Results of peripheral endovascular procedures in the operating room

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Purpose: **This study presents the results of closed (percutaneous) and open endovascular procedures performed exclusively by vascular surgeons in the operating room and compares them with results from combined series from the literature, including primarily closed procedures in radiology or cardiology facilities.**
Methods: **Retrospective review of 607 consecutive peripheral arterial and venous angioplasties, stents, thrombolytic cases, and inferior vena caval filters in 446 patients was analyzed for immediate success rate, complication rate, and 1-year life table patency rate.**
Results: **The incidence of initial technical success was: aorta, 89%; iliac artery, 91%; superficial femoral artery, 90%; popliteal artery, 91%; tibial arteries, 79%; arm arteries and veins, 86%; renal arteries, 100%; IVC filters, 98%; and iliofemoral veins, 100%. The 1-year primary patency rates, including technical failures, were 70.3% in 113 femoropopliteal procedures and 83.7% in 194 iliac arteries. Advantages to the use of the operating room included: (1) simultaneous angioplasty during a bypass operation for abnormalities proximal or distal to the graft, (2) correction of lesions first discovered during thrombectomy, and (3) optimum patient monitoring and sedation in the operating room.**
Conclusions: **Endovascular procedures performed by vascular surgeons in the operating room lead to results comparable with procedures performed in nonsurgical interventional suites, and the use of the operating room has advantages. (J Vasc Surg 1996;24:353-62.)**

Depending on the medical community, patterns of referral, and experience, corrections of arterial or venous stenoses or occlusions by catheter techniques, angioplasty, thrombolysis, or stenting are performed by cardiologists, interventional radiologists, and vascular surgeons. Good published results have been presented by specialists in each of these fields.

In contrast to several other reported series in which endovascular procedures by surgeons always involve open exposure of the artery or vein, in our community vascular surgeons perform both percutaneous and open procedures. The purpose of this study is to compare the results of endovascular procedures performed exclusively by vascular surgeons in the operating room (OR) with a combined series from the literature, including percutaneous procedures performed in radiology or cardiology facilities and some open endovascular procedures performed by vascular surgeons. For the purpose of this article, transluminal arterial or venous procedures are considered "closed" if percutaneous access was used, and "open" if a surgical incision was used to expose the access site.

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MATERIALS AND METHODS

We retrospectively reviewed all consecutive balloon angioplasty, catheter-directed thrombolysis, stent, and venous filter procedures for arteries and veins that were performed between 1990 and 1995 at Huntsville Hospital and Crestwood Hospital in Huntsville, Ala., by the three authors, who are all certified vascular surgeons. Only mesenteric and portal procedures were excluded. Procedures intended and initiated but not completed were methodically found and included. These latter cases were found not only by identifying Current Procedural Terminology (CPT) codes for endovascular therapeutic procedures, but also by searching for CPT codes that represent endovascular cannulation alone, and including these charts in our review. Ninety-eight percent of the procedures were performed in the OR and 2% (because of scheduling difficulties) by sur-

geons in a multipurpose cardiac and peripheral catheterization facility. Endovascular procedures represent about 15% of our total vascular surgical operations.

Mobile C-arm imaging equipment, including Philips BV 29 release 2 (Philips Medical Systems, Eindhoven, Netherlands), and GE Stenoscop D6/D9 (General Electric Medical Systems, Milwaukee) allowed three-axis rotation, digital images with averaging, subtraction, pulsed fluoroscopy, roadmapping, and images at peak opacification. Resolution is between 525 and 576 lines per image.

Individual cases sometimes necessitated ipsilateral or contralateral femoral, or upper extremity punctures, either proximally or distally directed. In various cases we used guiding catheters, size 0.018-inch through 0.035-inch hydrophilic wires, systemic heparin, regional heparin, aspirin, and monitoring of activated clotting time. Palmaz stents, Wallstents, and Gianturco-Roubin stents were used, but only for residual stenoses or important dissection after balloon angioplasty. The Wallstent was preferred for contralateral femoral approach, across joints, and in lengthy stented segments. Iliofemoral venous access always was attempted retrograde from the jugular vein, but it sometimes required puncture of the popliteal vein (n = 2).

Pressure gradients across the lesion were measured before and after most iliac dilations, but not usually for infrainguinal lesions. Most cases did not require powered injection and hand-injection sufficed, sometimes with custom-made, low-resistance, short, multihole catheters. Retrograde sheath injection often worked well for iliac stenoses, with a total contrast dose <20 ml. Laser, intravascular ultrasound, and mechanical atherectomy have not been used, except for some early trial laser cases. Many occlusions responded to thrombolytic treatment, usually with catheter-directed infusion of urokinase, often for 3 to 48 hours, through standard coaxial arrangements, multihole catheters, or a single catheter embedded at the top of the thrombus.

