



Fallopian tube recanalisation by guidewire

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www.nice.org.uk/guidance/ipg71

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 impact of implementing NICE recommendations</u> wherever possible.

1 Guidance

- Fallopian tube recanalisation by guidewire is safe enough for use, provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 The efficacy of the procedure in improving the chance of pregnancy is impossible to gauge from available research.
- 1.3 Clinicians wishing to undertake fallopian tube recanalisation by guidewire should take the following actions:
 - Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of NICE's information for the public is recommended.
 - Audit and review clinical outcomes including pregnancy rates of all patients having fallopian tube recanalisation by guidewire.

2 The procedure

2.1 Indications

- 2.1.1 Fallopian tube recanalisation by guidewire is a treatment for infertility caused by blocked fallopian tubes, especially if the blockage is close to the entrance to the uterus (proximal).
- 2.1.2 Alternative radiological methods of clearing tubal obstruction include balloon tuboplasty, which involves inflating a small balloon within the fallopian tube. Tubal

obstruction may also be treated surgically.

2.2 Outline of the procedure

2.2.1 Fallopian tube recanalisation by guidewire is carried out during the same treatment session as diagnostic salpingography and involves inserting a catheter into the fallopian tube. This, or the subsequent injection of radio-opaque dye, may clear the obstruction. If these strategies fail, a guidewire may be passed up into the fallopian tube through the catheter, and manipulated to clear the obstruction.

2.3 Efficacy

- No controlled studies were identified. In one study, successful recanalisation was reported in 77% (321 out of 417) of the tubes of 302 patients. Thirty (10%) of these 302 patients became pregnant without further infertility treatment within 12 months of undergoing the procedure. In another study, successful recanalisation was reported in 75% (176 out of 234) of patients. Of these, 22% (39 out of 176) had subsequent live births. For more details, see the overview.
- 2.3.2 One Specialist Advisor noted that the degree of efficacy may depend on patient selection.

2.4 Safety

- In the studies identified, the rate of tubal perforation ranged from 1% (4 out of 417) to 11% (4 out of 38), and the rate of tubal pregnancy from 0.4% (1 out of 234) to 8% (3 out of 38). Other reported complications were sepsis in 0.9% (2 out of 234) of patients, and pain requiring medication in 3% (7 out of 234, and 4 out of 150) of patients. For more details, see the overview.
- 2.4.2 The Specialist Advisors listed the main potential complications as fallopian tube perforation, intra-abdominal bleeding and infection.

2.5 Other comments

- 2.5.1 There is a distinction between efficacy in terms of opening the fallopian tubes and in terms of achieving pregnancy.
- 2.5.2 The procedure is often used as an adjunct to other fertility treatments.
- 2.5.3 There is a potential risk of tubal perforation that may then reduce the chance of pregnancy.
- 2.5.4 Although the evidence showed an increased risk of tubal pregnancy, it was noted that there was generally a greater risk of tubal pregnancy in patients with tubal disease, even without this procedure.

3 Further information

3.1 NICE has issued a guideline on fertility problems: assessment and treatment.

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.