Outpatient Iliac Artery Intervention

The use of low-profile stent delivery systems and suture-mediated closure devices allows outpatient iliac artery intervention to be performed safely with low morbidity and high cost-effectiveness.

BY ANDREW HOLDEN, MBChB, FRANZCR

At our institution, we have conducted a prospective study of the clinical and economic impact of same-day discharge after iliac artery interventions. This management strategy was possible because of the use of (1) preprocedural noninvasive assessment of lower-limb arterial anatomy with contrast-enhanced magnetic resonance angiography (CE-MRA), (2) reduced profile of self-expanding arterial stent delivery systems, and (3) a suture-mediated closure device (SMCD).

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MATERIALS AND METHODS

Fifty-six consecutive patients (40 males, 16 females) with a mean age of 69.4 years (range, 35-90 years) underwent stent revascularization of iliac artery lesions (Table 1) between March 2003 and January 2004 at a single institution. Patients presented with symptomatic peripheral arterial occlusive disease (PAOD), including intermittent claudication (claudication distance <100 meters), rest pain, and tissue loss. These patients were initially imaged with CE-MRA to define arterial anatomy, size angioplasty balloons and stents, and plan arterial access.

During the interventional procedures, 70 common femoral artery (CFA) retrograde, percutaneous access-site punctures were performed. Ultrasound guidance was used to select a noncalcified segment of anterior artery wall for single-wall puncture. Seven-French sheaths were used in 30 CFAs, 6-F sheaths were used in

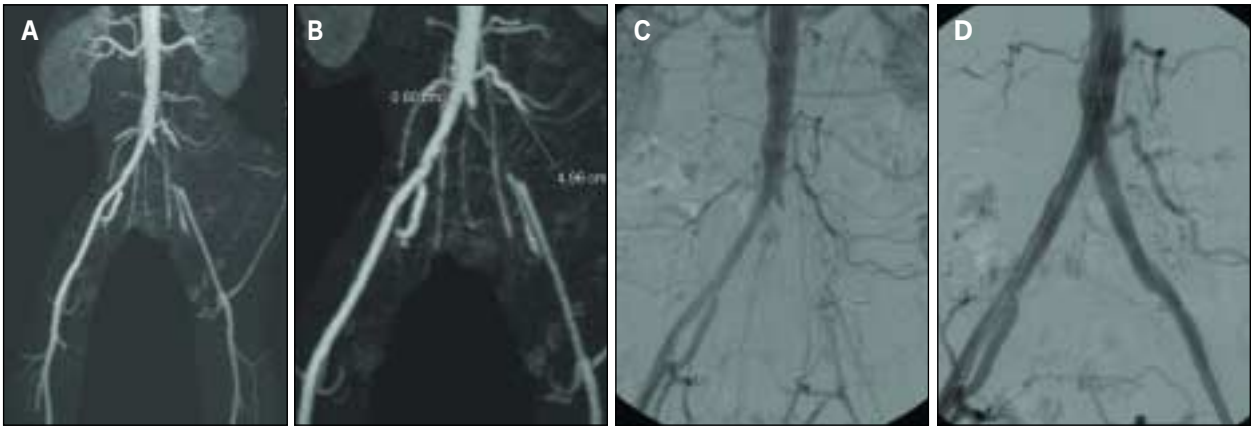

Figure 1. Left common iliac artery revascularization. CE-MRA demonstrating a left common iliac artery occlusion with reconstituted but underperfused external and internal iliac arteries (A). Measurements obtained from the CE-MRA prior to endovascular revascularization (B). Left common iliac artery occlusion confirmed on digital subtraction angiography (C). Revascularization after stent placement. Note the "kissing" stents reconstructing the aortic bifurcation (D).

34 CFAs, and 5-F sheaths were used in 6 CFAs. A total of 104 stents were deployed, 98 of which were nitinol self-expanding stents. Six balloon-expandable stents were used.

After stent revascularization, groin closure was achieved using an SMCD (Perclose AT "Auto-Tie," Abbott Vascular Devices, Redwood City, CA). Device description and deployment have been previously described with the auto-tie mechanism simplifying the knot-tying step.[1] A modification used for iliac artery interventions was to leave the guidewire in place until pulsatile flow was seen through the marker lumen, rather than when the guidewire exit port reached skin level. This important technique prevents iliac stent or arterial damage by the tip of the Perclose device advanced without a guidewire.

All patients received intravenous antibiotic prophylaxis (cephazolin, 1 g) and intra-arterial heparin (2,500-5,000 IU). Standard aftercare involved a total of 3 hours of bedrest and discharge from a Day Ward within 4 hours. The time to hemostasis was recorded in three categories: <3 minutes, 3 to 10 minutes, and >10 minutes. Complications were recorded as minor (minor groin bleeding, small hematoma) or major (hematoma >6 cm, bleeding requiring transfusion, false aneurysm requiring treatment, access artery thrombosis, groin infection). All patients were contacted by telephone within 60 days to record any delayed adverse events.

