NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of endovascular stent-grafting of popliteal aneurysms

Treating popliteal aneurysms by inserting a mesh tube

The popliteal artery is situated behind the knee and conveys blood to the lower leg and foot. An aneurysm is an abnormal swelling in the wall of an artery. Endovascular stent-grafting of popliteal aneurysm involves inserting a 'stent-graft' device through the femoral artery (in the groin) lining the inside of the aneurysm. The aim is for the stent-graft to bridge the weak spot within the artery and exclude the aneurysm, to reduce its risk of clotting or rupture.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in October 2010.

Procedure name

- Endovascular stent-grafting of popliteal aneurysms

Specialty societies

- Vascular Society of Great Britain and Ireland
- British Society of Interventional Radiology (BSIR).

Description

Indications and current treatment

Popliteal artery aneurysms are the most common peripheral aneurysms. They can cause leg ischaemia by embolism or thrombosis (and may lead to loss of the limb): occasionally they may rupture. Traditional treatment is usually by open surgical bypass grafting. Post-operative antiplatelet therapy is generally given.

The development of small calibre stent-grafts has enabled the possibility of endovascular treatment of popliteal aneurysms, but it involves placing a stent-graft behind the knee joint where it is subject to considerable flexion and extension movement: the long-term efficacy and safety of placement in this position is unknown.

What the procedure involves

Endovascular stent-grafting of popliteal aneurysms is done under local or general anaesthesia. After surgical exposure or percutaneous puncture of the femoral artery, a stent-graft device is inserted under fluoroscopic guidance 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.

A range of different stents are available and the technology has evolved over the past decade.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to endovascular stent-grafting of popliteal aneurysms. Searches were conducted of the following databases, covering the period from their commencement to 4 January 2011: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with popliteal aneurysm.
Intervention/test	Endovascular stent-grafting.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on approximately 460 patients from a meta-analysis of 1 randomised controlled trial (RCT), 3 non-randomised comparative studies and 27 case series, an additional 4 case series and 1 case report[1–9].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on endovascular repair of popliteal aneurysms

Abbreviations used: CI, confidence interval; CT, computed tomography; DSA, digital subtraction angiography; OR, odds ratio

Study details	Key efficacy findings	Key safety findings	Comments
Cina CS (2010)[1] **Meta-analysis** Canada Search date: June 2009 Study population: patients with popliteal aneurysms **n = 320 (comparative data for 159 patients, 43 endovascular versus 116 open repair)** Mean age: not reported Sex: not reported Study selection criteria: all studies reporting the outcome patency were included. 1 RCT and 3 cohort studies were included: Antonello et al. (2005), n = 30; 15 vs. 15 Stone et al. (2005), n = 55; 7 vs. 48 Antonello et al. (2007), n = 18; 6 vs. 12 Curi et al. (2007), n = 56; 15 vs. 41 27 additional case series were included (number of patients ranged from 1 to 73). Technique: several different types of stent were used (including Cragg EndoPro system, Mintec; Passager stent graft, Boston Scientific; Corvita stent graft, Boston Scientific; Wallstent-PTFE, Boston Scientific; Wallgraft; Hemobahn/Viabahn stent grafts, WL Gore & Associates; Anaconda limbs, Vascutek). Follow-up: not reported Conflict of interest/source of funding: the author received a consulting fee from Vascutek and Cook companies.	Number of patients analysed: **320** Mean number of stents used = 2 (range 1–3) **Primary patency rate of endovascular versus open repair at 1 year (n = 159):** • Endovascular = 83.7% (36/43) • Open = 85.3% (99/116), p = 0.46 **Secondary patency rate of endovascular versus open repair at 1 year (n = 159):** • Endovascular = 86.0% (37/43) • Open = 94.8% (110/116) OR (random effects model) = 0.26 (95% CI 0.06 to 1.09, p = 0.07) Using a fixed effect model, the difference reached statistical significance, favouring open repair (results not presented). **Cumulative analyses of patency rates for endovascular repair (n = 320)** • 30-day patency rate = 94% (95% CI 91% to 97%) • Primary patency rate at 1 year = 83% (95% CI 79% to 88%) • Secondary patency rate at 1 year = 86% (95% CI 82% to 91%) **Three-year primary patency rates:** • All studies (6 studies, n = 139) = 74% (95% CI 67% to 81%) Hemobahn/Viabahn stents (3 studies, n = 94) = 78% (95% CI 69% to 86%) **Three-year secondary patency rates:** • All studies (5 studies, n = 141) = 85% (95% CI 78% to 91%) • Hemobahn/Viabahn stents (4 studies, n = 124) = 85% (95% CI 79% to 92%)	No safety outcomes were reported.	**Study design issues**: • Results were summarised using random effects models, to take account of the heterogeneity of the cohort of patients included. • The authors note that the difference in secondary patency rates at 1 year between endovascular and open repair reached statistical significance when a fixed effect model was used (analysis not shown in the paper). The authors state that this type of analysis may be credible for these data. • The paper did not describe a definition of primary and secondary patency. Secondary patency rates include patients who underwent additional interventions during follow-up. • Different studies were included in the 3-year primary and secondary patency rate outcomes. **Study population issues**: • In the majority of patients, the endovascular repair was done in the presence of a good tibial run-off; at least 2 patent tibial arteries were present in 71% of patients. • The cohort of patients was heterogeneous with regard to symptoms, poor run-off versus good run-off, different types of stent used for endovascular repair and different types of conduit used for open repair.