Local anesthesia was sufficient for some cases, but epidural anesthesia was preferred for nonthrombolytic cases to improve patient comfort and thereby avoid needless premature termination of the more complicated procedures. In all but 10 cases, an anesthesiologist or anesthetist was present for the entire procedure. In three cases of epidural anesthetic, thrombolytic infusion treatment had not been anticipated and was performed at moderate dosage despite the epidural catheter, without complication, but the epidural hardware was not removed until after confirmation of nearly normal coagulation studies.

Standard life table calculations were used to determine primary patency rates at 1-year of follow-up. Referral and follow-up patterns preclude reliable vascular surgical office records of long-term endovascular successes after the first year, so life table statistics were not carried past 1 year. At death, loss to follow-up, or failure of the treated segment, patients were censored from numbers at risk. Failure included occlusion, restenosis, need for a secondary procedure, and most amputations. Amputations caused by occlusion at a site distal to the treated segment, with known proximal patency, were not withdrawn. Redone procedures were not reentered into the primary patency series. Technical failures were not counted again as complications. Endovascular management of a graft was included with the artery of the same level. Initial success was defined as (1) immediate technical result that converted stenosis or occlusion to stenosis <30%; (2) severe claudication, moderate claudication, rest pain, ulceration, or gangrene improved by one category; and (3) ankle/brachial index increased >0.10 in the absence of additional untreated lesions, or amplitude of pulse volume recording at least doubled in cases of falsely high ankle/brachial index.

An independent registered nurse hired for this study retrospectively tabulated parameters of success at outpatient visits. Continued patency implied no deterioration in the symptomatic category, no decrease of more than 0.10 in the ankle/brachial index, no decrease in an improved pulse volume recording, or direct confirmation of patency by duplex imaging or arteriography. Tandem treated lesions required careful and fair decision in some cases, leaning against falsely missed recurrence. Amputation at any level, including the toe, was considered a failure of primary patency unless separate data, as detailed above, confirmed patency. The patient's comfort level was evaluated by a questionnaire completed during an interview with the nurse.

To develop a control series of comparative current results for iliac and femoropopliteal segments, primarily in cardiology or radiology laboratories, several MEDLARS searches of multiple combinations of subject headings were carried out to locate series published between 1992 and 1995 that included more than 10 patients and in which at least the immediate technical success rate was reported. All of the following types of studies were excluded: (1) review articles with no original data; (2) restatements of duplicate patients from other publications; (3) FDA trials; and (4) most papers that did not report

long-term results. Some papers about tests of new devices and papers that compared specific new variations in treatment were included, but only the fraction of patients treated with generally accepted techniques were used. The combined series includes radiologic and cardiologic percutaneous procedures, but no operative percutaneous procedures, and is a suitable control group against ours. The series includes stenoses, occlusions, and stented cases. Because of the lack of open access in radiologic series, representative series that reported intraoperative results were included. Separate analysis, eliminating these surgical patients from the control group, does not alter the results in the control group.

Series that calculated patency by first excluding technical failures were corrected by adding back these patients to adjust the initial number at risk and patency rate. When such technical failures were not even counted and listed, adjustment was made by the combined initial failure rate for the other control papers. Determination of the cumulative number of grafts that were known to be patent or occluded at 1 year for series that did not include a table of actual patients lost to follow-up in each time interval was calculated as "weighted n" in the table, which is the initial number in the series multiplied by the occlusion rate implied by the patency curve at 12 months, added to the number of patients at risk in the following interval. Combined series patency then was calculated as the total number of patent grafts implied by adding the products of adjusted weighted n × patency and dividing by the sum of weighted n's. Some data were interpolated. Secondary patency rates for the combined series, often not reported, were not calculated. The results for the combined series were compared with those from our series with a χ^2 test after multiplying our primary patency or failure rate at 12 months by the number of patients then at risk.

Lower extremity arterial procedures were separated by arterial segment, including aorta, iliac artery, common femoral artery, superficial femoral artery, popliteal artery, or infrapopliteal arteries. Infrapopliteal vessels were defined as anterior tibial, posterior tibial, peroneal, dorsalis pedis, and tarsal branches, or grafts at these locations. Treatment of two separate segments at the same operation was tabulated as two separate procedures for immediate and long-term reporting. Common and external iliac arteries counted as one procedure, but superficial femoral and popliteal arteries were counted separately. Iliac arteries at their origin were not counted as an aortic procedure unless separate higher dilation of the aorta was performed. Limb-threatening ischemia is defined as ischemic rest pain, ischemic ulceration, or gangrene. Patients who had a very low ankle/brachial index but none of the clinical indications listed above were not classified as having limb-threatening ischemia.

