



Falloposcopy with coaxial catheter

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

1 Guidance

- 1.1 Current evidence on the safety and efficacy of falloposcopy with coaxial catheter does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake falloposcopy with coaxial catheter should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of <u>NICE's</u> <u>information for the public</u> is recommended.
 - Audit and review clinical outcomes of all patients having falloposcopy with coaxial catheter.
- Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Falloposcopy with coaxial catheter is used to investigate and treat subfertility in women.

2.1.2 Conventional investigation of subfertility in women often includes examination of the fallopian tubes using hysterosalpingography, or laparoscopy with dye injection, to check the patency of the fallopian tubes. Occasionally, salpingoscopy is performed – this involves inspection of the inside of the fallopian tubes from the outer fimbrial end during laparoscopy or laparotomy.

2.2 Outline of the procedure

2.2.1 Falloposcopy with coaxial catheter is a technique for direct inspection of the inside of the fallopian tubes via the cervix and uterus. The coaxial technique involves inserting a narrow catheter over a guidewire through the cervix and uterine cavity into a fallopian tube. The surgeon then passes an endoscope through the catheter. Unlike X-ray methods or laparoscopy, falloposcopy allows balloon dilatation to be performed on obstructive lesions at the time of the procedure.

2.3 Efficacy

- 2.3.1 No controlled studies were found, and none of the studies identified were of high quality. Some studies were on the investigative use of falloposcopy with coaxial catheter and others looked at the procedure as a therapeutic technique.
- Among the studies on investigation, the rate of successful fallopian tube cannulation/catheterisation ranged from 83% (30 out of 36) to 85% (110 out of 130). In two studies, the failure rate of falloposcopy was 11% (9 out of 84, and 8 out of 71), but some women may have been included in both studies. Successful imaging or 'correct' visualisation of the fallopian tube ranged from 30% (33 out of 110) to 88% (28 out of 32).
- 2.3.3 One of the studies on the procedure's therapeutic use found coaxial falloposcopy with direct balloon tuboplasty to be successful in treating endotubal lesions in 41% (13 out of 32) of tubes. Another study reported 96% (52 out of 54) of recanalisations to be technically successful, but of the tubes successfully recanalised, only 31% (16 out of 52) were as a result of falloposcopy with coaxial

catheter (the other 36 were treated by selective salpingography). Five pregnancies occurred in this study, but it was not possible to determine whether these occurred in women who underwent falloposcopy with coaxial catheter.

- 2.3.4 One comparative study on the consistency between the results of hysterosalpingography and falloposcopy was identified. In this study, only 15% (3 out of 20) of tubes found to be blocked when using hysterosalpingography were found to be blocked when using falloposcopy. However, no 'gold standard' test was available to determine the validity of the results. For more details, see the overview.
- 2.3.5 One Specialist Advisor noted that the images obtained by falloposcopy with coaxial catheter were often of poor quality and the 'normal' internal appearance of the tube was not clearly defined.

2.4 Safety

- In the studies identified, the main complications reported were: tubal perforation, which occurred in 1% (1 out of 130) to 4% (3 out of 67) of tubes; and uterine perforation, which occurred during procedures on 2% (3 out of 130) of tubes. One study reported a complication rate of 23% (3 out of 13) for distal fallopian tube obstructions, but it was not clear whether these women had undergone falloposcopy with coaxial catheter. For more details, see the overview.
- 2.4.2 One Specialist Advisor considered the main potential adverse effect of this procedure to be perforation of the fallopian tube; this is usually a minor complication.

2.5 Other comments

2.5.1 This is one of a number of techniques for examining the fallopian tubes, but it is seldom used in the UK.

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 <u>Healthcare Improvement Scotland</u>.