Abbreviations used: CI, confidence interval; CT, computed tomography; DSA, digital subtraction angiography; OR, odds ratio

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Antonello M (2005, 2007)[2,3]

RCT (1999–2003) and non-randomised comparative study (2004–2006)

Italy

Study population: patients with asymptomatic popliteal aneurysms

n = 42 patients, 48 aneurysms (21 endovascular, 27 open repair)

Mean age (years): 65.7 (endovascular), 62.8 (open); range 51–85

Sex: 86% male

Patient selection criteria: aneurysmal lesion in the popliteal artery with a diameter of ≥ 2 cm at the angio-CT scan; proximal and distal neck of the aneurysm with a length of > 1 cm to offer a secure site of fixation of the stent graft. Exclusion criteria were age < 50 years old; poor distal run-off; contraindication to antiplatelet, anticoagulant or thrombolytic therapy; symptoms of nerve and vein compression.

Technique: Hemobahn/Viabahn (Gore, USA) stent graft was used for endovascular repair, under locoregional anaesthesia. To verify endograft flexibility during knee joint movement, intraoperative control digital subtraction angiography (DSA) with a knee flexion > 120° was performed.

Mean follow-up: 47 months (range 10–97)

Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 42 (48 aneurysms; 21 versus 27)

There were no conversions to open surgery.

Exclusion of the aneurysm was successful in all cases. No signs of endoleak and no endograft kinking during leg flexion were observed at intraoperative DSA.

Primary patency rates (Kaplan-Meier)
<table>
<tr><th>Follow-up period</th><th>Endovascular</th><th>Open</th></tr>
<tr><td>12 months</td><td>80.9%</td><td>100%</td></tr>
<tr><td>72 months</td><td>71.4%</td><td>88.1%</td></tr>
</table>
Secondary patency rates (Kaplan-Meier)
<table>
<tr><th>Follow-up period</th><th>Endovascular</th><th>Open</th></tr>
<tr><td>12 months</td><td>90.5%</td><td>100%</td></tr>
<tr><td>72 months</td><td>85.7%</td><td>88.1%</td></tr>
</table>
‘No statistical differences were observed at the log-rank test’.

During the entire study period, 14.3% (3/21) patients in the endovascular group required open repair because of endograft occlusion.

Results from RCT only (n = 30)

Mean operative time (min):
• Endovascular = 75.4 (range 50–90)
• Open = 155.3 (range 120–255), p < 0.01

Mean hospital stay (days):
• Endovascular = 4.3 (range 2–9)
• Open = 7.7 (range 7–11), p<0.01</td>
<td>Endograft thrombosis occurred in 9.5% (2/21) of cases the day after the procedure. In 1 patient, intra-arterial thrombolytic therapy followed by an additional endovascular procedure was successful. The other patient required open repair after 72 hours.</td>
<td>This study was included in the meta-analysis (Cina CS, 2010)

Follow-up issues:
• Long-term follow-up was based on clinical evaluation at 1 and 3 months and every 6 months thereafter with duplex ultrasonography and ankle-brachial index measured. DSA was done if there were signs of restenosis.

Study design issues:
• The first 30 patients (15 versus 15) were part of an RCT. The remaining patients were part of a prospective comparative study. Patient selection for this part of the study was not described.
• The authors calculated that a sample size of 302 patients was necessary to reveal a statistical difference at 1-year follow-up but decided to continue with a lower number to test safety and efficacy of endovascular repair.

Study population issues:
• There were no statistically significant differences between the groups with regard to age, sex, smoking, diabetes, hypertension, coronary artery disease, hypercholesterolaemia or chronic obstructive pulmonary disease.

Other issues:
• There was a discrepancy in operative times reported in the paper; those quoted in the main text have been used.</td>
</tr>
</table>

Abbreviations used: CI, confidence intervals; CT, computed tomography; DSA, digital subtraction angiography; OR, odds ratio			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Curi MA (2007)[4] **Non-randomised comparative study** Study period: 2000–6 Spain Study population: patients with popliteal aneurysms **n = 43 patients, 56 limbs (15 endovascular, 41 open repair)** Mean age (years): 75 (endovascular), 68 (open), p < 0.05 Sex: 93% male Patient selection criteria: not described Technique: Viabahn endografts were used for endovascular repair, oversized 10% to 15% relative to the landing zones. **Mean follow-up (months): 16.5 (range 0.5–56)** Conflict of interest/source of funding: none	Number of patients analysed: **43** (56 aneurysms) Technical success = 100% in both groups. **Mean length of stay (days)** • Endovascular repair = 1 • Open repair = 5, p ≤ 0.05 **Primary patency rates at 24 months:** • Endovascular repair = 83% ±15% • Open repair = 88% ± 6%, p = not significant **Secondary patency rates at 24 months:** • Endovascular repair = 100% • Open repair = 92% ± 5%, p = not significant **Survival at 24 months:** • Endovascular repair = 90% ± 9% • Open repair = 90% ± 6%, p = not significant	'Major complications' • Endovascular = 7% • Open = 7% Outflow thrombectomy or thrombolysis: • Endovascular repair = 17.1% (7/41) • Open repair = 6.7% (1/15), p = not significant 1 endovascular repair patient experienced femoral puncture site bleeding that required suture repair. Wound abscesses that required intervention developed in 3 open repair patients. One of these infections resulted in sepsis and death. Endoleaks = 20% (3/15 endovascular repair patients) (1 due to endograft migration was resolved by deployment of additional endografts. The other 2 were followed up conservatively, with shrinkage of 1 aneurysm and no change in the other). **Postoperative warfarin** (indications included long-term treatment of intracranial atherosclerosis or atrial fibrillation, and a new diagnosis of hypercoagulable state): • Endovascular repair = 0% • Open repair = 22%, p ≤ 0.05 **Postoperative clopidogrel** (indications not stated): • Endovascular repair = 87% • Open repair = 11%, p ≤ 0.05	**This study was included in the meta-analysis (Cina CS, 2010)** **Study design issues:** • Retrospective review. • Graft patency was the primary end point. Secondary end points included complication rates, frequency of endoleak and overall survival. • Patency was defined as continued presence of palpable pulses or maintenance of a postoperative ankle-brachial index with a change of < 0.15. • There was an absence of standardised inclusion and exclusion criteria. • Patency and survival rates were compared using Kaplan-Meier plots and log-rank analysis. **Study population issues:** • There was a higher proportion of symptomatic patients in the open repair group compared with the endovascular group (54% versus 13%, p ≤ 0.05). • There were 5 urgent cases, all of whom received open repair. • Patients in the endovascular group were statistically significantly older than those in the open repair group. • Rates of comorbidities were high and similar between the groups. Aneurysm size, location and outflow were similar between groups.