RESULTS

Six hundred seven procedures were completed in 446 patients. Ninety-seven patients had Greenfield filters inserted. The method for inferior vena caval filter insertion was closed in 81 and open in 16, with the right jugular vein approach used in 84, and right femoral vein access in 13. One carotid needle puncture had no adverse effect. The most common reason for open placement was trouble encountered with expeditious percutaneous puncture in an anticoagulated patient. Open femoral access was used in two cases. In one patient who had right femoropopliteal venous thrombosis extending into the distal common femoral vein, transvenous subclavian pacing wire–dependence prevented safe jugular access. Open femoral exploration allowed us to positively stay above the common femoral vein thrombus. A similar approach was required for a similar venous thrombus in a case of coexisting infected subclavian central line. In two patients, filters were inadvertently deployed in the iliac vein. In both, a second filter was placed at a higher level, in the infrarenal inferior vena cava. In another patient who had pulmonary embolism and iliofemoral venous thrombosis, we bent a filter strut during successful venous thrombolysis, presumably penetrating the cava, but no adverse event was noted.

As detailed in Table I, technical success was achieved in most cases of renal artery, aortic, upper extremity artery, upper extremity vein, and iliofemoral venous angioplasty or lysis. Three hundred twenty-five patients underwent 478 procedures for lower extremity arterial occlusive disease. One hundred ninety-one male patients (59%) and 134 female patients had a mean age of 62 years (range, 30 to 94). Two hundred five patients had claudication (63%), and 120 had limb-threatening ischemia; 22% were diabetic. Of the 325 patients, 245 underwent a single procedure and 80 underwent additional procedures at the same time or at a separate time. The 80 patients with additional procedures included 124 procedures at additional sites (many bilateral iliac) and 29 secondary procedures at the same site. A secondary procedure was classified as primary failure of the original procedure and was not included in 1-year primary patency calculations. For records that did not clearly state the location or length of the lesion, original arteriograms were reviewed. Infrapopliteal

Table I. Lower extremity arterial and other endovascular procedures

	Procedure completed	*Procedure intended, but not completed**	*Technical failure at completion*	*Initial success/total procedures intended*	*Stenosis/occlusion indication for completed procedures*	*Open/percutaneous technique for completed procedures*	*Lytic Rx used*	*Stent used*
Aorta	9	0	1	8/9	9/0	2/7	0	2
Iliac artery	244	12	12	232/256	227/17	83/161	9	33
Common femoral artery	3	0	0	3/3	3/0	0/3	0	0
Superficial fem. artery	141	5	9	132/146	128/13	38/103	11	11
Popliteal artery	43	2	2	41/45	35/8	25/18	4	4
Infrapopliteal arteries	38	5	4	34/43	31/7	14/24	7	5
Upper extremity veins	13	0	2	11/13	9/4	10/3	3	5
Upper extremity arteries	8	1	0	8/9	8/0	4/4	0	0
Renal arteries	7	0	0	7/7	7/0	0/7	0	4
IVC filter	97	2	0	97/99	—	16/81	—	—
Iliofemoral veins	4	0	0	4/4	0/4	0/4	4	3

*Usually due to inability to traverse quidewire through lesion.

procedures included anterior tibial (7), peroneal (6), posterior tibial (9), tibioperoneal trunk (9), and pedal arteries (6). Procedures on bypass grafts in 27 cases were classified by the artery at the equivalent level of the treated lesion. Many graft procedures involved angioplasty of an anastomotic or perianastomotic narrowing. Patency results were unchanged when bypass grafts were omitted.

Patients were also classified according to the primary site that was originally treated, either aorta, iliac, or common femoral artery (AI), or infrainguinal (FPT) arteries. According to patients treated (rather than according to artery), the indication for intervention was limb-threatening ischemia in 28% of the AI group (51 of 180), and 51% of the FPT group (79 of 155). Eleven percent of the patients in the AI group had diabetes, compared with 35% of the patients in the FPT group. The mean age of AI patients was 59.6 years, compared with 64.8 years for FPT patients. When analyzed according to the procedures done, including additional procedures in the same patient, the indication for intervention was limb-threatening ischemia in 22% of AI procedures and 47% of FPT procedures (42% for femoropopliteal and 69% for infrapopliteal). Balloon diameter was usually 6- to 10-mm (especially 8-mm) for iliac artery, 3- to 8-mm (especially 5-mm) for femoropopliteal, and 2- to 5-mm (especially 3-mm) for infrapopliteal arteries. Thirty-one procedures needed lytic therapy, and 55 had one or more stents. The indication for placement of a stent in lower extremity arterial cases was arterial recoil in 46 procedures, unacceptably irregular dissection in six, and recurrent stenosis in three. Primary stenting was never performed for successful first balloon angioplasty of a lesion. In addition to the above procedures, 24 procedures were intended, but never completed, usually as a result of failure of guidewire traversal. Many were converted to open bypass.

