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Endovascular Management of Isolated infrarenal Aortic Occlusive Disease is Safe and Effective in Selected Patients

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Short title: Endovascular treatment of aortic stenosis.

Key words: Angioplasty; stent; aorta; endovascular management; complications.

Abstract

Objective

To examine the safety and efficacy of endovascular management of isolated infrarenal aortic occlusive disease within our centre.

Design and Methods

Retrospective analysis of all patients who underwent endovascular treatment of occlusive disease that is confined to the infrarenal aorta between September 1993 and November 2004.

Results

Primary aortic stenting was carried out in 16 women and 5 men using self-expanding (12 patients) and balloon expanding stents to treat both occlusions (6) and stenoses (15). Indications included intermittent claudication (13), critical limb ischaemia (6), and distal embolisation (3). Significant postoperative complications within 30 days were noted in 3, including one death. At one month, duplex sonography confirmed patency of the aortic segment in all the 20 patients. Resting ABPI before and after the procedure was recorded in 16 patients and it improved from a median of 0.5 (range 0 –0.8) before treatment to 0.9 (0.5 – 1.1) after treatment. Fifteen patients completed one-year follow-up with primary patency in 14 and secondary patency in the remaining patient. Clinical improvement was documented in all patients.

Conclusion

Primary stenting for occlusive disease isolated in the infrarenal aorta is relatively safe in selected patients with encouraging early follow-up results.

Introduction

Endovascular techniques are not widely used to treat occlusive disease of the infrarenal aorta despite their popularity in other arterial segments. This is because isolated aortic disease is not as common and also due to a perception that endoluminal manipulation of a severely diseased aorta could be hazardous. Conventional surgical solutions are durable but associated with significant perioperative mortality and morbidity^{1,2}.

The aim of this study was to examine retrospectively the safety and efficacy of endovascular management of isolated infrarenal aortic occlusive disease within our centre.

Materials and Methods

All patients who underwent endovascular treatment of occlusive disease confined to the infrarenal aorta within one centre between September 1993 and November 2004 were identified from a prospectively compiled electronic database and their case notes were retrieved for retrospective analysis. During the same period, a number of patients underwent endovascular treatment of aortic lesions concomitant to iliac segments and were not included in this analysis. It has been our usual practice not to attempt endovascular treatment when the occlusion extended to within one centimetre to the origin of the lower main renal artery (Juxtarenal occlusions).

Technique of intervention

The technique is similar to the treatment of iliac disease. It is our standard practice to establish bilateral common femoral access followed by the administration of unfractionated heparin. The lesion is then crossed using a hydrophilic guidewire, which is then exchanged for a stiffer wire. Appropriately sized sheaths are then advanced across the lesion over the

stiff guidewires. Currently available self-expanding stents of up to a nominal diameter of 14 mm can be delivered through 6F sheaths (Luminexx®, Bard Peripheral Vascular Inc, Tempe, AZ, USA) and premounted balloon expandable stents of up to 9 mm can be delivered through 7 F sheaths (Advanta ®, Atrium Medical Corp, Hudson, NH, USA). The stent or stents are then positioned within the lesion, sheaths are withdrawn and the stents are deployed in the usual manner. It is standard practice to use the 'kissing balloons' technique when dealing with the distal aortic segment (expand). Occasionally, additional trans-brachial access is used for accurate reference imaging and to pass the initial guidewires in the antegrade direction in order to minimise the risk of creating a cephalad-extending dissection of the aorta.

The procedure is usually undertaken under local anaesthesia with monitoring of ECG, pulse oxymetry and blood pressure. It is attempted to provide the best medical therapy before the procedure and during follow-up.

Results

Patient details

Seventeen elective and 4 emergency procedures were undertaken during the study period under local anaesthesia. The 16 (75%) female patients were significantly younger (mean age 58 yrs, range 32-89) than the 5 men (mean 70, range 61-86) (Fisher's exact, doublesided $p=0.0486$). American Society of Anaesthesiologists (ASA) risk grading was Gr 1 in 6 patients, Gr 2 in 8, Gr 3 in 5 and it was not documented in two. Five patients, all females, were documented to have Activated Protein C resistance.

Indications for the treatment were disabling claudication in 13 (62%), critical ischaemia in 4, critical ischaemia with distal embolisation in two and distal embolisation alone in one patient.

An additional patient presented with acute occlusion of an aortobifemoral bypass that was salvaged by intra-arterial thrombolysis. The procedure was to treat the precipitating cause, a severe stenosis at the aortic anastomosis. All lesions were atherosclerotic in aetiology. The aorta was occluded in six patients, described as 'nearly occluded' in one and stenotic in the remaining 14. Infrainguinal arteries were free from significant occlusive disease in 13 patients. Occlusion of the femoropopliteal segment was noted on both sides in one patient and on one side only in 6.

Procedural success and safety

Stents were inserted primarily in all patients. They included both self-expanding stents (12 patients) and balloon expandable stents (Include stent makes). Nominal diameters of the stents used ranged from 12 to 16 mm (median 12) and these were dilated using balloons of nominal diameters ranging from 9 to 16 mm (median 10).

