Intravascular ultrasound scanning improves long-term patency of iliac lesions treated with balloon angioplasty and primary stenting

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Purpose: **Underdeployment of an intravascular stent has been identified as a cause of restenosis or occlusion of a treated arterial lesion. Intravascular ultrasound (IVUS) has been shown to initially improve the anatomic and clinical stenting. The purpose of this study was to determine whether the use of IVUS increased long-term patency of this intervention.**

Methods: **Between March 1992 and October 1995, 71 limbs (52 patients) with symptomatic aortoiliac occlusive disease underwent balloon angioplasty with primary stenting. IVUS and arteriography were used in 49 limbs (36 patients) to evaluate stent deployment. Arteriography alone was used in 22 limbs (16 patients) to evaluate stent deployment. Patients were captured prospectively in a vascular registry and retrospectively reviewed.**

Results: **Mean age of patients treated with IVUS was 61.1 ± 9.0 years (range, 38-85) versus 70.0 ± 10.1 years (range, 57-87) in patients treated without IVUS ($P < .01$). There was no difference between the groups with respect to preoperative comorbidities, ankle-brachial indices, or number of stents per limb. Mean follow-up for IVUS patients was 62.1 ± 7.3 months (range, 15-81) and 57.9 ± 8.7 months (range, 8-80) for patients treated without IVUS (P = not significant). In 40% (20/49) of limbs, IVUS demonstrated inadequate stent deployment at the time of the original procedure. Kaplan-Meier 3- and 6-year primary patency estimates were 100% and 100% in the IVUS group and 82% and 69%, respectively, in limbs treated without IVUS ($P < .001$). There have been no secondary procedures performed in limbs treated with IVUS and a 23% (5/22) secondary intervention rate in the non-IVUS group ($P < .05$). Overall Kaplan-Meier survival estimates at 3 and 6 years for all patients were 84% and 67%, respectively.**

Conclusion: **Balloon angioplasty and primary stenting of symptomatic aortoiliac occlusive lesions is a durable treatment option. Long-term follow-up of treated patients shows outcomes that are comparable with direct surgical intervention. IVUS significantly improved the long-term patency of iliac arterial lesions treated with balloon angioplasty and stenting by defining the appropriate angioplasty diameter endpoint and adequacy of stent deployment. (J Vasc Surg 2002;35:316-23.)**

Intravascular stents are used as a means of improving the patency of arterial occlusive lesions that have undergone treatment with balloon angioplasty by reducing the incidence of technical failure and restenosis.[1,2] Underdeployment of an intravascular stent has been identified as a cause of restenosis or occlusion of a treated arterial lesion.[3] Intravascular ultrasound scanning (IVUS) is a catheter-delivered imaging system that provides an accurate measurement of the diameter of both diseased and true lumens of arteries.[4,5] It can be used as a means of evaluating plaque morphology and structural information related to the arterial wall for calcification, branch vessel location, and extent of disease involvement. It is also a means of assessing the adequacy of stent deployment and provides the measurement information necessary for complete expansion of a stent to ensure its full apposition to the arterial wall.[6-8] Earlier studies have shown that arteriography, when compared with IVUS, fails to provide accurate information about stent deployment in as many as 40% of iliac arteries treated with balloon angioplasty and stenting.[9-14]

The purpose of this study was to determine whether the use of IVUS influenced the long-term patency of aortoiliac occlusive lesions treated with balloon angioplasty and primary stenting.

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METHODS

Patients. Between March 1992 and October 1995, 71 consecutive limbs (52 patients) with aortoiliac occlusive disease underwent balloon angioplasty and primary stenting of symptomatic iliac lesions at a single center multi-specialty clinic. All patients were entered prospectively in a vascular registry, and their clinical course and outcomes were retrospectively reviewed. In 1998, we reported initial and intermediate results (mean, 28 months), which suggested that those patients whose iliac

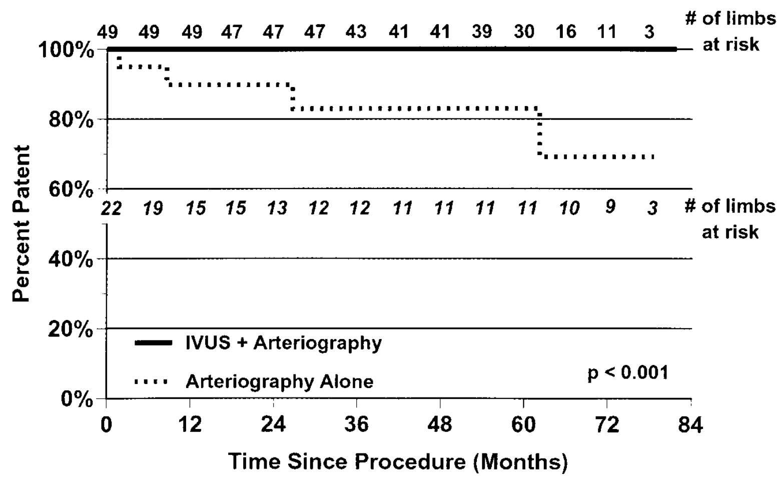

Fig 1. Kaplan-Meier estimates of vessel patency for both the group of limbs evaluated with IVUS and the group of limbs not evaluated with IVUS.