Complications within 30 days included groin hematoma or pseudoaneurysm in 14 AI patients and three FPT patients (15 unoperated, two surgically corrected), distal embolization in three AI patients, contralateral embolization in one AI patient and in one FPT patient, acute thrombosis at the treated site requiring open operation in one AI patient and one FPT patient, occlusion of the contralateral iliac artery in a contralateral approach in two FPT patients, nonfatal myocardial infarction in three AI patients, infection at the access site in two AI patients, and one case of diffuse femoropopliteal vein graft spasm in popliteal angioplasty via the graft, resolved spontaneously after 4 days of anticoagulation. Eight procedures resulted in restenosis; all required a bypass operation during the same admission, including five infrainguinal bypasses and two aortofemoral or iliofemoral operations.

Five of 325 patients died within 30 days (three in the AI group, two in the FPT group), but four of these patients had additional bypass surgery in that time. Deaths included two patients with metastatic cancer, two myocardial infarctions (one occurred 7 days before endovascular intervention, the other 3 weeks later during resumption of jogging), and one patient who had septic shock. In two cases, complications occurred during stent deployment, both in

the iliac artery. In one, the stent was dislodged from the percutaneous balloon, coming to lie freely in the iliac artery, but it was retrieved on open femoral exploration. In another, a thin balloon engaged the strut of a Palmaz stent during open iliac angioplasty with femoropopliteal bypass. As a last step before directly exploring the iliac artery, the stent was forcefully extracted with the balloon, which resulted in an endarterectomy of the external iliac artery, with an acceptable result, that was patent at 2 years of follow-up.

For 38 completed infrapopliteal angioplasties, four complications occurred in 30 days. A stenotic, calcific peroneal artery that was treated by angioplasty with a 2.5-mm balloon at high inflation pressures caused extravasation and later occlusion, but no hematoma developed. In this case, concomitant posterior tibial-origin angioplasty sufficed to cause healing of the ischemic ulcer. A second infrapopliteal case had healing of a toe amputation, but prolonged hospitalization from cardiac arrhythmias and non–q-wave myocardial infarction, from which he recovered. A third patient who had extensive distal dissection of a diffusely diseased peroneal artery needed amputation, because femoral-pedal artery bypass was impossible as a result of diffuse beaded stenoses of posterior tibial, dorsalis pedis, and tarsal arteries. A fourth patient sustained deep venous thrombosis, which improved after anticoagulation.

Of the 160 open procedures, 105 required an open approach because a concomitant open vascular procedure was being performed. Of these, 56 were iliac angioplasties performed during femoropopliteal/tibial bypass. Thirty-one were femoropopliteal angioplasties performed to improve runoff during aortofemoral or femorofemoral artery bypass or revision. Five were aortoiliac or iliac angioplasties performed because of the discovery of a severe iliac artery stenosis as the causative lesion during transfemoral iliac thrombectomy. Four were infrainguinal angioplasties that were performed as a result of the discovery of a causative superficial femoral, popliteal, or tibial stenosis during transfemoral thrombectomy for distal thrombosis. Seven cases were transluminal corrections of a distal anastomotic or native arterial stenosis during segmental replacement or patch of a vein graft stenosis. One open case involved transluminal stenting of one limb of an 8-year-old aortofemoral graft after thrombectomy uncovered chronic excessive graft lengthening, with angulation and kink. In one case, clamp injury of an iliac artery during repair of an abdominal aortic aneurysm was immediately corrected by open, transfemoral, transluminal angioplasty, avoiding conversion to an aortofemoral graft, then with continued patency at 2 years. Fifty-five of 160 open procedures involved difficulty in percutaneous access. Twenty-two were planned because of worrisome, known, high anastomosis of a previous saphenous vein, polytetrafluoroethylene, or umbilical vein graft at the groin. Four procedures had a known pseudoaneurysm of a previous aortofemoral graft, which prevented safe percutaneous cannulation. In 29 procedures percutaneous access was attempted but was unsuccessful. Although we routinely perform high, antegrade cannulation of the common femoral artery with guidance of a wire into the superficial femoral artery, sometimes this technique cannot be used, which accounts for some of these conversions to open angioplasty. Others involve severely scarred groins caused by earlier procedures. In three cases, dense scar prevented sheath insertion, despite needle and guidewire entry.