Abbreviations used: CI, confidence intervals; CT, computed tomography; DSA, digital subtraction angiography; OR, odds ratio

Study details	Key efficacy findings	Key safety findings	Comments
Tielliu IF (2007)[5] **Case series** The Netherlands Study period: 1998–2007 Study population: patients with popliteal aneurysms > 20 mm in diameter **n = 60 patients, 73 aneurysms** Mean age (years): 67 (range 51–94) Sex: 95% (57/60) male Patient selection criteria: not described. Technique: The Hemobahn (WL Gore & Associates Inc.) stent graft was used before 2003. After June 2003, the Viabahn stent graft also became available and was used for all arteries with a suitable landing zone. **Mean follow-up: 37 ± 28 months (range 1–104)** Conflict of interest/source of funding: not reported	Number of patients analysed: **60** (73 aneurysms) **Primary patency rate at 3 years = 77%** **Secondary patency rate at 3 years = 86%** **Primary patency rate at 5 years = 70%** **Secondary patency rate at 5 years = 76%** Re-intervention rate = 26% (19/73) (including 2 open repairs – details listed in safety column)	Complications • Occlusion of stent graft = 24.7% (18/73) (thrombolytic therapy was used in 8 patients, thrombectomy in 2 patients, open bypass surgery in 1 patient and the other 7 were managed conservatively. 5 stent-grafts reoccluded. All resulted in claudication, not necessitating open repair. • Stent migration = 12.3% (9/73) • Stent fracture = 4.1% (3/73) (2 led to occlusion) • Stenosis = 2.7% (2/73) (time of events not stated, treated by percutaneous transluminal angioplasty) Of the 14 cases of stent migration, fracture and stenosis, 8 required re-intervention (including 2 extension stent-grafts, 2 thrombin injections, 1 bridging stent-graft, 1 ligation and open bypass, 2 percutaneous transluminal angioplasty). Comparison of first 23 patients (group A) with remainder of cohort (group B): Occlusion rate: • Group A = 34.8% (8/23) • Group B = 20.0% (10/50), p = 0.22 Total events (occlusions, migrations, fractures and stenoses): • Group A = 60.1% (14/23) • Group B = 32.0% (16/50), p = 0.02	**Study design issues:** • Primary outcome was stent-graft patency. • Time-to-event variables were studied with Kaplan-Meier survival analysis. • During the study, several changes of protocol were initiated. These included the introduction of a more aggressive postoperative anticoagulation protocol with clopidogrel. This point in time was used to divide the cohort of patients into 2 groups. **Study population issues:** • 6 aneurysms were treated as emergency cases because of acute ischaemia. • Selection criteria evolved over the study period towards avoiding patients with inflow disease, and young and active patients. **Other issues:** • The authors noted that they now avoid overlap between 2 stent-grafts in 'critical zones', including the hinge point of the popliteal artery.

Abbreviations used: CI, confidence intervals; CT, computed tomography; DSA, digital subtraction angiography; OR, odds ratio