arterial occlusive lesions were evaluated with IVUS at the time of endovascular treatment had improved outcomes.[3,10] All patients have been observed in the long term and serve as the cohort for this report. IVUS and arteriography were used in 49 limbs, and arteriography alone was used in 22 limbs as a means of evaluating stent deployment.

The indications for treatment were categorized with classifications suggested by Rutherford et al[15] and included disabling claudication in 59.6% of cases, ischemic rest pain in 26.9% of cases, and tissue loss in 13.4% of cases. Subjects were examined before treatment by using both noninvasive lower-extremity arterial testing and arteriography.

Operative technique. We have described in detail the equipment and techniques used for treating the 52 patients in this ongoing study.[3] All patients were pretreated with at least 162 mg of aspirin preoperatively and underwent systemic anticoagulation with heparin intraoperatively to achieve an activated clotting time (ACT) of two times normal. Iliac occlusive lesions were treated with balloon angioplasty and primary stenting by using Palmaz balloon expandable stents (Johnson & Johnson International Systems, Warren, NJ). Most procedures (67/71 limbs) were performed with an open femoral artery exposure technique. Associated femoral arterial occlusive lesions (15/67 limbs) were managed by means of direct surgical repair (endarterectomy, patch angioplasty) at the time of the endovascular intervention. Treated lesions included 64 limbs with hemodynamically significant stenoses (resting systolic pressure gradient >20 mm Hg) and seven total iliac occlusions.[3]

IVUS and arteriography were used as a means of evaluating iliac artery diameter and stent deployment in 49 treated limbs. A 20-MHz or 30-MHz ultrasound transducer (Hewlett-Packard Sonos Intravascular, Andover, Md) was used as a means of imaging the vessel. IVUS measurement of actual vessel diameter was used as a means of determining the size of the angioplasty balloon catheter and stent. A stent was considered underdeployed when any part of the stent was not in complete apposition to the arterial wall. Underdeployed stents identified by means of IVUS underwent further expansion with a larger angioplasty balloon until complete stent-to-vessel wall apposition occurred. Pull down pressure measurements were made across each treated lesion in both the IVUS plus arteriography group and the arteriography alone group.

In the 22 limbs evaluated by means of arteriography alone, angioplasty balloon diameter and stent size used for treatment of the occlusive lesion were derived from diameter measurements of the non-stenosed segment of either the ipsilateral or contralateral iliac artery. The measurements were made in a "normal" vessel either proximal (preferably) or distal to the lesion identified for treatment. The use of the distal measurement was avoided whenever possible to exclude the post-stenotic dilatation effect.

Postoperatively, all patients received 162 mg of aspirin and 150 mg of dipyridamole daily, which was continued indefinitely. Those patients (7 in the IVUS plus arteriography group and 2 in the arteriography alone group) who had their distal abdominal aorta and common iliac arteries reconstructed with bilateral stents by using the "kissing balloon" technique and whose stents were in apposition at the aortic bifurcation underwent anticoagulation with Coumadin (international normalized ratio, 2.0-2.5) for a period of 3 to 6 months.

Postoperative surveillance. The preprocedural and postprocedural clinical records, arteriograms, segmental limb pressure measurements, and pulse volume recordings of all patients were retrospectively reviewed. Postoperative follow-up of all patients included clinical examination and noninvasive lower-extremity vascular testing at 3, 6, and 12 weeks and at 6-month intervals thereafter. Noninvasive lower-extremity vascular testing consisted of segmental

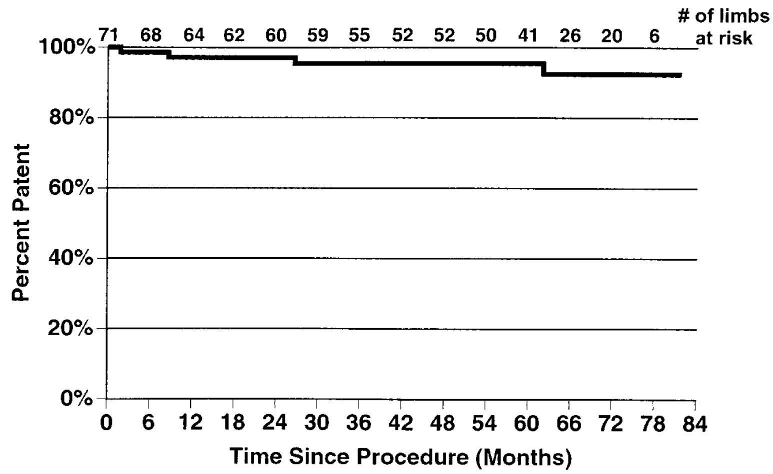

Fig 2. Kaplan-Meier estimates of vessel patency for all limbs studied.