Because of the difficulty in correlating hospital charges with actual medical resource use, we looked instead at length of stay (LOS). LOS was 4.5 ± 3.7 days for AI patients (median, 3 days; $n = 166$) and 6.1 ± 8.3 days for FPT patients (median, 3 days; $n = 140$), significant to $p < 0.03$. The most important risk factor for increased LOS is limb-threatening ischemia, with nondiabetic LOS of 4.1 ± 3.9 days ($n = 134$) in claudication, and 6.6 ± 4.3 days ($n = 71$) in limb-threatening ischemia ($p = 0.00004$), when compared with diabetic LOS of 4.0 ± 4.7 days ($n = 40$) in claudication, and 6.3 ± 5.3 days ($n = 35$) in limb-threatening ischemia ($p = 0.05$). Open angioplasty often included proximal or distal bypass, so an LOS of 7.22 days for open iliac angioplasty exceeded the 2.97-day LOS for closed iliac angioplasty. This latter LOS difference was not observed in FPT patients.

Thrombolytic infusion successfully recanalized seven of nine occluded iliac arteries, all of which required subsequent angioplasty, stents, or both. For infrainguinal arteries, thrombolytic recanalization occurred in 12 of 15 femoropopliteal arteries. One failed femoropopliteal thrombolysis patient had a history of repeated arterial thromboses and was diagnosed with a dysplasminogenemia. Of twelve femoropopliteal thrombolytic recanalizations, eleven arteries were treated with angioplasty after thrombolysis, but one did not require further treatment. The latter case was in a patient who had popliteal arterial occlusion after blunt trauma to the popliteal space with no orthopedic injury, and had a normal appearance after lysis of a 6-cm thrombus.

Early hemodynamic data are shown in Table II.

Table II. Lower extremity arterial endovascular procedures, Doppler results

	Preop ABI (mean ± 1 SD), n	*Postop ABI (mean ±1 SD), n*	*p* (Student's *t* test)
Aorta	0.65 ± 0.36, 12	1.06 ± 0.19, 12	$p < 0.01$
Iliac artery	0.61 ± 0.24, 136	1.02 ± 0.18, 178	$p < 0.001$
Common femoral artery	—	—	—
Superficial femoral artery	0.545 ± 0.26, 83	1.04 ± 0.17, 92	$p < 0.001$
Popliteal artery	0.48 ± 0.20, 17	0.965 ± 0.21, 19	$p < 0.001$
Infrapopliteal arteries	—	—	—

Primary patency rates, reported in Tables III and IV, were determined at 1 year. As a result of the resumption of follow-up by the primary care physician for successful cases, valid data were not available to determine patency reliably after 1 year. Secondary patency rates are not useful in this series because most symptomatic failures are treated with bypass surgery. Long-term life table results for iliac arteries begin with 256 procedures minus eight secondary procedures, for 248 arteries observed. Thirty-six were immediate or 30-day failures, for an 85.5% success rate at 30 days. During the subsequent year, one patient died, one was lost to follow-up, and 52 had uncertain follow-up information (though many were suspected patent) or did not reach 12 months' follow-up, for calculated withdrawal of 54 arteries. During that time, three were hemodynamic failures, and one had amputation because of iliac restenosis, for a total of four failures and an interval failure rate of 2.2%. For the 180 AI patients, two above-knee amputations, no below-knee amputations, no transmetatarsal amputations, and four toe amputations were performed in the first year. The cumulative 12-month patency rate is calculated at 83.7% (n = 194 followed to 1 year). Results of the control series and the current series for AI patients are reported in Table III. The 1-year patency rate is statistically no different from that of the control series (84.3%). We used stents less frequently (13.5% of arteries) and had a lower failure rate for guidewire traversal (4.7%), a lower complication rate (8.2%), but an equivalent rate of technical success.

Life table data for superficial femoral and popliteal lesions begins with 191 treated arteries minus 29 secondary procedures, leaving 162 to follow-up. Eighteen procedures were technical failures, which resulted in a first-day failure rate of 11.1%, and 144 procedures left for follow-up. For 155 FPT patients, 14 toe amputations, three transmetatarsal amputations, seven below-knee and two above-knee amputations were performed during the first year. During the first year, three arteries restenosed, one required later thrombectomy, and two required more aggressive dilation with a larger balloon for hemodynamic failure. There were 16 late hemodynamic failures, three amputations without proven patency, three deaths, 11 patients lost to follow-up, and 35 patients with outpatient data inadequate to evaluate patency or who had not yet reached 12 months. In the 1-day to 12-month interval, there were thus 25 failures and 49 withdrawals, for an interval failure rate of 20.9%, and a 1-year patency rate of 70.3% (113 patients followed-up to 1 year). This 1-year patency rate was significantly better than the patency rate of 56.2% for the control series ($p < 0.01$; Table IV). The immediate technical success rate of 90.6% was not significantly better than that of the control series.