Significant postoperative complications were noted in three patients. One patient developed a groin haematoma (conservatively treated) and another developed a pseudoaneurysm (needed surgical repair). There was one death within 30 days. This was of a patient with a life-threatening acute aortic occlusion and deep vein thrombosis in the presence of disseminated malignancy. An attempt to treat was considered justified by the multi-disciplinary team despite a short life-expectancy, leading to aortic recanalisation, stenting and intra-arterial thrombolysis. Although initially this appeared successful, he developed reocclusion within a week followed by unsuccessful surgical thrombectomy and death.

Follow-up

Standard follow-up was clinical examination and duplex sonography at one month and at one

year. Additional follow-up was provided when there were ongoing problems.

One month

At one month, duplex sonography confirmed patency of the aortic segment in all the 20 patients. All patients were also documented to have reported improvement in walking distance except one, who reported little change. Resting Ankle-Brachial Pressure Index (ABPI) before and after the procedure was recorded in 16 patients. The median value of ABPI before treatment was 0.5 (range 0 – 0.8), which increased to 0.9 (0.5 – 1.1) after treatment.

One year

One patient died within a year from cardiac disease. His aortic stent was patent at nine months on angiography for infrainguinal disease. Three patients underwent the procedure within the last year and remain asymptomatic. Of the 16 patients with longer follow-up, duplex sonography at one year confirmed primary patency in 15 and secondary patency in one, who required a reintervention (endovascular) at three months upon occlusion of the aortic stent.

Follow-up beyond one year

Seven patients were followed-up beyond the first year. Three patients simply preferred to return to the clinic. ABPIs in these patients remained unchanged at 18, 24 and 48 months compared to the postoperative values. The patient who required secondary intervention presented two years later with occlusion followed by an aortobifemoral bypass. Aortic stent patency was confirmed on angiography prior to infrainguinal procedures.

Discussion

The number of patients in this study was small due to the low incidence of the disease. The demographic data was unremarkable for the condition. The follow-up results were encouraging with satisfactory patency. Deficiencies of this study were due to its retrospective design and analysis. A prospective study would have yielded better follow-up data. It would also have been possible to identify any patients excluded from endovascular treatment and the reasons.

Aortic rupture is the most important complication of this intervention. Preoperative CT is considered in all to determine the extent of calcification within the target segment since a calcified aorta (particularly circumferential calcification) has a higher potential to rupture upon balloon dilatation. We consider it best to use smaller-diameter stents in such circumstances since recanalising the aorta even to a small calibre (however, not less than 8 or 9 mm,) is usually sufficient for clinical improvement. Conversely, dilatation to larger diameter increases the risk of aortic rupture and dissection. Such a pragmatic approach might have been responsible for the safety in our hands. Ensuring a ready availability of stent-grafts and other equipment necessary to manage aortic rupture is considered mandatory preparation for every aortic intervention.

Manipulation within aorta also carries a risk of creating extensive dissection and distal embolisation with serious consequences. Necessary precautions include adequate use of heparin (target Activated Clotting Time of 250-300 sec.) and meticulous caution with wires and catheters. It is perceived by many, including the Malmö group, that primary stenting reduces the risk of both these complications.

Over the years, a number of reports of endovascular treatment of occlusive disease of the infrarenal aorta have been published, although, the majority consisted of small numbers of patients³⁻⁸. It is worth noting that immediate technical success rates are a hundred percent in the majority of these reports and acceptable in the remaining. Minor and major complication rates and long-term patency also appear to be within acceptable range. Our results are comparable to the existing reports.

Selection of intervention for occlusive aortic disease is influenced by the risk of complications in individual patients. Some centres adopt a cautious approach and do not submit patients at a higher risk of procedural complications to endovascular surgery. It is standard practice in our unit to offer endovascular surgery to all patients requiring an intervention, with the exception of juxtarenal occlusions. It has not been possible, however, to verify deviation from this practice due to the retrospective nature of this study. Our approach is based upon a combination of factors including a state of preparedness to deal with any complications and a perception that the risks with endovascular approach are still favourable when compared to conventional surgery. Our results justify such an approach.

The alternative intervention is conventional surgery. Aortobifemoral bypass is a durable procedure but is associated with significant mortality and morbidity in the majority of centres. Extra-anatomic bypass would be an alternative for poor-risk patients but graft-infection is a major concern, especially with the increasing incidence of MRSA. Endovascular treatment can be expected to lower morbidity and mortality in addition to cost savings. There is little doubt that recovery and mobilisation occur sooner after endovascular procedures.

A recognition that occlusive disease of the infrarenal aorta can be safely treated by endovascular surgery is essential for the promotion of a widespread use of this technique, which is a prerequisite for the initiation of prospective studies that aim to establish a better level of evidence comparing the endovascular surgical technique with the conventional surgical alternatives in terms of safety, efficacy, durability and economy. In conclusion, our experience demonstrates that endovascular management of infra-renal aortic occlusive disease is relatively safe in selected patients with encouraging early follow-up results.

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Legend for Figure

Figure 1 **A)** Digital subtraction angiography via a transbrachial catheter showing a short occlusion of the infra-renal aorta. Run-off appears white due to late filling by contrast material. **B)** Final image after primary deployment of a Luminexx[®] stent that has been incrementally dilated from 10 to 14 mm.