systolic limb blood pressure measurements, segmental air plethysmographic recordings (pulse volume recordings), and selective use of Doppler waveform evaluation. Duplex imaging was used when necessary as a means of evaluating stent patency and measuring flow velocities. Repeat arteriography was used when indicated by means of abnormal clinical information (severe claudication or ischemic rest pain) or noninvasive vascular testing. Abnormal vascular testing was defined as a 30 mm Hg or greater segmental systolic pressure drop across the treated lesion or significant deterioration (category change) in pulse volume recordings in the affected limb.

The limitations of clinical and noninvasive follow-up as a means of evaluating endovascular procedures on the iliac arteries required that each intervention be assessed on a per-limb basis by using several hemodynamic and clinical criteria. Each limb was observed from the time of the initial procedure to the time of a second intervention on that limb or to the time of last follow-up. Secondary interventions were subjected to the same follow-up protocol that was used for primary interventions. Determinations of success and failure were made on the basis of the suggested standards for reports that deal with lower-extremity ischemia.[15-18]

Statistical analysis. All averages are given as the mean plus or minus the SEM. Age, number of stents deployed per limb, preoperative ankle-brachial indices (ABIs), and postoperative ABIs were analyzed by using the two-sample *t* test. Other variables, including demographics, complications, restenosis, morbidity, and mortality, were evaluated by using the Fisher exact test. Kaplan-Meier estimates were used as a means of evaluating patency and survival. *P* values less than .05 indicated statistical significance.

RESULTS

The mean age of patients who were examined with IVUS plus arteriography was 61.1 ± 9.0 years (range, 38-85 years) versus 70.0 ± 10.1 years (range, 57-87 years) for patients examined with arteriography alone ($P < .01$; Table I). There were no statistical differences noted between the two treatment groups in the presence of comorbidities, including coronary artery disease, diabetes mellitus, chronic obstructive pulmonary disease, hypertension, obesity, or length of follow-up. Also, the number of stents used per limb and the preoperative and immediate postoperative lower-extremity arterial testing results were comparable in both groups (Table II).

In the IVUS plus arteriography group, the anatomic site of the treated atherosclerotic lesion was the common iliac artery in 35 limbs (72.2%), the external iliac artery in eight limbs (16.6%), and a combination of the common and external iliac arteries in six limbs (11.1%). There were seven recanalized total iliac arterial occlusions in this group. The ipsilateral superficial femoral artery was documented by means of arteriographic examination to be widely patent or bypass grafted in 35 limbs (72.2%), stenotic in six limbs (12.2%), and occluded in eight limbs (16.6%).

In the 22 limbs evaluated with arteriography alone, the common iliac artery was treated in 18 limbs (81.2%) and the external iliac artery in four limbs (18.8%). There were no iliac artery occlusions in this group. The ipsilateral superficial femoral artery was documented by means of arteriographic examination to be patent in 18 limbs (81.2%), stenotic in three limbs (12.5%), and occluded in one limb (6.2%).

Forty percent (20/49) of limbs were found to have underdeployed stents by means of IVUS evaluation, although they appeared to be adequately expanded by means of arteriography. Further stent expansion with a larger balloon was necessary for accurate stent-to-vessel wall apposition. After the procedure, pull down pressure measurements were made across the treated lesions, and no gradient was accepted in either group of patients. Completion arteriography was also accomplished at that time.

Table I. Demographics

	Without IVUS (%)	*With IVUS (%)*	P *value*
Number of limbs	22	49	
Mean age (y; range)	70 ± 10 (57-87)	61 ± 9 (38-85)	< .01
Comorbidities			
CAD	22 (100)	44 (89)	.30
Chronic tobacco use	19 (88)	44 (89)	1.00
COPD	15 (69)	41 (83)	.28
Diabetes mellitus	11 (50)	12 (25)	.11
Obesity	3 (13)	5 (11)	1.00

IVUS, Intravascular ultrasound scanning; *CAD,* coronary artery disease; *COPD,* chronic obstructive pulmonary disease.