In more than 50% of cases, interventions by anesthesia staff were found that are not usually performed in a typical dedicated angiography suite, including continuous monitoring of blood pressure and other hemodynamic parameters, with adjustments of fluid status, management of hyperglycemia, and monitoring of O_2/CO_2 level leading to respiratory assistance. In many cases adequate patient comfort required substantial narcotic doses and then temporary mask ventilation or reversal of drugs; this requirement allowed completion of a complicated procedure without premature termination. In at least 10 cases temporary endotracheal intubation was performed during sedation. Reactions to analgesic and sedative medicines, as well as cardiac arrhythmias, were promptly handled. In all cases, including both percutaneous and open access, the sterility of angioplasty balloons, catheters, and stents was optimized by the use of masks by all personnel, air filtration, and daily cleansing of operating rooms according to the standards of the Joint Commission on Accreditation of Hospitals.

Comfort level was surveyed in 63 patients. For patients who underwent both preoperative diagnostic arteriography in the radiology suite and intervention in the OR, the opinion of the patient or family members universally demonstrated less discomfort with therapeutic than diagnostic procedures, despite the greater complexity and time required for thera-

Table III. Iliac artery endovascular procedures

Publication	*n*	*Failure of guidewire traversal*	*Immediate technical success*	*Complication rate*	*Primary patency at 1 yr (%)*	*Weighted n*	*Adjusted patency (%)*	*Adjusted weight*	*Number of stented arteries*
Williams ('94)[1]	104	10/104	84/94	12/94	—	—	—	—	94/94
Jorgensen ('92)[2]	174	12/174	162/174	31/174	81	124	81	124	0/174
Blum ('93)[3]	47	1/47	46/47	7/47	95.7	37	93.7	38	18/47
Vorwerk ('92)[4]	125	22/125	103/125	5/125	94.6	86	94.6	86	85/85
DeMasi ('94)[5]	11	0/11	11/11	3/11	100	2	100	2	13/13
Lorenzi ('94)[6]	268	21/267	246/267	27/268	85.1	227	85.1	227	22/268
Bull ('93)[7]	46	—	46/46	5/46	77	36	77	36	0/46
Hsiang ('93)[8]	37	—	35.6/37	7.1/37	90	10	90	10	—
Wolf ('93)[9]	81	—	75/81	—	73.8	74	73.8	74	—
Nine series combined	893	66/728 (9%)	809/882 (91.7%)	97.1/802 (12%)			84.3	597	232/727 (32%)
Present series	256	12/256 (4.7%)	232/256 (90.6%)	21/256 (8.2%)	83.7	194	83.7	194	33/244 (13.5%)
χ^2, combined vs present series		$p = 0.04$	$p = 0.67$	$p = 0.1$			$p = 0.8$		

Table IV. Femoropopliteal arterial endovascular procedures

Publication	*n*	*Failure of guidewire traversal*	*Immediate technical success*	*Complication rate*	*Primary patency at 1 yr (%)*	*Weighted n*	*Adjusted patency (%)*	*Adjusted weight*	*Number of stented arteries*
Matsi ('94)[10]	140		184/208	6/168	47	126.5	42	143	2
Becquemin ('94)[11]	103	14/103	81/103	7/103	60	68.7	60	68.7	0
Ashleigh ('94)[12]	123	9/123	93/103	7/123	—	—	—	—	—
Hunink ('93)[13]	131	—	125/131	12/126	57	105	57	105	0
El-Bayar ('92)[14]	27	—	18/27	3/27	90	18	59	27	0
Currie ('94)[15]	51	—	40/51	10/51	42	46.6	42	46.6	—
Gordon ('94)[16]	57	—	42/57	—	29	57	29	57	0
Jeans ('94)[17]	137	14/137	107/137	—	59.6	133	59.6	133	0
Murray ('95)[18]	44	2/44	41/44	5/44	85.9	37	85.9	37	0
Vroegindeweij ('95)[19]	35	0/35	35/35	1/35	71	25	71	25	0
White ('95)[20]	32	0/32	32/32	2/32	83	28	83	28	31
Do ('94)[21]	160	—	—	—	69	112	59	112	—
Hsiang ('93)[8]	51	—	48/51	8/51	84.5	23	84.5	23	0
Wolf ('93)[9]	49	—	—	—	59	49	59	49	0
Fourteen series combined	1,040	39/474 (8.2%)	846/979 (86.4%)	61/760 (8%)			56.2	854	33/1040 (3.2%)
Present series	191	7/191 (3.7%)	173/191 (90.6%)	9/191 (4.7%)	70.3	113	70.3	113	15/184 (8.2%)
χ^2, combined vs present series		$p = 0.05$	$p = 0.15$	$p = 0.16$			$p < 0.01$		