Study details	Key efficacy findings	Key safety findings	Comments
Midy D (2010)[6] **Case series** France Study period: 1999–2007 Study population: patients with popliteal aneurysms **n = 50 patients, 57 aneurysms** Mean age (years): 72 (range 57–96) Sex: 96% (48/50) male Patient selection criteria: localised expansion > 20 mm in diameter or > 150% of the normal vessel diameter with proximal and distal healthy vessels measuring at least 15 mm in length. The main reasons for choosing endovascular treatment instead of open repair were unavailability of a suitable autologous vein graft for a bypass in 37 patients and unacceptable high risk for general anaesthesia in 13 patients. Technique: Hemobahn/Viabahn (WL Gore & Associates Inc.) stent grafts were used in 42 procedures, Wallgraft (Boston Scientific Inc.) in 14 and Passager (Boston Scientific Inc.) in 1. Most procedures (75%) were done under general anaesthesia. Dual antiplatelet postoperative therapy was introduced in 2004. **Mean follow-up: 36 ± 19 months (range 6–96)** Conflict of interest/source of funding: none	Number of patients analysed: **50** (57 aneurysms) A single stent graft was used in 66.7% (38/57) of cases, 2 stent grafts in 28.1% (16/57) and 3 stent grafts in 5.3% (3/57). **Procedural success (complete exclusion after dilatation) = 98.2% (56/57)** In 1 long aneurysm, 2 stent grafts were insufficient and a third was unavailable at the time. The next day, a third stent was used with complete exclusion. Mean duration of hospital stay = 5 ± 1.8 days (range 3–11 days) 4 patients died at 2, 24, 34 and 46 months after the procedure due to unrelated causes. Overall limb salvage rate = 96.5% (55/57) **Primary and secondary patency rates (Kaplan-Meier)** Follow-up / Primary patency rate / Secondary patency rate 6 months: 87.7% / 89.4% 1 year: 85.8% / 87.5% 3 years: 82.3% / 87.5% The authors stated that the main determinants of success were suitable aneurysm anatomy and dual antiplatelet postoperative therapy. At univariate analysis, age of the patient, diameter of the aneurysm, number and diameter of the endoprostheses, number of run-off vessels (1 vs. 2 or 3) and clinical presentation (symptomatic vs asymptomatic) were not identified as risk factors.	Complications • Stent graft occlusion = 15.8% (9/57) (2 patients were successfully treated by thrombolysis and 5 underwent successful femoropopliteal bypass. 1 patient was asymptomatic and was not treated. In the remaining patient, treatment of the occlusion was delayed leading to severe limb ischaemia, and amputation was required.) 4 of the 9 occlusions occurred within 2 months of the procedure. • Endoleak = 10.5% (6/57) (1 primary endoleak was due to the aneurysm being too long for the 2 available stent grafts. Of the 5 secondary endoleaks, 4 were due to stent graft migration and 1 was due to stent graft failure. 4 patients were treated by inserting an additional stent graft and the other 2 underwent femoropopliteal bypass.) • Distal embolisation = 1.8% (1/57) (patent stent graft, major amputation was required). Overall complication rate: • Wallgraft endoprostheses = 50.0% (7/14) • Hemobahn/Viabahn endoprostheses = 19.0% (8/42), p = 0.04	**Follow-up issues:** • No patients were lost to follow-up. **Study design issues:** • Retrospective multicentre study with consecutive patients. • Primary and secondary patency rates were analysed using the Kaplan-Meier method. **Study population issues:** • Most aneurysms (74%) were asymptomatic. 9 patients had associated claudication, 5 had critical limb ischaemia and there was 1 ruptured aneurysm. • 54.4% (31/57) of limbs had at least 1 occluded tibial or peroneal artery. **Other issues:** • The authors noted that after dual antiplatelet postoperative therapy was introduced, no occlusions occurred in the first 2 months after exclusion. • The authors noted the importance of anatomical features in determining indications for endovascular exclusion. The Wallgraft endoprosthesis was used at the beginning of the study and there was a preference for using Hemobahn/Viabahn stent grafts at the end of the study.

Abbreviations used: CI, confidence intervals; CT, computed tomography; DSA, digital subtraction angiography; OR, odds ratio

Study details	Key efficacy findings	Key safety findings	Comments
Idelchik GM (2009)[7] **Case series** USA Study period: 2000–2007 Study population: patients with symptomatic popliteal aneurysms **n = 29 patients, 33 aneurysms** Mean age (years): 68 ± 6 (range 54–88) Sex: 93% (27/29) male Patient selection criteria: patients with symptoms of lower extremity claudication; localised popliteal artery dilatations > 2 cm in diameter (or > 150% of the normal vessel diameter) or aneurysms with mural thrombus regardless of size. Technique: the Wallgraft endoprosthesis (Boston Scientific) was used until 2006; Viabahn stent-grafts (WL Gore & Associates Inc.) were used after 2005. All patients received aspirin indefinitely. As of 2004, all patients received clopidogrel for at least 3 months postoperatively. **Mean follow-up: 35.4 ± 32.1 months (range 6–120)** Conflict of interest/source of funding: none	Number of patients analysed: **29** (33 aneurysms) An average of 1.9 (range 1–3) stent-grafts were implanted per aneurysm. All popliteal artery aneurysms were successfully excluded from the arterial circulation. Mean length of hospital stay = 1.4 ± 1.0 days All patients with symptomatic aneurysms had symptomatic improvement after stent-graft placement; patients with popliteal artery aneurysm-associated venous thrombosis had gradual resolution of popliteal vein occlusion with anticoagulant therapy. **Primary and secondary patency rates (Kaplan-Meier)** Follow-up / Primary patency rate / Secondary patency rate 6 months: 93.9% / 100% 1 year: 93.9% / 96.9% 2 years: 87.5% / 96.8% 4.5 years: 84.8% / 96.8% There was no limb loss.	Periprocedural complications: • Access-site haematoma = 9.1% (3/33) (1 required surgical repair and transfusion, 1 patient also had a concurrent pseudoaneurysm that was successfully treated with duplex-guided manual compression). • Acute thrombosis = 6.1% (2/33) (1 immediate and 1 within 24 hours of the procedure; both were successfully recanalised with catheter-directed thrombolysis and balloon angioplasty or rheolytic thrombectomy) Complications during follow-up: • Subacute thrombosis = 9.1% (3/33) (at 10, 16 and 18 months; 2 patients presented with limb ischaemia and were treated with rheolytic thrombectomy, the third patient was asymptomatic). • Acute thrombosis = 3.0% (1/33) There were no endoleaks, aneurysm ruptures or thromboembolism.	**Follow-up issues:** • Clinical follow-up evaluation was recommended at 6 and 12 months and yearly thereafter or on worsening symptoms as noted by the patient; duplex ultrasonography was performed at the discretion of the primary physician. **Study design issues:** • Consecutive patients. • Primary patency was defined as duplex ultrasonography showing < 50% stenosis of the luminal diameter at the site of the stent graft. • Primary and secondary patency rates were analysed using the Kaplan-Meier method. **Study population issues:** • 4 patients had popliteal venous thrombosis. 28 of the treated popliteal artery aneurysms had associated mural thrombus.