Table II. Treatment comparisons

	Without IVUS (range)	*With IVUS (range)*	P *value*
Number of limbs	22	49	
Preoperative ABI	0.44 ± 0.12	0.43 ± 0.16	.91
Immediate postoperative ABI	0.81 ± 0.14	0.82 ± 0.15	.90
Mean number of stents used	1.7 ± 1.0 (1-3)	1.8 ± 1.2 (1-3)	.46

IVUS, Intravascular ultrasound scanning; *ABI,* ankle-brachial index.

Associated significant occlusive lesions in the common femoral, proximal profunda, and/or superficial femoral arteries were managed at completion of the endovascular procedure with localized endarterectomy and patch angioplasty repairs. The adjunctive procedures were necessary in 22.4% (11/49) of limbs in the IVUS plus arteriography group and 22.7% (5/22) of limbs in the arteriography alone group (P = not significant; Table III).

Long-term follow-up of patients. Complete long-term clinical follow-up was available for 50 of 52 patients (96%). A mean follow-up period of 62.1 ± 7.3 months (range, 15-81 months) was achieved for the IVUS plus arteriography group. The mean follow-up for patients examined and treated with arteriography alone was 57.9 ± 8.7 months (range, 8-80 months; P = not significant).

Patients examined with intravascular ultrasound scanning. There were no restenoses or occlusions in the IVUS plus arteriography group, as measured indirectly by using the criteria outlined by Ahn et al.[18] A sustained improvement in the ABI was documented in all 49 limbs at the time of last follow-up. The mean ABI improvement was 0.39 from the preoperative measurement ($P < .000001$). Kaplan-Meier 3-year and 6-year primary patency estimates were 100% and 100%, respectively, in the IVUS plus arteriography group (Fig 1). No limbs in the IVUS plus arteriography group underwent repeat arteriographic examination because of suspected restenosis or occlusion of the treated lesion. However, eight patients underwent either coronary or cerebral arteriography and had incidental arteriographic evaluation of the earlier balloon-dilated and stented iliac lesions that were found to be patent.

Patients examined with arteriography alone. Seventeen of 22 limbs (11/16 patients) evaluated and treated with arteriography alone had a sustained mean ABI improvement of 0.37 from the preoperative measurement to that taken 3 years after their primary intervention ($P < .000001$). Kaplan-Meier 3-year and 6-year primary patency rate estimates were 82% and 69%, respectively.

Early restenosis or occlusion of stented lesions occurred in 18% (4/22) of limbs evaluated and treated with arteriography alone ($P < .01$) after a mean follow-up period of 5.5 months (range, 4 to 7 months). These early failures were evaluated indirectly by means of criteria outlined by Ahn et al.[18] Severe restenoses (2 patients) and occlusions (2 patients) at the site of the earlier stented lesions were documented by means of subsequent arteriographic and IVUS evaluations. Underdeployed stents were demonstrated by means of IVUS in all four cases. Femoral artery outflow was not considered to be a factor in these four failures because the superficial femoral artery was widely patent in three limbs and occluded at the adductor canal in the fourth case. This latter case had a large widely patent profunda femoris artery. Additional endovascular intervention was necessary to salvage these reconstructions. They remained patent through their last follow-up evaluation.

Two late failures occurred in the group treated with arteriography alone. One of these failures was documented by means of arteriography to be related to occlusive disease progression in the treated limb, including the earlier balloon-dilated and stented common and proximal external iliac arteries. This patient was treated with standard prosthetic aortobifemoral arterial bypass grafting surgery, and this reconstruction remained patent until the patient's death 2 years later. The second late failure was not evaluated by means of arteriography because of the patient's other comorbid conditions, which precluded consideration for intervention. An above-knee amputation

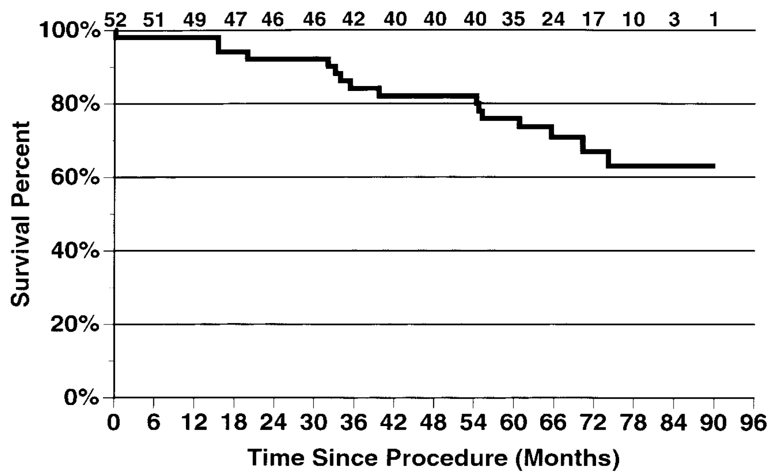

Fig 3. Kaplan-Meier estimates of patient survival.