peutic operations. Anesthetic services were not routinely available during diagnostic angiography, but are always used during angioplasty.

DISCUSSION

This series reports a large cohort of patients treated by vascular surgeons where endovascular procedures are routinely performed in the OR. Advantages of management by the vascular surgeon in the OR included the efficient correction of many lesions that were evident at open operation and were best repaired at that time. In addition, we avoided the infectious risk of a percutaneous procedure at the site of insertion of a prosthetic graft soon thereafter and obtained the additional benefit of simultaneous inflow and outflow repair, which is known to improve the patency of each site.[22,23] For safe monitoring and treatment, anesthesiologists at our institution prefer the use of the OR to the radiology laboratories for performing endovascular procedures. Also, the sterility that is required when the procedure is converted to an open operation is not possible in most radiology or cardiology suites, although at some centers substantial capital investment has allowed

dual endovascular/OR procedure rooms outside of the main OR complex.

Our 3-day hospital LOS for many percutaneous patients, due to separate diagnostic angiograms and endovascular procedures, can and will be reduced. On the other hand, it is likely that hospital stay for the 176 open procedures was lower than expected, either by avoiding a second day for converting percutaneous to open approach or by combining the endovascular step with the bypass or endarterectomy. Even when diagnostic and therapeutic endovascular interventions are combined into one event, the facility and personnel time that is conserved is often not evident because of a second direction or site of puncture and an additional contrast dose. Discussion with and permission from the patient and the family can be difficult when diagnostic study includes intervention. Evolving technologies, such as duplex ultrasound or magnetic resonance angiography, may permit elimination of diagnostic angiographic imaging in the hospital for many patients.[24,25]

Our results compare favorably with published iliac and femoropopliteal series. The data from the control groups may not be entirely comparable with the data in our series, partly because of differences in severity of ischemia and acuity, which are often difficult to quantitate for the publications used as our control group. Radiologic or cardiologic technical success for the dilation of aorta, renal, and infrapopliteal arteries, implantation of IVC filters, and lysis/angioplasty/stenting of iliofemoral venous thrombosis all exceed 90%, and our success compares favorably with that of these groups as well. This series demonstrates that endovascular techniques can be an important component of intraoperative treatment of peripheral vascular disease by vascular surgeons.

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DISCUSSION

Dr. Daniel F. Fisher (Chattanooga, Tenn.). When I was asked to discuss this paper, I quickly admitted that I had no personal experience dilating arteries and no personal experience placing stents into arteries after dilation. At Erlanger Medical Center in Chattanooga all of this work is done by a talented group of interventional radiologists, but fortunately we get the opportunity to evaluate most of these patients before they perform these procedures. I realize that I'm preaching to the choir, but most radiologists and cardiologists have very little or no understanding about the pathophysiologic mechanisms of and the indications for these procedures. Radiologists and cardiologists see arterial stenoses purely as a technical exercise. They put in a guide wire, they dilate the artery, they insert a stent, and then they forget about the patient. Virtually no meaningful follow-up is reported in the radiology or the cardiology literature.

This presentation on endovascular procedures is very unusual, and I think that patients in the Huntsville, Ala., area are the direct beneficiaries. First of all, all of these procedures were performed in the OR by a talented group of three surgeons who clearly have more patience with catheters than most of us. Second, strict preoperative indications were followed. Third, pressure gradients were measured in all of the larger arteries to ensure real results. Fourth, the anesthesiologists were involved with all cases to assure patient comfort and optimum cardiorespiratory monitoring. And fifth, 1 year of follow-up was presented for all patients, which by itself makes this paper distinctive in contrast to those published by the typical radiologist.

Dr. Gross, you mentioned that 27 procedures were attempted but never completed because of the failure to pass a guide wire through an obstructing lesion. In retrospect, do you believe that you wasted your time at even attempting to dilate these arteries, which certainly represent the toughest case for this technology? As all of us move into the area of managed care, will you be able to justify the additional time in the OR and expense of this technology to your referring physicians and medical care organizations?

