

Endovascular stent-grafting of popliteal aneurysms

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Current evidence on endovascular stent-grafting of popliteal aneurysms is limited in quantity but shows no major safety concerns. Evidence on efficacy is inadequate because it is limited to the short-term. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake endovascular stent-grafting of popliteal aneurysms should take the following actions
- Inform the clinical governance leads in their Trusts.
 - Ensure that patients and their carers understand the uncertainty about the procedure's long-term efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
 - Audit and review clinical outcomes of all patients having endovascular stent-grafting of popliteal aneurysms (see section 3.1).
- 1.3 Patient selection for this procedure should be carried out by a multidisciplinary team which should include a vascular surgeon and an interventional radiologist with specific training and experience in the technique.
- 1.4 NICE encourages further research into endovascular stent-grafting of popliteal aneurysms and may review this procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Popliteal artery aneurysms are the most common peripheral aneurysms. They can cause leg ischaemia by embolism or thrombosis and may rupture. Current treatment is usually by open surgical bypass grafting. Postoperative antiplatelet therapy is generally given.

2.2 Outline of the procedure

- 2.2.1 Endovascular repair stent-grafting of popliteal aneurysms is carried out with the patient under local or general anaesthesia. Under fluoroscopic guidance, a stent-graft device is inserted into the femoral artery using standard catheter and guidewire techniques. Care is taken to ensure adequate length of anchoring stent in the normal vessel, both proximally and distally, to bridge the popliteal aneurysm and fully exclude the aneurysm from the circulation.
- 2.2.2 A range of different stents are available for this procedure.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 2.3.1 A meta-analysis of 320 patients treated by endovascular repair reported primary and secondary patency rates at 1 year of 83% (95% confidence interval [CI] 79% to 88%) and 86% (95% CI 82% to 91%) respectively. In the same meta-analysis, comparative data were available for 159 patients: the primary patency rate at 1 year for endovascular repair was 84% (36 out of 43), compared with 85% (99 out of 116) for open repair ($p=0.46$). Secondary patency rates at 1 year were 86% (37 out of 43) for endovascular repair and 95% (110 out of 116) for open repair

($p=0.07$). A non-randomised comparative study of 43 patients (56 limbs; 15 endovascular and 41 open repair) reported primary patency rates of 83% and 88% respectively at 24-month follow-up (p =not significant). A case series of 60 patients at 24 months were 100% and 92% for endovascular and open repair respectively (p =not significant). A case series of 60 patients reported that the primary patency rate was 77% at 3 years and 70% at 5 years. Primary patency is defined as uninterrupted patency following revascularisation. Secondary patency implies that re-intervention has been required to restore patency.

- 2.3.2 A case series of 50 patients reported that 98% (56 out of 57) of aneurysms were completely excluded after endovascular repair.
- 2.3.3 The case series of 50 patients reported a limb salvage rate of 97% (55 out of 57).
- 2.3.4 A randomised controlled trial (RCT) of 42 patients treated by endovascular or open repair reported that 14% (3 out of 21) of patients in the endovascular group required open repair because of endograft occlusion during a mean follow-up of 47 months. In the case series of 50 patients, stent-graft occlusion occurred in 16% (9.57) of aneurysms (2 were successfully treated by thrombolysis, 5 were treated by femoropopliteal bypass, 1 patient was asymptomatic and was not treated, and in the remaining patient, treatment of the occlusion was delayed leading to severe limb ischaemia requiring amputation).
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as successful exclusion of the aneurysm, long-term prevention of thrombosis and distal embolisation, prevention of rupture, and limb salvage.

2.4 Safety

- 2.4.1 Endograft thrombosis occurred in 10% (2 out of 21) of patients treated by endovascular repair the day after the procedure in the RCT of 42 patients. In 1 patient, intra-arterial thrombolytic therapy followed by an additional endovascular procedure was successful. The other patient required open repair after 72 hours. Acute thrombosis was reported in 6% (2 out of 23) of aneurysms within 24 hours of the procedure in the case series of 29 patients; both aneurysms were successfully recanalised with catheter-directed thrombolysis and balloon

angioplasty or rheolytic thrombectomy. In this study, a further 4 patients were diagnosed with thrombosis during follow-up (1 was described as acute and 3 as subacute).

- 2.4.2 Stent fracture in 4% (3 out of 73) of aneurysms (2 leading to occlusion) and stent migration in 12% (9 out of 73) of aneurysms were reported in the case series of 60 patients. Stent migration was reported in 7% (4 out of 57) of procedures in the case series of 50 patients.
- 2.4.3 Stenosis was reported in 3% (2 out of 73) of procedures (timing of events not stated) in the case series of 60 patients. These were treated by percutaneous transluminal angioplasty.
- 2.4.4 There was 1 report of distal embolisation necessitating amputation in the case series of 50 patients.
- 2.4.5 The Specialist Advisers listed anecdotal adverse events as stent occlusion leading to acute limb ischaemia, stent-graft thrombosis, graft failure due to repeated mechanical stress, endoleak and puncture-site arterial bleeding. They considered theoretical adverse events to include stent-graft infection and loss of aneurysm control.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant [audit criteria](#) and has developed an [audit tool](#) (which is for use at local discretion).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).