Table III. Adjunctive femoral artery procedures

	Without IVUS	*With IVUS*
Adjunctive procedure	5/22 limbs (22.7%)	11/49 limbs (22.4%)
Common femoral endarterectomy and patch angioplasty	1	4
Common femoral/profunda femoral endarterectomy and patch angioplasty	3	5
Common femoral/proximal SFA endarterectomy and patch angioplasty	1	2

IVUS, Intravascular ultrasound scanning; *SFA,* superficial femoral artery.

was performed in this patient. There were no secondary procedures performed in limbs evaluated and treated with IVUS plus arteriography. This contrasts with a secondary intervention rate in the arteriography alone group of 23% (5/22 limbs; $P < .05$). The overall patency rate for the 71 limbs, by means of Kaplan-Meier estimates, in this study was 94% at 6 years (Fig 2).

Perioperative morbidity and mortality. Perioperative complications occurred in four of 52 patients (7%). A severe myocardial infarction resulted in death within 30 days of operation in a patient examined and treated with arteriography alone (2% overall mortality rate for the whole series). One vessel perforation in the IVUS-assisted group occurred during angioplasty of a heavily calcified vessel and required direct surgical repair. This vessel perforation occurred during the balloon dilatation before stent deployment. The initial balloon size was determined by means of angiographic criteria, and as a result, the complication could not be related to the use of either the stent or IVUS. One groin hematoma occurred in both groups, and one lymphocele developed in the IVUS-assisted group. These were treated conservatively. No statistical difference was noted in the complication rates in the two groups.

Survival analysis. Overall Kaplan-Meier survival estimates for this group of patients with significant aortoiliac occlusive disease were 84% at 3 years and 67% at 6 years (Fig 3). Late cardiac events accounted for mortality in 68% of the patients who died.

DISCUSSION

Intravascular stents are used as a means of improving the results of balloon angioplasty by compressing disrupted atheroma, intima, and media against the vessel wall and thereby maintaining the integrity of the balloon-dilated arterial lumen. Balloon angioplasty and stenting of aortoiliac occlusive lesions is an acceptable course of management for this disease process. Five-year patency rates for balloon angioplasty of iliac occlusive lesions range from 59% to 87% in several reported series.[19-22] When endoluminal stenting is added to the angioplasty procedure, patency rates from 63% to 100% have been reported by recent studies, with follow-up periods ranging from 2 to 6 years. However, several of these studies had inadequate follow-up and surveillance of these patients.[23-25]

The strength of our study is the very close vascular surgery follow-up of 71 consecutive limbs treated with balloon angioplasty and primary stenting of symptomatic iliac occlusive lesions. The patients in this study received continuous care in a multi-specialty clinic environment, and 96% of their treated limbs had complete vascular follow-up at a mean of 5 years.

Arteriography has historically been the standard means of evaluating endovascular treatment and delineating the severity and extent of arterial occlusive disease. Arteriography visualizes contrast within the lumen of a vessel and presents a two-dimensional representation of a threedimensional structure. In some circumstances, heavy vessel wall calcification can be identified at the time of arteriography. No information about plaque morphology or true non-diseased vessel diameter can be obtained by means of conventional arteriographic techniques. Because of magnification and imaging angle, the actual severity of an arterial lesion may be misrepresented.[26]

Multiplane arteriographic views would be required to adequately evaluate the degree of stenosis at any given lesion site, because most atherosclerotic lesions are eccentrically located within the vessel.

The real time 360° cross-sectional imaging of an artery provided with IVUS permits an accurate measurement of both diseased and true lumen diameters of vessels, defines the composition and extent of occlusive lesions, and accurately assesses the results of an endovascular intervention.[6-8,10-14,27] Arteriography has been shown to underestimate the true diameter of the vessel as much as 50% of the time.[3] Incomplete apposition of a stent to the arterial wall was not detected by means of arteriography in 20% to 40% of patients subsequently examined with IVUS.[3,9,10] Another study using IVUS in the coronary circulation showed that 80% of stents needed further balloon expansion for complete vessel wall apposition, although their deployment was thought to be optimal by means of coronary arteriographic assessment.[28] In our study, IVUS was used as a means of measuring the true arterial lumen diameter, and this information influenced the selection of the size of the angioplasty balloon and stent used to treat the occlusive lesion. It was also used as a means of determining the adequacy of apposition of a deployed stent to the vessel wall and identifying any complications that might require additional treatment (dissection, etc). Inadequate vessel dilatation and incomplete stent deployment have been identified as suspected causes for restenosis or occlusion of treated lesions.[3] Incomplete apposition of a stent to the arterial wall leaves a space where platelets, fibrin, and thrombus accumulate. If this area is in contact with fractured intima and/or media of the vessel wall, we postulate that it may serve as a nidus for initiating the restenotic process.