Abbreviations used: CI, confidence intervals; CT, computed tomography; DSA, digital subtraction angiography; OR, odds ratio			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Miller MJ Jr (2007)[8] **Case report** USA Study period: not reported Study population: patient with popliteal aneurysm **n = 1** Age): 65 years Sex: male Technique: Viabahn (WL Gore & Associates Inc.) stent graft was used. Conflict of interest/source of funding: not reported	**Acute compartment syndrome related to stent-graft exclusion** Patient presented with right lower extremity claudication and left popliteal aneurysm. During attempted deployment of stent-graft, a buckling or 'bowstring' movement was encountered. The stent graft was released in a radiographically acceptable position. Once released, the distal guidewire tip was noted to be in a small branch of (presumably) the posterior tibial artery. The wire was repositioned again into the distal popliteal artery, where it remained for the rest of the procedure. A second stent-graft was positioned, again with a degree of bowstringing. A third graft extended coverage into the proximal superficial femoral artery. Following release of the third stent-graft, the patient complained of mild tightness in his calf. Angiography showed a focal area of extravasation from a branch arising from the posterior tibial artery where the guidewire tip had previously been placed. Coil embolisation was performed and the bleeding was controlled. Approximately 3 hours after the procedure, there was asymmetric enlargement of the left calf, which was taut and tender to palpation. Pressures were measured at 70 to 90 mmHg in all 4 compartments. A single-incision four-compartment fasciotomy was performed. The patient recovered uneventfully and was discharged on day 5 post stent-graft placement.		

Abbreviations used: CI, confidence intervals; CT, computed tomography; DSA, digital subtraction angiography; OR, odds ratio			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Tielliu IF (2010)[9] **Case series** The Netherlands Study period: 1998–2009 Study population: patients with popliteal aneurysms **n = 64 patients, 78 aneurysms** Mean age (years): 69 (range 51–94) Sex: 95% (61/64) male Patient selection criteria: only true atherosclerotic aneurysms were included. Exclusion criteria included the absence of a landing zone in the proximal and distal popliteal artery of at least 3 cm length, extensive aneurysmal or stenotic disease at the level of the iliac and femoral arteries and the absence of at least 1 good tibial or peroneal artery serving as a run-off vessel. Technique: The Hemobahn/Viabahn stent grafts were used (WL Gore & Associates Inc.) **Mean follow-up: 50 months (range 1–127)** Conflict of interest/source of funding: none	Number of patients analysed: **64** (78 aneurysms) In 27% (21/78) of aneurysms, a single stent-graft was used. In the remaining 73% (57/78) of cases, multiple stent-grafts were used.	15 circumferential fractures occurred in 13 (17%) cases. In 1 case where a single stent-graft was used, an endoleak was found due to disruption of the graft material. No X-ray was available to prove a stent fracture in this case. The patient underwent an infragenicular bypass in another hospital. Younger age of the patient was a significant predictive factor for stent-graft fracture (p = 0.007). Mean age of group with stent-graft fracture = 61 years. Mean age of group without stent-graft fracture = 68 years. 93% (14/15) of the stent-graft fractures occurred with multiple stent-grafts. Cumulative stent-graft fracture-free survival: • 5 years = 78% • 10 years = 73% Occlusion of the stent graft = 27% (21/78) (including 5 with stent fracture). Cumulative primary patency rate was not different for the fracture group compared with the nonfracture group (p = 0.284).	**Same patients as Tielliu et al., 2007[5]** **Follow-up issues:** • Follow-up was performed at 1 month, 6 months and yearly thereafter and included X-ray of the knee in 1 projection. **Study design issues:** • The primary aim was to investigate the incidence and origin of stent fractures and their clinical impact. **Study population issues:** • 6 aneurysms were treated as emergency cases because of acute ischaemia.

Efficacy

Primary and secondary patency

A meta-analysis of 320 patients treated by endovascular repair reported primary and secondary patency rates at 1 year of 83% (95% 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% (36/43), compared with 85% (99/116) for open repair (p = 0.46)[1]. Secondary patency rates at 1 year were 86% (37/43) for endovascular repair and 95% (110/116) for open repair (p = 0.07). A non-randomised comparative study of 43 patients treated by endovascular or open repair reported primary patency rates of 83% and 88% respectively at 24-month follow-up (p = not significant). Secondary patency rates 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. The secondary patency rate was 86% at 3 years and 76% at 5 years[5]. A case series of 50 patients reported primary patency rates of 86% and 82% at 1 and 3 years respectively, and secondary patency rates of 88% at 1 and 3 years[6]. A case series of 29 patients reported primary patency rates of 94% and 85% at 1 and 4.5 years respectively, and secondary patency rates of 97% at 1 and 4.5 years[7].

Aneurysm exclusion

Two comparative studies of 42 and 43 patients reported that complete exclusion of the aneurysm was achieved in all patients[2–4]. A case series of 50 patients reported that 98% (56/57) of aneurysms were completely excluded after endovascular repair and a case series of 29 patients reported that 100% (33/33) of aneurysms were successfully excluded from the circulation[6,7].

Limb salvage rate

One case series of 50 patients reported a limb salvage rate of 96% (55/57)[6]. A case series of 29 patients reported that there was no limb loss[7].

Re-intervention rate

An RCT of 42 patients treated by endovascular or open repair reported that 14% (3/21) of patients in the endovascular group required open repair because of endograft occlusion during a mean follow-up of 47 months[2,3]. In a case series of 50 patients, stent-graft occlusion occurred in 16% (9/57) of aneurysms. Two were successfully treated by thrombolysis and 5 were treated by femoropopliteal bypass. One patient was asymptomatic and was not treated. In the remaining patient, treatment of the occlusion was delayed leading to severe limb ischaemia, and amputation was required[6]. In a case series of 60 patients, the re-intervention rate was 26% (19/73), including 2 open repairs[5].

