

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

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

Erectile dysfunction (impotence) is the inability to get or maintain an erection. Sometimes this is caused by poor blood flow to the penis, because a blood vessel in the pelvis has narrowed. In this procedure a balloon is inflated, or a small tube made of metal mesh (a stent) is placed across the narrowing. This opens the blood vessel, improving blood flow to the penis, with the aim of making an erection possible.

The National Institute for Health and Care Excellence (NICE) is examining angioplasty and stenting to treat peripheral arterial disease causing refractory erectile dysfunction and will publish guidance on its safety and efficacy to the NHS. NICE's Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about angioplasty and stenting to treat peripheral arterial disease causing refractory erectile dysfunction.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.
- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 20 November 2015

Target date for publication of guidance: February 2016

1 Provisional 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

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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 is atherosclerotic disease which limits blood flow by narrowing or blocking arteries in the pelvis or 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 arteriogenic 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 With the patient 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](#) [add URL].

- 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% (16/27) of patients (95% 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 (\pm 5.2) before the procedure to 15.2 (\pm 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% (4/20) at 1 and

3 months, and in 15% (3/20) 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% (15/20) of patients after 1 month, in 65% (13/20) after 3 months and in 60% (12/20) 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 (\pm 8.1) cm/s before the procedure (n=14) and 42.0 (\pm 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% (10/30) 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 (23/23).
- 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](#) *[add URL]*.

- 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

7.1 For related NICE guidance, see the [NICE website](#).

Bruce Campbell

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October, 2015