A review of a historical series of 40 consecutive patients who underwent iliac artery stent revascularization with overnight hospital stay was performed. The mean hospital stay was documented. The procedural costs for all angiographic procedures were considered the same in both treatment groups and were not compared. Additional costs for the outpatient treatment group included the cost of 4 hours of Day-stay aftercare, the SMCD, and the prophylactic antibiotic. The cost of the inpatient treatment group included the cost of daily inpatient hospital care multiplied by the mean postprocedural aftercare duration.

TABLE 1. ARTERIAL LESIONS TREATED

Iliac Artery Stenoses/Occlusions	
Single CIA	22
Single EIA	12
Unilateral CIA/EIA	4
Bilateral CIA	14
Total	**52**
Distal Aortic Stenoses	4

Abbreviations: CIA: common iliac artery; EIA: external iliac artery.

RESULTS

Technical success was achieved in all patients (100%). A total of 73 SMCDs were deployed in 70 groins. On three occasions, initial Perclose deployment was unsuccessful due to suture breakage. The devices were

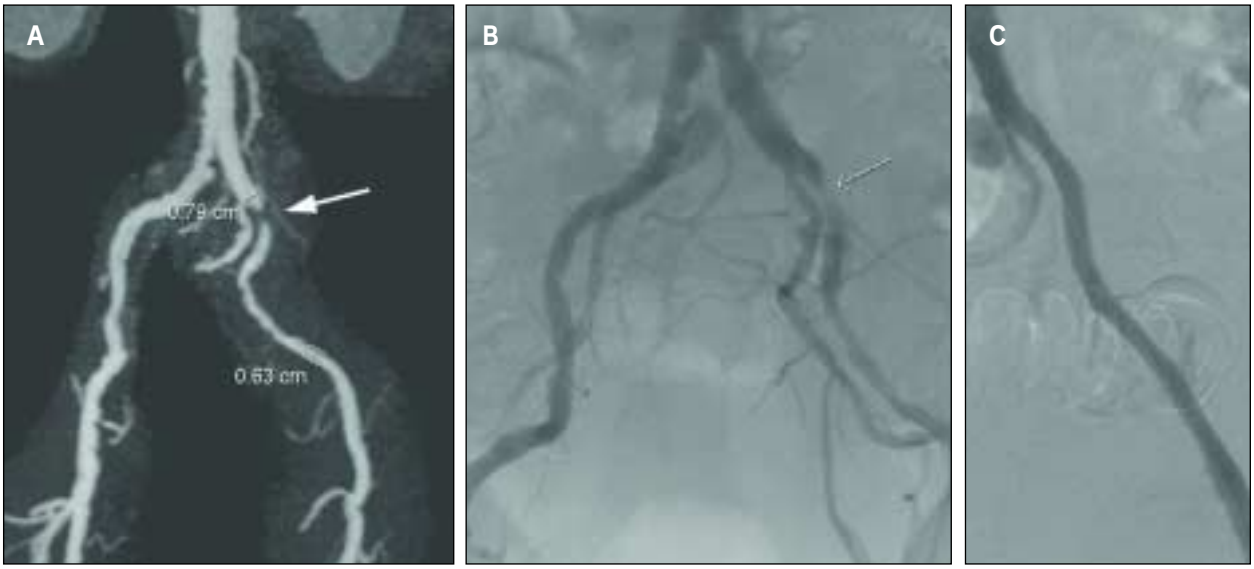

Figure 2. Left external iliac artery revascularization. CE-MRA demonstrating a proximal left external iliac artery stenosis (A). Left external iliac artery stenosis confirmed on digital subtraction angiography (B). Digital subtraction angiography after stent placement (C).

replaced over guidewires with uncomplicated deployment of replacement Perclose devices. Hemostasis was achieved in 60 access sites (86%) in less than 3 minutes. In 10 access sites (14%), hemostasis was achieved between 3 and 10 minutes: these were managed with manual pressure after SMCD deployment. Hemostasis did not take longer than 10 minutes to achieve in any of the patients. There were no major complications, and all patients were discharged within 4 hours. There were no adverse events reported at telephone follow-up.

The cost for outpatient iliac intervention (excluding angiographic and equipment costs) was assessed at NZD $800 per patient. The cost for outpatient iliac artery intervention was NZD $1,170 per patient, with an average inpatient hospital stay of 1.2 days. Thus, an outpatient management strategy was associated with a 32% cost savings.

DISCUSSION

Stent revascularization of iliac artery stenoses and occlusions in patients with symptomatic PAOD is well established.[2,3] However, primary patency rates after stent revascularization are reduced in patients with external iliac artery disease, poor infrainguinal runoff, and those of female gender.[2,4]

Patients undergoing iliac artery stenting have traditionally undergone full diagnostic angiography and appropriate iliac artery intervention followed by an overnight hospital stay. This postprocedural aftercare has been considered necessary to minimize groin-related complications (ie, hematoma, false aneurysm) after removal of large (7- to 8-F) access sheaths in the typical elderly patient group presenting with PAOD. Several reports have suggested outpatient iliac intervention can be safely performed[5,6] because major complications are usually evident while the patient is still in the angiography suite.