Safety

Thrombosis

In the RCT of 42 patients, endograft thrombosis occurred in 10% (2/21) of patients treated by endovascular repair the day after the procedure. In 1 patient, intra-arterial thrombolytic therapy followed by an additional endovascular procedure was successful. The other patient required open repair after 72 hours[2,3]. A case series of 29 patients reported acute thrombosis in 2 patients within 24 hours of the procedure; both were successfully recanalised with catheter-directed thrombolysis and balloon angioplasty or rheolytic thrombectomy[7]. In this study, a further 4 patients were diagnosed with thrombosis during follow-up (1 described as acute and 3 as subacute).

Stent fracture/migration

In the case series of 60 patients, stent fracture was reported in 4% (3/73) of aneurysms (2 leading to occlusion); stent migration was reported in 12% (9/73) of aneurysms[5]. In a later case series from the same study centre, stent-graft fracture was reported in 17% (13/78) of aneurysms after a mean follow-up of 50 months[9]. Younger age was identified as the only significant predictor for stent fracture ($p = 0.007$).In a case series of 50 patients, stent migration was reported in 7% (4/57) of procedures[6].

Stenosis

In the case series of 60 patients, stenosis was reported in 3% (2/73) of procedures (timing of events not stated)[5]. These were treated by percutaneous transluminal angioplasty.

Other complications

There was 1 report of distal embolisation necessitating amputation in a case series of 50 patients[6].

A case series of 29 patients reported access-site haematoma in 9% (3/33) of aneurysms (1 required surgical repair and transfusion, and 1 patient also had a concurrent pseudoaneurysm that was successfully treated with duplex-guided manual compression)[7].

There was 1 case report of acute compartment syndrome related to stent-graft exclusion of a popliteal aneurysm[8]. A single incision four-compartment fasciotomy was performed and the patient made an uneventful recovery.

Validity and generalisability of the studies

- The studies include heterogeneous populations with regard to symptoms.
- The RCT only included asymptomatic patients[2,3].

- In the non-randomised comparative study, significantly more patients in the open repair group were symptomatic compared with the endovascular group (54% vs. 13%, $p \leq 0.05$)[4].
- The studies included different stent-grafts and treatment protocols (for example, postoperative use of antithrombotic agents).

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

There is currently no NICE guidance related to this procedure.

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr D Kessel, Mr I Robertson (British Society of Interventional Radiology)
Mr I Nyamekye, Mr MacSweeney (Vascular Society)

- Two Specialist Advisers have never performed the procedure, one Adviser has performed it at least once and one performs it regularly.
- Three Specialist Advisers considered the procedure to be novel and of uncertain safety and efficacy, and one described it as established practice.
- The appropriate comparator is open surgical repair.
- Known adverse events include stent occlusion leading to acute limb ischaemia, stent graft thrombosis, distal embolisation, stent fracture or migration, graft failure due to repeated mechanical stress, endoleak and puncture-site arterial bleeding.
- Theoretical adverse events include stent graft infection and loss of aneurysm control.
- There is concern about the long-term durability of a stent in a position that receives repeated flexion.

- Key efficacy outcomes include successful exclusion of the aneurysm, long-term prevention of thrombosis and distal embolisation, prevention of rupture, and limb salvage.
- Two Advisers thought that the procedure would have a minor impact on the NHS and one thought that the impact would be moderate.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

None other than those described above.

References

1. Cina CS (2010) Endovascular repair of popliteal aneurysms. Journal of Vascular Surgery 51: 1056–60.

2. Antonello M, Frigatti P, Battocchio P et al. (2005) Open repair versus endovascular treatment for asymptomatic popliteal artery aneurysm: results of a prospective randomized study. Journal of Vascular Surgery 42: 185–93.

3. Antonello M, Frigatti P, Battocchio P et al. (2007) Endovascular treatment of asymptomatic popliteal aneurysms: 8-year concurrent comparison with open repair. Journal of Cardiovascular Surgery 48: 267–74.

4. Curi MA, Geraghty PJ, Merino OA et al. (2007) Mid-term outcomes of endovascular popliteal artery aneurysm repair. Journal of Vascular Surgery 45: 505–10.

5. Tielliu IF, Verhoeven EL, Zeebregts CJ et al. (2007) Endovascular treatment of popliteal artery aneurysms: is the technique a valid alternative to open surgery? Journal of Cardiovascular Surgery 48: 275–9.

6. Midy D, Berard X, Ferdani M et al. (2010) A retrospective multicenter study of endovascular treatment of popliteal artery aneurysm. Journal of Vascular Surgery 51: 850–6.

7. Idelchik GM, Dougherty KG, Hernandez E et al. (2009) Endovascular exclusion of popliteal artery aneurysms with stent-grafts: A prospective single-center experience. Journal of Endovascular Therapy 16: 215–23.

8. Miller MJ Jr, Stirling MJ, Chang YH et al. (2007) Acute compartment syndrome related to stent-graft exclusion of a popliteal arterial aneurysm. Seminars in Interventional Radiology 24: 307–11.

9. Tielliu IFJ, Zeebregts CJ, Vourliotakis G et al. (2010) Stent fractures in the Hemobahn/Viabahn stent graft after endovascular popliteal aneurysm repair. Journal of Vascular Surgery 51: 1413–8.

