvage.

rate of the angioplasty site ranged from 58% to 100%, with inferior results for more distal lesions.

In other smaller series, initial technical success was similar, but late patency results are less well defined, ranging from 0[29] to 86%[19] at 2 years. Whether the cause of late graft failure could be attributed to failure at the endovascularly treated site was not elucidated in most reports.

Areas of controversy exist. Some investigators have questioned the appropriateness of vascular surgeons, rather than interventional radiologists, performing endovascular procedures.[41,42] Some favor a staged approach with preliminary endovascular treatment in the radiology suite,[1,3,36,38,43] with at least the theoretic concern that suboptimal angioplasty results achieved in the operating room may compromise graft patency. Finally, we acknowledge that the vascular surgeon's ability to perform endovascular treatments might bias toward its preferential use even when open treatment may be more durable. We therefore questioned whether failure at the angioplasty site was in fact a frequent cause of late graft failure.

Our immediate results for combined procedures are similar to those reported by other groups. The 93% (BYPASS group) and 88% (REVISION group) initial technical success rates with the angioplasty procedures may have been somewhat higher if operative "bail-out" was not a ready option. Most technical failures were for suboptimal angioplasty results. We did not exclude these failures from patency calculations, although it might be argued that such an intent-to-treat analysis might dilute the true effect of concomitant endovascular treatment. Because this represented only 7% of the BYPASS group, the effect, whether positive or negative, was likely small.

Aside from the conversions to open procedures, there were no complications specifically attributable to the endovascular procedure itself in either group. Overall morbidity was as expected for the open surgical procedures alone, with no discernible added morbidity to combining the endovascular component.

Analysis of late results is confounded somewhat by the varying types of grafts and endovascular procedures performed. We acknowledge this limitation of our study—subgroup analysis was simply not possible for most variables because of small sample size. However, despite the variabity of patients and procedures, the overall finding that late graft failures were infrequently caused by failure at the endovascular site remains valid. Although seven of 23 revisions performed in the BYPASS group for failing but patent grafts were in fact for angioplasty site lesions, of 19 late graft thromboses, in only five was there evidence of restenosis at the angioplasty site as a potential contributor to graft occlusion. A more distal angioplasty site was more likely to be associated with graft thrombosis. Importantly, three of these five patients had failed to undergo scheduled duplex scan graft monitoring before graft occlusions, emphasizing the importance of careful duplex scan surveillance to enhance patency results.

The discordance of primary patency and assisted primary patency results reflects our aggressive treatment of lesions discovered on duplex scan surveillance. The cumulative assisted primary patency rate of 65.1% at 5 years is reasonable given the frequency of limb salvage indications, the prevalence of secondary operations, the multilevel nature of the occlusive disease, the need for prosthetic infrainguinal grafts in a substantial minority, and the significant subset (17.8%) of patients with end stage renal disease.

Although a previous randomized prospective study did not show superior patency with primary stenting,[44] we have more liberally used stents at the iliac position in recent years. Timaran et al[31] found significantly better bypass patency in patients with iliac lesions treated with stents compared with angioplasty alone and concluded that primary stenting should be performed when a bypass will be constructed downstream. We were unable to show improved graft patency with stenting, although a trend toward better results was noted.

Our findings in the REVISION group mirrored those in the BYPASS group, although meaningful life-table analysis was confounded by the varying age and patency histories of grafts at the time of the combined procedure. However, in tracking causes of graft thrombosis observed in late follow-up, in only three of 22 was there evidence of stenosis or occlusion at the angioplasty site at the time of graft occlusion. Again, two of these three cases were overdue for duplex scan surveillance.

Cost assessment was not a focus of this analysis. It is difficult to compare costs of sequential versus concomitant combined treatment, and the comparison greatly depends on local hospital factors and practices. However, with increasing sophistication of duplex scan and magnetic resonance imaging,[45-47] it may be possible to forego diagnostic arteriography in the radiology suite altogether in some patients with multilevel disease. This would certainly reduce resource utilization.