It has been suggested that over-dilatation of a balloon-dilated and stented lesion could be used in place of IVUS guidance as a means of obtaining complete stent-to-vessel wall apposition.[26] However, angioplasty over dilatation runs the risk of vessel disruption, especially in heavily calcified vessels or moderately diseased external iliac arteries. Additionally, despite satisfactory coronary arteriographic findings, Columbo and associates found that after routinely over-dilating stented coronary lesions, in approximately 30% of cases, stents were shown by means of subsequent IVUS evaluation to still be underdeployed or other procedure-related problems were identified that required additional treatment.[28,29]

The weaknesses of this study are that it is retrospective, that it has fewer numbers of limbs in the group examined by arteriography alone, and that all procedures were done with an open femoral artery exposure technique. Also, a statistically significant younger population comprised the IVUS plus arteriography group. Sullivan et al[30] reported that age can be associated with initial and late failure of iliac artery angioplasty and primary stenting, and therefore, the age difference in the two groups may have had some effect on outcome.

Other than the difference in age, the treated lesions and extent of occlusive disease in the two groups were comparable. Furthermore, the IVUS plus arteriography group had seven limbs with complete iliac arterial occlusion and six limbs with common and external iliac artery lesions that required treatment. This implies that these 13 limbs had more severe disease involvement, yet all have remained patent to date.

Ipsilateral superficial femoral artery patency has been described as a factor contributing to the long-term results of iliac arterial angioplasty and stenting.[15-17] Sullivan et al[30] found a positive correlation between superficial femoral artery patency and the patency of ipsilateral balloon-dilated and stented iliac lesions. In our study, the superficial femoral artery was patent or bypass grafted in 35 limbs (72%) in the IVUS plus arteriography group and in 18 limbs (81.2%) in the group evaluated with arteriography alone. The superficial femoral artery was considered to be stenotic in six limbs (12.2%) in the IVUS plus arteriography group and in three limbs (12.5%) in the group evaluated with arteriography alone. These data suggest that femoral artery outflow for both groups was comparable. The IVUS group did have more occluded superficial femoral arteries (8 limbs, 16.6%) compared with the arteriography alone group (1 limb, 6.2%). This suggests that limbs in the IVUS group may have had more diffuse occlusive disease. However, because most procedures were performed through open exposure of the femoral artery, any associated occlusive lesions in the common femoral, proximal profunda femoral, and/or superficial femoral arteries were managed at the time of the endovascular procedure by using endarterectomy and patch angioplasty repair. The percentage of cases requiring this type of intervention was similar in both the IVUS and non-IVUS assisted groups (22.4% vs 22.7%).

We have been reluctant to conduct a randomized prospective study with and without IVUS assistance for balloon angioplasty and stenting of iliac arterial occlusive lesions. Our experience, like that of other authors reported for both the coronary and peripheral circulation, shows that IVUS provides very useful information that influences the treatment process. In our opinion, not using IVUS for angioplasty and stenting procedures would put some of those patients randomized to a non-IVUS evaluation group at a disadvantage.

The use of IVUS adds additional cost to an endovascular procedure. The catheter-delivered transducer used in this study was disposable and cost approximately $400. An experienced technician was necessary to operate the IVUS system, and the system itself costs approximately $120,000. Our IVUS unit is shared with the Division of Interventional Cardiology, with approximately one third of the use attributed to peripheral endovascular procedures. The financial department of our institution estimates a cost-per-case for the technician and equipment, exclusive of the disposable transducer, to be approximately $680. The combined added cost-per-case for IVUS would then equal $1080. The use of IVUS is reimbursed through a specific current procedural terminology code. This reimbursement is less than the cost of the disposable catheter-delivered transducer. However, the expense associated with the salvage of an endovascular intervention once it has failed is estimated to be approximately $12,000 to $15,000 in our institution. In this series, if the use of IVUS had salvaged the four early failures at the time of initial treatment, it would have paid for its use in all 52 patients.

