

Angioplasty and stenting to treat peripheral arterial disease causing refractory erectile dysfunction

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 Recommendations

- 1.1 Current evidence on the safety and efficacy of angioplasty and stenting to treat peripheral arterial disease causing refractory erectile dysfunction is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.
- 1.2 Further research should provide clear details of patient selection. Efficacy outcomes should include procedural success (as measured by arterial imaging and blood-flow measurement), validated scoring systems of erectile dysfunction, and the duration of treatment effect. All complications should be reported. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

- 2.1 There are many causes of erectile dysfunction (ED). It is often multifactorial and precise identification of a cause may be complex. One cause of arteriogenic ED is atherosclerosis causing narrowing or blocking of the arteries in the pelvis or the penis and reducing blood flow to the penis. This guidance is limited to treatment of atherosclerosis in arteries distal to the internal iliacs. It does not include angioplasty or stenting of the iliac arteries done for intermittent claudication, with ED as an accompanying symptom.
- 2.2 Treatment of ED secondary to atherosclerosis includes management of

cardiovascular risk factors (stopping smoking, antithrombotic medication and statin treatment) and oral phosphodiesterase-5 inhibitors. In ED that has not responded to conservative treatments or phosphodiesterase-5 inhibitors, other options (including vacuum erection devices, intracavernosal or intraurethral prostaglandin, and penile prostheses) or surgical revascularisation may be considered.

3 The procedure

- 3.1 Angioplasty and stenting of atherosclerosis in the small arteries distal to the internal iliac arteries aim to offer a less invasive alternative to open surgical revascularisation to patients with arteriogenic erectile dysfunction (ED) that is refractory to standard treatments.
- 3.2 Under local anaesthesia and using fluoroscopic guidance, a catheter is introduced percutaneously through the femoral artery and guided into the narrowed target artery (usually the internal pudendal or common penile artery). Balloon angioplasty of the narrowed artery may be done to dilate the narrowing, or a stent may be placed across the narrowing with or without prior angioplasty.

4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#).

- 4.1 A case series of 30 patients with atherosclerotic erectile dysfunction (ED) treated by zotarolimus-eluting stents (45 lesions stented) reported international index of erectile function (IIEF; total scores range from 1 to 75, from worst to best) mean scores (\pm standard deviation [SD]) of 40.4 (\pm 9.0, n=30) before the procedure and 52.9 (\pm 15.8, n=28) 6 months after the procedure. At 6 months, 59% (16 of 27) of patients (95% confidence interval [CI] 39% to 78%) reported an improvement of 4 or more points on the IIEF-6 questionnaire (scores range from 1 to 30, from worst to best).

- 4.2 A case series of 20 patients with ED and isolated penile artery stenosis treated by balloon angioplasty of the penile artery reported significant improvement in mean IIEF-5 scores (scores range from 1 to 25, from worst to best) from 10.0 (± 5.2) before the procedure to 15.2 (± 6.3) after 6 months (change of +5.2 points, 95% CI 3.0 to 7.4, $p < 0.001$). IIEF-5 scores of 22 or higher were reported in none of the patients at baseline, in 20% (4 of 20) at 1 and 3 months, and in 15% (3 of 20) after 6 months. Clinical success (change in the IIEF-5 score from baseline by 4 or more points or IIEF-5 score of 22 or greater) was reported in 75% (15 of 20) of patients after 1 month, in 65% (13 of 20) after 3 months and in 60% (12 of 20) after 6 months.
- 4.3 The case series of 30 patients reported mean peak systolic velocities of the cavernosal arteries (\pm SD) of 16.4 (± 8.1) cm/s before the procedure ($n=14$) and 42.0 (± 26.9) cm/s after 6 months ($n=23$).
- 4.4 The case series of 30 patients reported restenosis (defined as more than 50% diameter stenosis on follow-up angiography) 6 months after the procedure in 33% (10 of 30) of patients (34% [11/32] of lesions, 95% CI 19% to 53%). Two of these 11 cases of restenosis were observed on non-target lesions (left obturator artery and middle rectal artery, the latter of which occurred after stent migration).
- 4.5 The case series of 20 patients reported technical success (defined as residual diameter stenosis of 30% or less and adequate distal run-off) for all vessels treated (23 of 23).
- 4.6 The specialist advisers listed the following key efficacy outcomes: immediate angiographic evidence of opening of a stenosis at the time of the procedure, objective measures of improved flow (assessed by Doppler ultrasound or fractional flow reserve), improvement in ED assessed using the International Index of Erectile Function and Sexual Encounter Profile (SEP) 3, resolution of ED, and a sustained improved response to medical therapy for ED (phosphodiesterase-5 inhibitors).

5 Safety

This section describes 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 [interventional procedure overview](#).

- 5.1 Flow-limiting dissection was reported in 1 patient in a case series of 20 patients with erectile dysfunction and isolated penile artery stenosis treated by balloon angioplasty of the penile artery. It occurred after dilating the stenotic common penile artery lesion with a balloon catheter. After prolonged dilatation with the same balloon catheter, adequate distal run-off was established.
- 5.2 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not list any anecdotal adverse events. They considered that the following were theoretical adverse events: puncture site complications, haemorrhage, pseudoaneurysm formation, vascular injury, distal embolisation leading to pelvic organ or buttock ischaemia, pelvic haematoma, contrast reaction, long-term complications related to angioplasty, stent migration, occlusion of stent.

6 Committee comments

- 6.1 The committee noted that careful patient selection for angioplasty and stenting to treat peripheral arterial disease causing refractory erectile dysfunction is very important, in view of the many factors which may be involved in causing erectile dysfunction.

7 Further information

Information for patients

NICE has produced [information on this procedure for patients and carers](#). 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](#).