NICE guidance

Uterine artery embolisation for treating adenomyosis

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 uterine artery embolisation for treating adenomyosis shows that the procedure is efficacious for symptom relief in the short and medium term for a substantial proportion of patients. There are no major safety concerns. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 During the consent process patients should be informed, in particular, that symptoms may not be relieved, that symptoms may return and that further procedures may be needed. Patients contemplating pregnancy should be informed that the effects of the procedure on fertility are uncertain.

1.3 Patient selection should be carried out by a multidisciplinary team, including a gynaecologist and an interventional radiologist.

1.4 NICE encourages further research into the effects of uterine artery embolisation compared with other procedures to treat adenomyosis, particularly for patients wishing to maintain or improve their fertility.

2 Indications and current treatments

2.1 Adenomyosis is a benign condition characterised by the presence of ectopic endometrial glands and stroma within the myometrium. It frequently occurs coincidentally with fibroids. Adenomyosis may cause no symptoms but some women with adenomyosis experience heavy, prolonged menstrual bleeding with severe cramps, pelvic pain and discomfort.

2.2 Treatment for symptomatic adenomyosis includes anti-inflammatory medications, hormone therapy and endometrial ablation. For severe symptoms that do not respond adequately, hysterectomy has been the conventional surgical treatment. Uterine artery embolisation may be an alternative option for patients who do not wish to have hysterectomy and/or who wish to preserve their fertility.

3 The procedure

3.1 The aim of uterine artery embolisation for treating adenomyosis is to block the blood supply to the adenomyosis, causing it to shrink. The intended benefits of the procedure are that it offers a less invasive alternative to hysterectomy, and fertility may be preserved.

3.2 With the patient under sedation and local anaesthesia, a catheter is inserted into the femoral artery (bilateral catheters are sometimes used). Fluoroscopic guidance is used to manipulate the catheter into the uterine artery. Small embolisation particles are injected through the catheter into both uterine arteries.

3.3 Various embolisation agents can be used for this procedure.

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 overview.

4.1 In a case series of 54 patients with adenomyosis, 78% (42 of 54) of whom presented with menorrhagia, resolution of menorrhagia was reported in 26% (10 of 39) of patients at a mean follow-up of 5 years. In a case series of 40 patients (90% [36 of 40] presenting with menorrhagia), symptoms had resolved in 78% (28 of 36) of patients at a median follow-up of 40 months.

4.2 In a case series of 27 patients, complete resolution of dysmenorrhoea was reported in 38% (7 of 18), 57% (9 of 16), 36% (4 of 11) and 64% (7 of 11) of

patients at 6, 12, 24 and 36 months respectively.

4.3 In the case series of 54 patients with adenomyosis, 43% (23 of 54) presented with bulk-related symptoms. Complete resolution of these symptoms was reported in 35% (8 of 23) of patients at a mean follow-up of 5 years. In the case series of 27 patients, complete resolution of bulk-related symptoms was reported in 38% (7 of 18), 31% (5 of 16), 46% (5 of 11) and 55% (6 of 11) of patients at 6, 12, 24 and 36 months respectively.

4.4 In a case series of 15 patients, a significant improvement in quality of life was reported at a mean follow-up of 8 months in the following domains: ability to perform activities of daily life, ability to socialise outside the home, overall energy level, pain or cramping during menstruation ($p<0.001$), and pain during sexual intercourse ($p=0.02$).

4.5 In the case series of 54 patients with adenomyosis, 5 patients became pregnant (3 delivered successfully and 2 opted for abortion).

4.6 In a case series of 18 patients with adenomyosis, 44% (8 of 18) of patients had subsequent treatments because of treatment failure or recurrent symptoms. Twenty-eight per cent (5 of 18) of patients underwent hysterectomy (4 months after the procedure in 1 patient because of treatment failure, and between 9 and 27 months after the procedure in 4 patients because of recurrent symptoms). Eleven per cent (2 of 18) of patients needed additional treatments and 6% (1 of 18) of patients needed endometrial balloon thermocoagulation because of recurrent symptoms (timing unclear).

4.7 The specialist advisers listed key efficacy outcomes to be quality of life, symptom resolution and need for further treatment.

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 overview.

5.1 Severe cramping pain (4 days after the procedure; treated successfully by analgesia) was reported in 1 patient in the case series of 18 patients.

5.2 Worsening of symptoms was reported in 82% (9 of 11) of patients in the case series of 27 patients at 3 years follow-up. Three patients opted for hormonal therapy to help with symptom relief and none chose hysterectomy.

5.3 Amenorrhoea was reported in 4% (2 of 54) of patients (aged 41 and 44 years) immediately after the procedure in the case series of 54 patients (no further details available).

5.4 Transient increased vaginal discharge was reported in 8% (3 of 40) of patients in a case series of 40 patients (timing unclear).

5.5 The specialist advisers noted that adverse events from uterine artery embolisation used for adenomyosis are unlikely to differ significantly from those occurring when the procedure is used for fibroids. They include post-embolisation syndrome and non-target embolisation.

6 Committee comments

6.1 In assessing safety, the committee was mindful of its previous evaluations of the large volume of evidence on uterine artery embolisation for the treatment of fibroids. It considered that the safety profile of uterine artery embolisation was unlikely to be different when used for adenomyosis (and patients with a combination of adenomyosis and fibroids dominated the published evidence).

6.2 The committee noted that the patient commentaries reported good symptom relief following the procedure in a majority of patients but not in all. Occurrence of menopausal symptoms after the procedure was reported by some patients.

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information on this procedure for the public. 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.