Uterine artery embolisation for fibroids

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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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG1 and IPG94.

1 Guidance

- 1.1 Current evidence on uterine artery embolisation (UAE) for fibroids 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 and audit.
- 1.2 During the consent process patients should be informed, in particular, that symptom relief may not be achieved in some women, that symptoms may return and that further procedures may therefore be required. Patients contemplating pregnancy should be informed that the effects of the procedure on fertility and on pregnancy 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 UAE compared with other procedures to treat fibroids, particularly for women wishing to maintain or improve their fertility.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Uterine fibroids, also known as uterine leiomyomas or uterine myomas, are benign tumours of smooth muscle cells and fibrous tissue that develop within the wall of the uterus. They are classified by their location relative to the layers of the uterus (subserous, intramural or submucous) and can be single or multiple.
- 2.1.2 Uterine fibroids are one of the most common gynaecological problems among women in the UK. They may be asymptomatic or may cause symptoms such as abnormal uterine bleeding, urinary incontinence, a feeling of pelvic pressure, or pain. They may also be associated with reproductive problems such as infertility and miscarriage.
- 2.1.3 Asymptomatic fibroids require no treatment. Treatments for symptomatic fibroids include hysterectomy and myomectomy.

2.2 Outline of the procedure

- 2.2.1 The aim of uterine artery embolisation (UAE) for fibroids is to offer a less invasive alternative to hysterectomy or myomectomy with preservation of the uterus, and a faster recovery time. UAE is sometimes used before a planned myomectomy.
- 2.2.2 With the patient under conscious 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 the arteries supplying the fibroids, with the aim of causing thrombosis and consequent fibroid infarction.
- 2.2.3 Various embolisation agents can be used 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 register of 1,387 patients reported that 84% and 83% of patients had an improvement in their symptoms after UAE at 6 and 24 months respectively. The register of 1,387 patients reported an improvement in mean health-related quality-of-life scores (on a scale from 0 to 100) from 44.1 at baseline to 79.5 after UAE at a maximum 3-year follow-up (p<0.001).
- In a register of 2,112 patients, the mean symptom score (on a scale from 0 to 100) 2.3.2 improved from 58.6 at baseline to 16.5 among 1,218 patients at 3-year follow-up (p<0.001).
- 2.3.3 A randomised controlled trial (RCT) of 157 patients treated by UAE or surgery (hysterectomy or myomectomy) reported symptom improvement in both groups, but this improvement was significantly greater among patients treated by surgery than by UAE (p=0.004 at 1 month, p=0.03 at 12 months).
- 2.3.4 The register of 1,387 patients reported a mean uterine volume reduction of 40% (n=666) and a mean reduction in fibroid diameter of 2.2 cm (n=847).
- 2.3.5 The register of 2,112 patients reported a re-intervention rate of 15% during a 3-year follow-up (10% hysterectomy, 3% myomectomy and 2% repeat UAE).
- An RCT of 177 patients treated by UAE or hysterectomy reported that 28% (23 2.3.6 out of 81) of UAE-treated patients had required hysterectomy at 5-year follow-up.
- 2.3.7 An RCT of 121 women treated by UAE or myomectomy reported that 50% (13 out of 26) of women who tried to conceive after UAE became pregnant compared with 78% (31 out of 40) of women after myomectomy at a mean follow-up of 25 months (p<0.05). The rate of spontaneous abortion or missed miscarriage was 64% in the UAE group and 23% in the myomectomy group (p<0.05).
- The Specialist Advisers listed key efficacy outcomes as symptom improvement, 2.3.8

quality of life and the need for further treatment.

2.4 Safety

- 2.4.1 Uterine infection was reported in 2% (28 out of 1,387) of patients in one of the registers (there were significantly fewer infective complications after discharge in patients who received prophylactic antibiotics compared with those who did not; figures not provided). Septic shock and multiple organ failure leading to death 25 days after UAE occurred in 1 patient in a case series of 21 patients, reported in a systematic review of 36 papers. Septicaemia and emergency myomectomy or hysterectomy were reported in 3% (17 out of 649) of UAE-treated patients in a non-randomised comparative study of 1,108 patients.
- 2.4.2 Arterial dissection or perforation were reported in 2 patients, groin bleeding or pseudoaneurysm were reported in 2 patients, and femoral artery occlusion was reported in 1 patient from the register of 1,387 patients (events reported before discharge from hospital; clinical sequelae not described).
- 2.4.3 One case of bowel perforation treated by laparotomy was reported in the register of 1,387 patients.
- 2.4.4 A severe vasovagal event requiring atropine was reported in 1 out of 106 UAEtreated patients in the RCT of 157 patients.
- 2.4.5 The Specialist Advisers listed adverse events reported in the literature as uterine infarction, bladder and vulval damage, ovarian damage, post-embolisation syndrome, pain, vaginal discharge and premature menopause.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. 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.