For those of you who are interested in reading a superb critique of this subject, I would refer you to Dr. John M. Porter's editorial in the June 1995 issue of the *Journal of Vascular Surgery* (J Vasc Surg 1995;21:995-7). Dr. Porter, in his eloquent way, points out that we have no substantive cohort data that objectively establish the role of interventional therapy in any area of arterial or venous disease. Anecdotes abound, and hard data are scarce. Dr. Porter points out that in the past three decades the Vineberg procedure, chelation therapy, gastric freezing, carotid body excision, extracranial-intracranial bypass, and laser angioplasty have all been procedures that had initial enthusiasm but fell out of favor when proponents failed to prove efficacy.

The important questions are: (1) how often do these procedures succeed; (2) how often do they cause complications; (3) what is the relative cost; and (4) what is their overall therapeutic value in comparison with well-performed vascular surgical procedures. The individual who proposes something new clearly has the burden of proof to establish beyond a reasonable doubt that endovascular arterial intervention is as good as traditional vascular surgery.

Dr. Gary M. Gross. Regarding the 27 attempts that were not completed, all endovascular series have initial failures. They are often hidden in the data or not reported, but we tried to honestly and openly report them. Many were occluded arteries. We initially do not know whether they are completely filled with plaque and calcification with an inaccessible lumen or whether they are partly thrombus. Testing with a guidewire is useful information in determining whether the lesion can potentially be opened with balloon dilatation or lytic therapy. Failure in our intention to perform an endovascular procedure is a successful diagnostic step in the decision to move on to a different treatment, which was often an immediate bypass operation at that time. In some circumstances, such as in very obese patients, failure of percutaneous access did not cause failure of the endovascular procedure because we were able to immediately convert to safe, open, endovascular access in a sterile OR.

In answer to the managed care setting and the justification of procedure time and expense, our length of stay was reasonable. In many patients we are now eliminating the postoperative observation day. For many cases we thought we reduced the cost of care by performing the endovascular step during the open procedure, such as repair of the causative stenotic lesion during arterial thrombectomy. I don't know that the operating room is necessarily more expensive than other hospital procedure suites. Hospital charges are often higher, but actual hospital resources expended are not higher. Despite the stated hourly hospital OR charge, the resources used per procedure for regular endovascular operations in an OR, including the number of nursing personnel, are considerably lower than, for example, an open aneurysm repair in that same OR.

Dr. Ali AbuRahma (Charleston, WVa). I admire the presentation of such extensive experience in terms of angioplasty. I perform roughly half, or maybe closer to a third, of the endovascular procedures in our institution; the other two thirds are performed by two radiologists and one cardiologist. But I am confining myself to what is approved by the FDA: iliac stenting and, of course, various balloon angioplasties plus filters. Because you have performed so many of the stenting procedures outside the territory of the iliac artery, which is primarily Palmaz and of course Wallstent, are you following certain institutional review board protocols? Are you explaining to these people that the procedures are not being accepted still by the government in these situations?

Secondly, only one specific polyethylene balloon by Meditech is approved for iliac angioplasty with a stent. The sheaths for these are 8F to 10F. If done percutaneously, that's a big hole. Are you modifying it like some of my cardiologists who are doing it using other balloons? And if you are, are you again explaining to the patient that the government did not approve that stent on that balloon?

I originally did not want to ask this question, but I heard you talk about the expenses. We made a deal with our hospital administration about needing a special type of arrangement in terms of expenses where we make the operating room cost equivalent to the cardiac catheterization facility and the radiology suite. It worked out very well with us, so whenever we perform an angioplasty the cost has been modified to be comparable to the cost of whatever it costs in the cardiac catheterization facility.

Dr. Gross. We only use stents approved by the FDA. In obtaining consent, I frequently tell the patient's family that the FDA does not prohibit additional device applications chosen by the physician for an individual patient, but current FDA regulations may not have yet extended approval for the company or physician to promote the product for the specific artery to be treated. Then I quote the known reported experience in these other locations, so the patient knows these issues. I now seldom use stents premounted on balloons, but prefer myself to mount the best stent for that lesion on the best balloon for that lesion. These products are changing nearly every week. The thinner balloons are becoming stronger, so we can often use a smaller or more compliant balloon, and a smaller sheath or catheter.

Regarding expense accounting, in the future, when physician-led independent practice associations or health maintenance organizations bargain with hospitals for determining reimbursement, a single price for OR setup and time must be replaced by a price related to resource use, which is lower for endovascular than for other vascular procedures. Your formula to compare with a cardiology or radiology laboratory is an appropriate and good idea.