Appendix A: Additional papers on endovascular repair of popliteal aneurysms

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Ascher E, Gopal K, Marks N et al. (2010) Duplex-guided endovascular repair of popliteal artery aneurysms (PAAs): a new approach to avert the use of contrast material and radiation exposure. European Journal of Vascular and Endovascular Surgery 39: 769–73.	Case series n = 15 Mean follow-up = 12 months	Endovascular repair can be performed under duplex guidance alone. Poor run-off and low mean popliteal artery volume flow may be predictors of poor graft patency.	Larger studies are included.
Cina CS, Moore R, Maggisano R et al. (2008) Endovascular repair of popliteal artery aneurysms with anaconda limbs: Technique and early results. Catheterization and Cardiovascular Interventions 72: 716–24.	Case series n = 12 patients	Primary patency rate at 6 months = 93%	Larger studies are included.
Etezadi V, Fuller J, Wong S et al. (2010) Endovascular treatment of popliteal artery aneurysms: a single-center experience. Journal of Vascular and Interventional Radiology 21: 817–23.	Case series n = 18 Mean follow-up = 15 months	Primary patency rate at 6 months = 86%	Larger studies are included.
Flessenkamper I, Marcus M, Podlesny B. (2002) The endovascular treatment of popliteal aneurysms with the hemobahn system. Chirurgia Polska 4: 113–6.	Case series n = 10 patients Mean follow-up = 16 months	80% (8/10) implantations were successful; there were 2 occlusions.	Larger studies with longer follow-up are included.
Gerasimidis T, Sfyroeras G, Papazoglou K et al. (2003) Endovascular treatment of popliteal artery aneurysms. European Journal of Vascular and Endovascular Surgery 26: 506–11.	Case series n = 9 patients Mean follow-up = 14 months	44% (4/9) thromboses (2 within 30 days and 2 during the late postoperative period). Primary patency rate at 1 month = 64% Primary patency rate at 12 months = 47% Secondary patency rate at 1month = 88% Secondary patency rate at 12 months = 75%	Larger studies with longer follow-up are included.
Ghotbi R, Sotiriou A, Schonhofer S et al. (2007) Stent-graft placement in popliteal artery aneurysms: Midterm results. Vascular Disease Management 4: 123–7.	Case series n = 24 patients Mean follow-up = 48 months	Technical success = 100% 2 occlusions, 1 after 3 months 2 central leaks (repaired endovascularly)	Larger studies are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Henry M, Amor M, Henry I et al. (2000) Percutaneous endovascular treatment of peripheral aneurysms. Journal of Cardiovascular Surgery 41: 871–83.	Case series n = 12 popliteal artery aneurysms Mean follow-up = 21 months	42% (5/12) thromboses Primary patency rate (femoropoliteal) = 78% Secondary patency rate (femoropopliteal) = 86%	Larger studies with longer follow-up are included.
Howell M, Krajcer Z, Diethrich EB et al. (2002) Wallgraft endoprosthesis for the percutaneous treatment of femoral and popliteal artery aneurysms. Journal of Endovascular Therapy 9: 76–81.	Case series n = 13 popliteal artery aneurysms Follow-up = 1 year	Procedural success = 92.3% (12/13) 31% (4/13) thromboses (3 were recanalised, 1 underwent bypass grafting) 1-year primary patency rate = 69% 1-year secondary patency rate = 92%	Larger studies with longer follow-up are included.
Jung E, Jim J, Rubin BG et al. (2010) Long-term outcome of endovascular popliteal artery aneurysm repair. Annals of Vascular Surgery 24: 871–5.	Case series n = 15 Mean follow-up = 54 months	Primary patency rate = 84.6% Secondary patency rate = 100%	Larger studies are included.
Lovegrove RE, Javid M, Magee TR et al. (2008) Endovascular and open approaches to non-thrombosed popliteal aneurysm repair: A meta-analysis. European Journal of Vascular and Endovascular Surgery 36: 96–100.	Meta-analysis n = 141 patients	Operative time was significantly longer but postoperative length of stay was shorter in the endovascular group. 30-day graft thrombosis and re-intervention were more likely following endovascular repairs.	A more recent meta-analysis is included (Cina et al. 2010).
Mohan IV, Bray PJ, Harris JP et al. (2006) Endovascular popliteal aneurysm repair: Are the results comparable to open surgery? European Journal of Vascular and Endovascular Surgery 32: 149–54.	Case series n = 25 patients Median follow-up = 24 months	Primary patency rates: • 6 months = 84.7% • 12 months = 80% • 24 months = 74.5% • 36 months = 74.5% Cumulative secondary patency rates: • 6 months = 88.7% • 12 months = 88.7% • 24 months = 83.2% • 36 months = 83.2%	Larger studies with longer follow-up are included.
Piffaretti G, Tozzi M, Lomazzi C et al. (2007) Stent-graft repair of popliteal artery aneurysms. Italian Journal of Vascular and Endovascular Surgery 14: 81–8.	Case series n = 15 patients Mean follow-up = 23 months	Primary patency rates: • 1 year = 84.6% • 3 years = 63.4% • 5 years = 47.6% 2 patients underwent major amputation (1 patient presented with diabetic gangrene of the foot and poor run-off at the time of intervention).	Larger studies with longer follow-up are included.
Pratesi G, Marek J, Fargion A et al. (2010) Endovascular repair of a ruptured popliteal artery aneurysm associated with popliteal arteriovenous fistula. European Journal of Vascular and Endovascular Surgery 40: 645–8.	Case report n = 1	Ruptured popliteal artery aneurysm associated with popliteal vein arteriovenous fistula was successfully treated with an endovascular approach.	Case report.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Rajasinghe HA, Tzilinis A, Keller T et al. (2007) Endovascular exclusion of popliteal artery aneurysms with expanded polytetrafluoroethylene stent-grafts: Early results. Vascular and Endovascular Surgery 40: 460–6.	Case series n = 16 patients Mean follow-up = 7 months	Technical success = 100% 96% (22/23) of limbs remained asymptomatic during follow-up. 1 thrombosis occurred after 6 months. 1-year primary patency rate = 93% 1-year secondary patency rate = 100%	Larger studies with longer follow-up are included.
Ranson ME, Adelman MA, Cayne NS et al. (2008) Total Viabahn endoprosthesis collapse. Journal of Vascular Surgery 47: 454–6.	Case report n = 1	**Failed repair secondary to infolding of stent-graft** Procedure was converted to an open bypass.	Stent-graft failure is already mentioned as a complication.
Scarcello E, Morrone F, Conti A et al. (2010) Surgical and endovascular treatment of popliteal artery aneurysms: Single centre experience. Italian Journal of Vascular and Endovascular Surgery 17: 79–82.	Non-randomised comparative study n = 21 Mean follow-up (months) = 37 (open) vs 15 (endovascular)	Primary patency rate • Endovascular = 60% • Open = 62.5% Secondary patency rate • Endovascular = 100% • Open = 87.5%	Larger studies are included.
Smith RJP, Gajendragadkar PR, Winterbottom AP et al. (2010) Endovascular occlusion of a ruptured popliteal artery aneurysm. Vascular and Endovascular Surgery 44: 298–301.	Case report n = 1	Successful endovascular repair of ruptured aneurysm.	Case report.
Stone PA, Armstrong PA, Bandyk DF et al. (2005) The value of duplex surveillance after open and endovascular popliteal aneurysm repair. Journal of Vascular Surgery 41: 936–41.	Non-randomised comparative study n = 55 aneurysms (48 open repair) Mean follow-up = 20 months	2 out of 7 endografts failed because of thrombosis. One third of popliteal artery aneurysms repaired by open or endovascular procedures required a secondary intervention within 2 years of repair.	Small number of patients in endovascular group. Study is included in the meta-analysis in table 2 (Cina et al. 2010).
Thomazinho F, Silvestre JMDS, Sardinha WE et al. (2008) Endovascular treatment of popliteal artery aneurysm. Journal Vascular Brasileiro 7: 38–43.	Case series n = 11 Mean follow-up = 27 months	1 pseudoaneurysm in immediate postoperative period 1 endoleak after 7 months and 1 stent-graft occlusion Primary patency rate = 90%	Larger studies with longer follow-up are included.
Tielliu IF, Verhoeven EL, Prins TR et al. (2003) Treatment of popliteal artery aneurysms with the Hemobahn stent-graft. Journal of Endovascular Therapy 10: 111–6.	Case series n = 21 patients Median follow-up = 15 months	Technical success = 100% Cumulative patency rate = 74% All occlusions occurred within 6 months of the procedure.	A larger, more recent case series from the same study centre is included (Tielliu et al. 2007).

