

Hysteroscopic metroplasty of a uterine septum for primary infertility

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg509

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 the safety of hysteroscopic metroplasty of a uterine septum for primary infertility includes some serious but rare complications. Current evidence on efficacy is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake hysteroscopic metroplasty of a uterine septum for primary infertility should take the following actions:
 - Inform the clinical governance leads in their NHS trust.
 - Ensure that women understand the uncertainty about the procedure's efficacy and its risks and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
 - Audit and review clinical outcomes of all women having hysteroscopic metroplasty of a uterine septum for primary infertility (see section 7.1).
- 1.3 Patient selection and treatment should be done by a multidisciplinary team including specialists in reproductive medicine, uterine imaging and hysteroscopic surgery.
- 1.4 Clinicians undertaking hysteroscopic metroplasty of a uterine septum for primary infertility should be trained in hysteroscopic surgery in accordance with the Royal College of Obstetricians and Gynaecologists training module.
- 1.5 Further research should include clear documentation of patient selection

and of all complications. Outcomes should include pregnancy rates, live birth rates and instances of preterm delivery. Comparative studies would be helpful. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

- 2.1 A uterine septum is a congenital anomaly (present from birth). The septum is a muscular or fibrous wall that divides the inside of the uterus, creating 2 cavities (a septate uterus). The septum may be complete or incomplete. It is more common in women with primary infertility and in women who have had repeated miscarriages, and may therefore be one cause of these problems.
- 2.2 Surgical removal of the septum (metroplasty) is usually considered for women who have a septate uterus in association with repeated adverse reproductive outcomes, including a history of recurrent miscarriage (usually defined as 3 or more miscarriages in a row) and preterm delivery. Metroplasty is also used to manage primary infertility but the causal relationship between this problem and the presence of a uterine septum is less certain.
- 2.3 Metroplasty was traditionally done by a transabdominal approach. A hysteroscopic approach aims to reduce morbidity and shorten the recovery period. Unlike transabdominal metroplasty, caesarean section is not mandatory for patients who conceive after hysteroscopic metroplasty.

3 The procedure

- 3.1 Hysteroscopic metroplasty of a uterine septum for primary infertility aims to create a normal uterine cavity by removing the uterine septum, which may help implantation of pregnancy.
- 3.2 Hysteroscopic metroplasty is usually done with the patient under general or spinal anaesthesia. After cervical dilation, a hysteroscope is inserted into the uterus through the cervix. The uterine cavity is distended with

fluid; fluid control must be carefully monitored to avoid overload. The septum is excised, most commonly using microscissors, electrosurgery or laser. The procedure may be done using ultrasound or laparoscopic guidance.

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](#).

- 4.1 A case series of 246 women with a septate uterus and a history of recurrent miscarriage or infertility reported that 57% (61/108) of women with unexplained fertility became pregnant after hysteroscopic metroplasty, with a live birth rate of 75% (44/71) of pregnancies; there were 12 ongoing pregnancies at the close of the study. The preterm delivery rate was 10% (7/71). A case series of 263 women with a septate uterus and a history of primary or secondary infertility or a history of recurrent miscarriage reported that 38% (57/149) of women with primary infertility became pregnant after hysteroscopic metroplasty, with a term delivery rate of 88% (50/57). A case series of 181 women with a septate uterus and a history of unexplained infertility or more than 1 miscarriage reported that 44% (43/98) of women with unexplained infertility became pregnant after hysteroscopic metroplasty; there were 51 pregnancies, 36 of which were spontaneous and the live birth rate was 80% (41/51). Of the 36 spontaneous pregnancies, 22% (8/36) had a preterm delivery.
- 4.2 A review of 2528 women (37 studies) with a septate uterus and a history of recurrent miscarriage, infertility, spontaneous abortion or preterm delivery that included a meta-analysis of 2074 women (29 studies) reported a live birth rate of 50% after hysteroscopic metroplasty (95% confidence interval [CI] 43 to 57; 19 studies, n=1525) (follow-up period not reported).
- 4.3 The specialist advisers listed key efficacy outcomes as a normal-sized uterine cavity, improved pregnancy outcome, improved fertility, malpresentation rate, and reduction in difficulty in labour and delivery.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. Evidence on both women with a history of recurrent miscarriage and those with primary infertility has been included because the procedure is the same for both and therefore the safety events are relevant to both conditions. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 Uterine perforation during hysteroscopic metroplasty was reported in 1% (17/2167) of women in a review of 2528 women (37 studies) and in 1% (8/923) of women in a case series of 973 women. Uterine perforation was reported in 1% (2/170) of women in a case series of 170 women; this was managed by laparoscopic bipolar coagulation and both patients were discharged the same day. One of these women subsequently had a pregnancy that carried to term, with delivery by caesarean section.
- 5.2 Uterine rupture during pregnancy or delivery was identified in 18 confirmed reports in the review of 2528 women; in 10 of the 18 cases, uterine perforation had occurred at the time of the hysteroscopic metroplasty.
- 5.3 Intraoperative bleeding with 'interruption of the procedure' was reported in 1 woman in the case series of 973 women. Excessive bleeding was reported in 1% (2/170) of women in the case series of 170 women; this was managed by an intrauterine balloon catheter kept in situ for 4 hours.
- 5.4 Cervical laceration (not further described) was reported in less than 1% (2/2167) of women in the review of 2528 women. Difficult dilatation leading to cervical injury (not further described) was reported in 1 woman in the case series of 170 women.
- 5.5 Pulmonary oedema was reported in 1 woman each in the review of 2528 women and in the case series of 973 women (no further details reported).
- 5.6 Uterine synechiae after hysteroscopic metroplasty were reported in 2% (4/181) of women in a case series of 181 women (these synechiae

were all treated surgically) and in 1 woman (1/2167) in the review of 2528 women (treatment not reported). Mild adhesions were reported in 7% (11/170) of women in the case series of 170 women (diagnosed by hysteroscopy). These adhesions were all treated by hysteroscopic adhesiolysis; 7 of the women subsequently became pregnant and had term deliveries.

- 5.7 Interstitial ectopic pregnancy after hysteroscopic metroplasty was reported in 1 woman in a case report. A laparotomy was done to resect a wedge of myometrium that was completely enclosing the gestational sac. A hysteroscopy was done 4 months later and showed only a fine linear scar at the fundus, and the uterine cavity was otherwise normal.
- 5.8 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 considered that the following were theoretical adverse events: incomplete resection of the septum, infection, placenta accreta and percreta, a negative effect on fertility through damage to the endometrium, and detrimental effect on uterine and endometrial blood flow.

6 Committee comments

- 6.1 The Committee found it difficult to assess the outcomes specifically for patients with primary infertility because many of the published data were pooled across different indications for hysteroscopic metroplasty, among which recurrent miscarriage appeared to be the most common.

7 Further information

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

This guidance requires that clinicians undertaking the procedure make special arrangements for audit. [NICE has identified relevant audit criteria and has developed an audit tool](#) audit tool(which is for use at local discretion).

Information for patients

NICE has produced [information on this procedure for patients and carers](#). 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](#).