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A Multicentre Evaluation of the Medtronic AVE Flexible Iliac Bridge Stent in the Iliac Arteries (the First Study)

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Purpose. *To investigate the short term and 6 month outcomes of a recently introduced iliac stent (the Medtronic AVE Flexible Iliac Bridge Stent).*
Method. *One hundred and sixteen patients, 122 limbs from 6 European sites with atherosclerotic occlusive disease were included if they either had a full occlusion or there was a residual gradient >10 mmHg following PTA. Clinical, haemodynamic and Duplex outcomes were recorded to 6 months.*
Results. *After stent placement there was no residual stenosis >30 and 8.1% of segments had a residual resting gradient of >10 mmHg. There were three local complications and three deaths at 30 days. Primary patency at 30 days and 6 months was 94.1 and 82.7%. Marked clinical improvement occurred in 87.6 and 86.2% at 30 days and 6 months.*
Conclusion. *The Medtronic AVE iliac stent has good 30 day and 6 months outcomes supporting the effective use of this device in occlusive disease.*

Keywords: Iliac artery; Stents; Follow-up study; Technology assessment; Biomedical.

Introduction

Ilaic artery occlusive disease is commonly managed using a metallic stent. The Medtronic AVE Flexible Iliac Bridge stent is a flexible balloon expandable stainless steel design with a CE (Conformité Européen) mark. So that 30 day and 6 month clinical outcomes could be made available to Interventionalists the multi-centre European FIRST (Flexible Iliac Bridge Stent Restenosis) study was undertaken.

Patients, Materials and Methods

The only published randomised trial investigating the efficacy of stents in iliac arteries indicated that selective placement of stents in stenoses with a residual gradient of >10 mmHg mean following angioplasty was as successful as stenting all lesions.[1] Current practise suggests that iliac occlusions are treated by primary stenting.[2,3] These data formed the basis of patient selection.

Inclusion criteria

1. All patients were to have symptomatic peripheral vascular disease thought, in part at least, to be due to atherosclerosis affecting the iliac arteries.
2. Iliac stenoses were only included into the study if, following angioplasty, there was a residual 10 mmHg peak systolic gradient at rest, or 15 mmHg after papaverine if the resting pressure was less than 10 mmHg.[1]
3. Occlusions of the common or external iliac artery were treated by primary stenting.
4. In each limb a maximum of two lesions could be included in the study.
5. Lesions were included from the aortic bifurcation to inguinal ligament.

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Exclusion criteria

1. Restenosis (any previous surgical or endovascular intervention upon the target iliac vessel).
2. Acute thrombosis.
3. Recent (<6 weeks) thrombolysis.
4. Ipsilateral common femoral artery occlusion.
5. Ipsilateral prosthetic femoro-popliteal or femoro-distal graft (to avoid the potential complication of infection following prosthetic graft puncture).

Technique

All patients were taking anti-platelet therapy (aspirin 75–300 mg/day). Heparin 5000 iu was given at the time of vascular access and continued for 24 h if the run-off score was one or less. Run-off was scored by summating the assessment of SFA and profunda femoris artery (main trunk) where 2 points = normal, patent with a >50% stenosis = 1 point, and complete occlusion = 0 points.

The Medtronic AVE Bridge Stent is CE marked and constructed from 316L stainless steel in a sinusoidal pattern. The stent is factory balloon mounted and available at the time of the study in diameters from 6 to 10 mm and lengths 39 and 59 mm. Stents were to be placed only in the iliac arteries and, therefore, kept above the circumflex iliac arteries. At the time of intervention the residual stenosis and pressure gradient were measured following angioplasty and following stent placement.

Clinical classification and follow-up

Patients were clinically stratified using the Fontaine classification and Rutherford category prior to treatment and at 30 days and 6 months.[4]

The Rutherford score was used to assess the outcome following intervention at the same time intervals.[4] Exercise treadmill testing is a scarce commodity and, therefore, the reactive hyperaemia test was substituted for exercise testing. The Rutherford category[4] requires a completed treadmill test and post exercise ankle pressure (AP) of >50 mmHg for category 1, a failed test and AP <50 mmHg for category 3, and something in-between for category 2. The article does not provide guidance on the classification of chronic limb ischaemia using the hyperaemia test and ankle pressures even though it states that hyperaemia and exercise testing are equivalent stress tests. In order to overcome this the Rutherford categories were altered to amalgamate categories 1 and 2 (Table 1).

The ABI and reactive hyperaemia ABI were performed on the index limb prior to intervention, and at 24 h, 30 days and 6 months following treatment. The Rutherford category and Rutherford score was recorded prior to intervention, and repeated at 30 days and 6 months. The stented segment was assessed by duplex examination at 30 days and 6 months. The peak systolic velocity was measured above the stent (PSV1) and in the stent at the site of maximum velocity (PSV2). The peak systolic velocity ratio was expressed as PSV2/PSV1 and was considered significant when this was equal to or greater than 2.

Because patient mobility is determined by the symptoms in the worst leg, the denominator for assessing clinical outcome using Rutherford category and score was the patient and not the individual limb. We, therefore, refer to the assessment of the management of the patient and not of the limb or foot etc. The limb was used as the denominator for patency and ABI.

Statistics

Both resting and hyperaemia ABI at each time after treatment were compared against baseline. The mean ABI was compared using the Wilcoxon Matched Pair Rank Test. The median Rutherford category at each time interval following intervention was compared against baseline using the Wilcoxon Rank Sums Test.

Table 1. Modified Rutherford categories

Rutherford category	Clinical description	Objective criteria
0	Asymptomatic	Normal hyperaemia test
1 and 2	Mild to mod claudication	AP after hyperaemia >50 mmHg but at least 20 mmHg lower than resting
3	Severe claudication	AP after hyperaemia <50 mmHg
4	Ischaemic rest pain	Resting AP <40 mmHg
5	Minor tissue loss	Resting AP <40 mmHg
6	Major tissue loss	Resting AP <40 mmHg

The conventional Rutherford categories 1 and 2 are combined as defined in the Table. AP, highest ankle pressure.