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Tielliu IF, Verhoeven EL, Zeebregts C et al. (2005) Endovascular treatment of popliteal artery aneurysms: results of a prospective cohort study. Journal of Vascular Surgery 41: 561–7.	Case series n = 57 patients Mean follow-up = 24 months	21% stent-grafts occluded during follow-up. 1-year primary patency rate = 80% 1-year secondary patency rate = 90% 2-year primary patency rate = 77% 2-year secondary patency rate = 87%	A larger, more recent case series from the same study centre is included (Tielliu et al. 2007).
Ying H, Gloviczki P. (2008) Popliteal artery aneurysms: Rationale, technique, and results of endovascular treatment. Perspectives in Vascular Surgery and Endovascular Therapy 20: 201–13.	Review	Current evidence only supports the use of stent grafts in those with high surgical risks and in the elderly.	A more recent meta-analysis is included (Cina et al. 2010).

Appendix B: Related NICE guidance for endovascular repair of popliteal aneurysms

There is currently no NICE guidance related to this procedure.

Appendix C: Literature search for endovascular repair of popliteal aneurysms

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	4.01.2011	Issue 12 of 12, December 2010
Database of Abstracts of Reviews of Effects – DARE (CRD website)	4.01.2011	n/a
HTA database (CRD website)	4.01.2011	n/a
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	4.01.2011	Issue 12 of 12, December 2010
MEDLINE (Ovid)	4.01.2011	1950 to December Week 3 2010
MEDLINE In-Process (Ovid)	4.01.2011	December 30, 2010
EMBASE (Ovid)	4.01.2011	1980 to 2010 Week 51
CINAHL (NLH Search 2.0/EBSCOhost)	4.01.2011	n/a
Zetoc (for update searches only)	4.01.2011	n/a

Trial sources searched on 13/05/2010

- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database
- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov

Websites searched on 06/05/2010 to 13/05/2010

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference search
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Aneurysm/
2	Popliteal Artery/
3	1 and 2
4	(popliteal adj3 aneurysm*).tw.
5	PAA.tw.
6	or/3-5
7	Blood Vessel Prosthesis Implantation/
8	(endovasc* adj3 (repair* or exclusion or treat* or stent* or graft*)).tw.
9	percutan*.tw.
10	endolumin*.tw.
11	Stents/
12	stent*.tw.
13	(stent-graft* or (stent adj3 graft*)).tw.
14	Polytetrafluoroethylene/
15	polytetrafluoroethylene.tw.
16	PTFE.tw.
17	(haemobahn or hemobahn).tw.
18	viabahn.tw.
19	fluency.tw.
20	wallgraft.tw.
21	nitinol.tw.
22	palmaz.tw.
23	lifestent.tw.
24	or/7-23
25	6 and 24
26	Animals/ not Humans/

27	25 not 26