In this study, three important strategies allowed successful outpatient iliac artery intervention—the use of preprocedural CE-MRA, reduced profile of stent delivery systems, and use of an SMCD.

There have been major recent developments in noninvasive imaging modalities for PAOD. Doppler sonography has value in the assessment of endovascular and surgical treatment sites but more comprehensive evaluation of lower-limb arteries is limited by incomplete sonographic visualization and prolonged procedure times. CE-MRA and CE-CTA offer full evaluation of lower-limb arterial pathology and facilitate management decisions. CE-MRA does not use ionizing radiation or iodinated contrast, and calcium does not produce signal competing with contrast; this has advantages and disadvantages. In this study, CE-MRA was used to fully assess lower-limb arterial anatomy, avoiding the need for full diagnostic lower-limb digital subtraction angiography. This allowed dedicated iliac artery intervention, significantly reducing procedure times. The CE-MRA also facilitated appropriate access planning and allowed accurate sizing of arterial stents and angioplasty balloons.

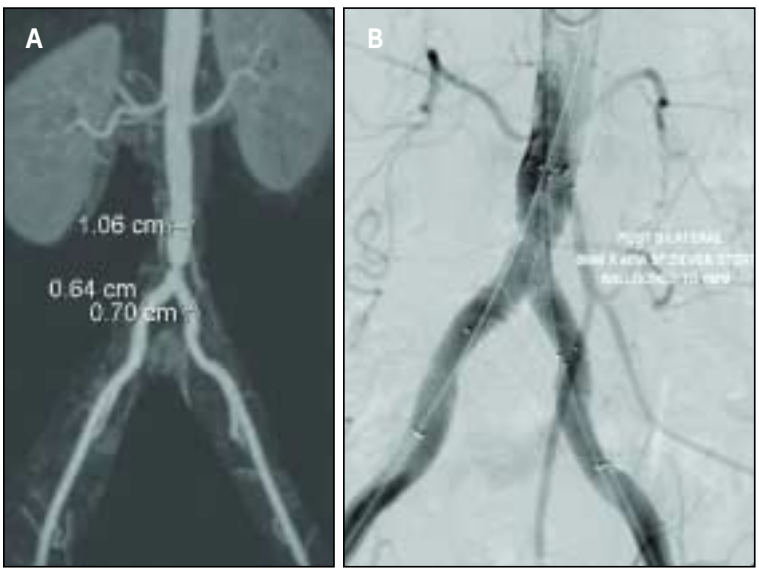

Figure 3. Stent revascularization of a distal aortic stenosis. CE-MRA demonstrating a distal aortic stenosis (A). "Kissing" stent reconstructing of the aortic bifurcation (B).

Most manufacturers have recently released nitinol self-expanding stents in typical iliac diameters (8-10 mm) deployed via 5- to 6-F delivery systems. These lower-profile systems are likely to be associated with fewer groin complications.

Most vascular closure systems can be classified as sealant or suture-mediated devices. The Perclose device is an SMCD and has been evaluated in prospective randomized trails for coronary angiography and intervention[1,7] and has been shown to significantly reduce time to hemostasis, ambulation, and hospital stay. Recently, the Perclose device has also been shown to reduce the same parameters in patients with PAOD,[8,9] although no alteration in the major complication rate was reported (as compared to manual groin pressure). In this study, no major complications were encountered after Perclose deployment, and hemostasis was achieved

Figure 4. Stent revascularization of bilateral common iliac artery stenoses. CE-MRA demonstrating bilateral common iliac artery stenoses (A). Digital subtraction angiography confirms the iliac disease (B). Stent revascularization of both common iliac arteries (C).

within 3 minutes in the majority of cases. A contributing factor was the use of ultrasound to select a nondiseased segment of CFA. Calcification of the CFA is considered a contraindication to Perclose. However, it is our experience, and that of others,[8] that most of this calcified plaque lies posteriorly in the CFA and does not interfere with anterior arterial wall puncture. We also believe it is important to leave the guidewire in place until pulsatile flow is seen through the marker lumen. Once this pulsatile flow is seen, the device does not have to be further advanced beyond the point and any damage to the iliac stent or artery can be avoided.

No patients in this series had a groin infection after Perclose deployment. Close attention to sterile technique is vital and antibiotic prophylaxis has been proposed by others.[10] Groin infection has been reported with use of the Perclose device,[11,12] with an incidence of 0.2% to 0.3%. The nonabsorbable, braided suture may act as a nidus for infection; a new monofilament suture system is now available.

CONCLUSION

Iliac artery intervention can be performed safely in an outpatient setting with low morbidity and high cost-effectiveness. Preprocedural assessment with CE-MRA combined with low-profile stent delivery systems and the use of an SMCD significantly reduces procedure time and aftercare duration, representing a major advance in percutaneous intervention. ■

Andrew Holden, MBChB, FRANZCR, is Director of Interventional Radiology, Auckland Hospital, Auckland, New Zealand. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Holden may be reached at +64 9 3797440; andrewh@adhb.govt.nz.

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