Aortofemoral prosthetic bypass grafting procedures have produced excellent long-term results for the management of aortoiliac occlusive disease, with an anticipated 3% per year failure rate. Unfortunately, this procedure has 1% to 5% perioperative mortality rates and 10% to 15% morbidity rates. Extra-anatomic bypass grafting procedures (axilofemoral or femoral-femoral) have lower mortality and morbidity rates, but may also have decreased durability. In comparison, the long-term patency rate of balloon-dilated and stented iliac artery occlusive lesions in our series has been excellent (94% at 60 months). Those limbs evaluated with IVUS had a 100% patency rate during follow-up evaluations, and even those limbs treated without the use of IVUS had an 82% patency rate at 5 years. Failures that occurred in the arteriography alone group were related to inadequate stent deployment and occurred early (<12 months after initial treatment). These were salvaged by using endovascular techniques. They subsequently remained patent for the duration of their follow-up. Our results are comparable with those of direct surgical intervention and have lower mortality and morbidity rates.

The patient survival rate in our study group was found to be 84% at 3 years and 67% at 6 years by using Kaplan-Meier survival estimates. As expected, cardiac events were responsible for 68% of the mortality. Survival results are similar to the earlier reported 28% 5-year mortality rate in patients with lower-extremity peripheral arterial disease.[31]

CONCLUSION

The use of IVUS as a means of defining the appropriate arterial diameter for an angioplasty procedure and assessing adequacy of stent deployment must be considered to be a factor for improving the long-term patency of iliac arterial occlusive lesions treated with balloon angioplasty and stenting.

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REFERENCES

1. Williams JB, Watts PW, Nguyen VA, Peterson CL. Balloon angioplasty with intraluminal stenting as the initial treatment modality in aorto-iliac occlusive disease. Am J Surg 1994;168:202-4.
2. Gunther RW, Vorwerk D, Antonucci F, Beyssen B, Essinger A, Gaux JC, et al. Iliac artery stenosis or obstruction after unsuccessful balloon angioplasty: treatment with a self-expandable stent. AJR Am J Roentgenol 1991;156:389-93.
3. Arko F, Mettauer M, McCollough R, Patterson D, Manning L, Lee S, et al. Use of intravascular ultrasound improves long-term clinical outcome in the endovascular management of atherosclerotic aortoiliac occlusive disease. J Vasc Surg 1998;27:614-23.
4. Tabbara M, Kopchok G, White R. In vitro and in vivo evaluation of intraluminal ultrasound in normal and atherosclerotic arteries. Am J Surg 1990;160:556-60.
5. Linker DT, Saether OD, Myhre HO, Angelsen RA, Yock PG. Intraarterial ultrasound: a potential tool for the vascular surgeon. Eur J Surg 1991;157:373-7.
6. Diethrich EB, Ivens Ferraz D, Hull K, AbuRahma AF. Intravascular ultrasound imaging of iliac stenoses during endovascular surgery. J Cardiovasc Technol 1989;8:287-93.
7. Chokshi SK, Hogan J, Desai V, Isner JM, DeFranco A, Braimen J. Intravascular ultrasound assessment of implanted endovascular stents. J Am Coll Cardiol 1990;15:29A.
8. Slepian MJ. Application of intraluminal ultrasound imaging to vascular stenting. Int J Card Imaging 1991;6:285-311.
9. Katzen BT, Benenati JF, Becker GJ, Zemel G. Role of intravascular ultrasound in peripheral atherectomy and stent deployment [abstract]. Circulation 1991;84(suppl II):152.
10. Arko F, McCollough R, Manning LG, Buckley CJ. Use of intravascular ultrasound in the endovascular management of atherosclerotic aortoiliac occlusive disease. Am J Surg 1996;172:546-50.
11. Yock PG, Johnson EL, Linker PT. Intravascular ultrasound: development and clinical potential. Am J Cardiovasc Imaging 1988;2:185-93.
12. Pandian NA, Kreis A, Brockway B, Isner JM, Sacharoff A, Boleza E, et al. Ultrasound angioscopy: real-time, two-dimensional, intraluminal ultrasound imaging of blood vessels. Am J Cardiol 1988;62:493-4.
13. Nishimura RA, Edwards WD, Warnes CA, Reeder GS, Holmes DR, Tajik AJ, et al. Intravascular ultrasound imaging: in vitro validation and pathologic correlation. J Am Coll Cardiol 1990;16:145-54.
14. Pandian NO, Kreis A, Brockway B, Isner JM, Sacharoff A, Boleza E, et al. Intravascular high frequency two-dimensional ultrasound detection of arterial dissection and intimal flaps. Am J Cardiol 1990;65: 1278-80.
15. Rutherford RB, Flanigan DP, Gupta SK, Johnston KW, Karmoday A, Whittemore AD, et al. Suggested standards for reports dealing with lower extremity ischemia. J Vasc Surg 1986;4:80-94.
16. Rutherford RB. Standards for evaluating the results of interventional therapy for peripheral vascular disease. Circulation 1991;83(suppl I):6-11.
17. Rutherford RB, Becker GJ. Standards for evaluating and reporting the results of surgical and percutaneous therapy for peripheral arterial disease. J Vasc Interv Radiol 1991;2:169-74.
18. Ahn SS, Rutherford RB, Becker GJ, Comerata AJ, Johnston KW, McClean GK, et al. Reporting standards for lower extremity arterial endovascular procedures. J Vasc Surg 1993;17:1103-07.
19. Johnston KW, Rae M, Hogg-Johnston SA, Colapinto RF, Walker PM, Baird RJ, et al. Five year results of a prospective study of percutaneous transluminal angioplasty. Ann Surg 1987;206:403-12.
20. Gallino A, Mahler F, Probst P, Nachbur B. Percutaneous transluminal angioplasty of the arteries of the lower limbs: a 5-year follow-up. Circulation 1984;70:619-23.
21. Hewes RC, White RI, Murray RR, Kaufmen SL, Chang R, Kadir S, et al. Long term results of superficial femoral artery angioplasty. AJR Am J Roentgenol 1986;146:1025-9.
22. Spence RK, Freiman DB, Gatenby R, Hobbs CL, Barker CF, Berkowitz HD, et al. Long-term results of transluminal angioplasty of the iliac arteries and femoral arteries. Arch Surg 1981;116:1377-86.
23. Gupta AK, Ravimandalam K, Rao VR, Joseph S, Unni M, Rao AS, et al. Total occlusion of iliac arteries: results of balloon angioplasty. Cardiovasc Intervent Radiol 1992;16:165-77.
24. Murphy KD, Encarnacion CE, Le VA, Palmaz JC. Iliac artery stent placement with the Palmaz stent: follow-up study. J Vasc Interv Radiol 1995;6:321-9.