CONCLUSION

Although limited by the retrospective nature of this analysis and the heterogenous mix of procedures, our data support the adjunctive use of endovascular therapies by vascular surgeons in the operating room when performing open procedures for multilevel arterial disease. Late graft thrombosis is infrequently related to failure at the endovascularly treated segment. The combined approach is convenient for the patient, allows immediate treatment for inadequate angioplasty results, and may result in less resource utilization and cost. It is our bias, although not provable with the available data, that adjunctive inflow procedures fare better than outflow procedures and that primary stenting of the iliac segment is generally indicated. Careful postoperative duplex scan surveillance of both the graft and the endovascular site is crucial to maximizing long-term success.

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DISCUSSION

Dr Donald P. Spadone (Columbia, Mo). When you are doing these concomitant procedures, do you do the endovascular balloon first and then construct your bypass, or do you do the bypass first? A concern, of course, is clamping and having a static column of blood in the region where you have done your annuloplasty if you are constructing a bypass.

Dr Matthew J. Dougherty. We generally have performed the endovascular procedure first, and I have not observed thrombosis with the use of full heparinization with that approach.

Dr George Andros (Encino, Calif). Your technique for doing these procedures together in the operating room may be moot once we all have access to the angio suite and can couple the angiogram to the angioplasty. I would hope that you have a chance to isolate these two procedures in the future as we have for many years.

Are you using the classical approach to angioplasty and measuring pressures across the iliac lesion? Are you checking ankle pressures intraoperatively to see the effect of your intervention on the SFA occlusions and distal circulation? It is possible that in some cases you may not need the bypasses.

Dr Dougherty. We do routinely measure pressures, usually after the bypass is done, with papaverine to uncover any gradient.

Dr Andros. No, I mean the angioplasty, not the bypass.

Dr Dougherty. Yes, the angioplasty site, we routinely measure pressures to ensure hemodynamic success as well as angiographic success.

And the second part of your question was regarding separating the procedure, and I think your comment. We feel differently. We feel that the convenience factor of being able to do this all in one go is probably helpful. Now, there are occasional patients where you might choose to separate the procedures if you think an inflow procedure alone might be sufficient. Many of these patients were patients with extensive gangrene and ulcers, and we knew that we were going to have to do both inflow and outflow procedures from the outset.

Dr Thomas F. O'Donnell, Jr (Boston, Mass). Since your division has been very interested in hospital costs and there are data available from your previous studies, could you describe the difference in length of stay between these patients who had a combined procedure and those that received a standard infrainguinal bypass?

As a corollary to the question that Dr Andros asked about the use of angio suite. Once the length of stay is reduced, the prime driver of costs in vascular procedures becomes the cost of the OR. People could argue that it is less costly to do the angio dilatation and stenting in an angio suite and save the OR for the operative procedure alone. Would you comment?

Dr Dougherty. With regard to your first question, we actually did not look at length of stay in this rather heterogeneous group of patients as compared with bypass procedures performed alone. We did not have any angioplasty-related complications other than those that were treated immediately in the operating room, so it seems unlikely that any prolonged length of stay would be on the basis of the endovascular procedure. However, I think it is probably entirely possible that these patients have more advanced disease in general and probably had longer lengths of stay than the routine, single-level bypass.

With regard to your second question, it is a very difficult issue; and one of the reasons that cost has not been looked at well is it is very difficult to get the data. As many of you know, the formula for assessing charges for angiography suites is completely different than what is used in the operating room. But I would state that in general the level of resources utilized in terms of anesthesia support and other personnel is really pretty similar between the two. And the big advantage here would be if you can do a single procedure as opposed to both a diagnostic and a therapeutic procedure at separate times.

Dr Joerg Dieter Gruss (Kassel, Germany). Did you ever try to do the endovascular procedure through the prosthetic graft so as to perform first the proximal or distal anastomosis and then go with your device through the graft and dilate the artery?

Dr Dougherty. Yes, in fact, that is one of the advantages of this technique is that you can utilize a healthy graft rather than sometimes very diseased arteries for your access.