25. Cikrit DF, Gustafson PA, Dalsing MC, Haris VJ, Lalka SG, Trerotola SO, et al. Long-term follow-up of the Palmaz stent for iliac occlusive disease. Surgery 1995;118:608-13.
26. Levitin A, Semba CP, Katzen BT, editors. Intravascular ultrasound. Techniques in vascular and interventional radiology. Philadelphia: WB Saunders; 2001.
27. Tabbara MR, White RA, Cavaye DM, Kopchok G. In vivo human comparison of intravascular ultrasound and angiography. J Vasc Surg 1992;14:496-504.
28. Tobis JM, Colombo A. Do you need IVUS guidance for coronary stent deployment? Catheter Cardiovasc Diagn 1996;37:360-1.
29. Nakamura S, Colombo A, Gaglione A, Almagor Y, Goldberg SL, Maiello L, et al. Intracoronary ultrasound observations during stent implantation. Circulation 1994;89:2026-34.
30. Sullivan TM, Childs MB, Bacharach JM, Bruce HG, Piedmonte MR. Percutaneous transluminal angioplasty and primary stenting of the iliac arteries in 288 patients. J Vasc Surg 1997;25:829-38.
31. Cronenwett, Gloviczki, Johnston, Kempczinski, and Krupski, editors. Rutherford vascular surgery. 5th ed. Philadelphia: WB Saunders; 2000.

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DISCUSSION

Dr Murray Shames (St Louis, Mo). Would the use of self-expanded stents have eliminated the problem with underexpansion using balloon-expandable stents?

Dr Clifford Buckley. We have not used many self-expanding stents. All of the stents used in the study were balloon expandable. I have not had the opportunity to interrogate many self-expanding stents with IVUS. Of those that I have studied with IVUS, the majority were not completely in apposition with the vessel wall at all locations. Self-expanding stents are usually limited in their degree of expansion by the narrowest part of the vessel which comes in circumferential contact with the stent wall.

You still have the problem of inadequate stent apposition to the wall if the wall has not been fully dilated so that the stent is able to embed itself against the wall.

Dr Takao Ohki (Bronx, NY). For the purpose of this analysis, I think you should eliminate the two late failures encountered in the non-IVUS group that were secondary from progression of disease, because that has nothing to do with whether one used IVUS or not. So you basically have four occlusions for the non-IVUS group and zero for the other, which kind of minimizes the difference between the two groups.

I do agree with basically all of your comments, except that you're recommending routine use for every single case. I think you can reduce the number of IVUS needed by doing careful aortogram, completion angiogram with biplane projection, and also with the use of pressure gradient pull-through method. By combining the methods, I think you can selectively use IVUS and still maintain the benefit that you're talking about. Can you comment on that approach?

Dr Buckley. What you say may be true. However, arteriography can fail to identify areas of dissection and it will not show you incomplete apposition of stent to the vessel wall in approximately 40% to 50% of cases. Also, IVUS gives the best measurement of true vessel lumen diameter so that you can size dilating balloons and stents accurately and avoid under-dilatation or over-dilatation and potential vessel rupture.