



# Hysteroscopic metroplasty of a uterine septum for recurrent miscarriage

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

#### 1 Recommendations

- 1.1 Current evidence on the safety of hysteroscopic metroplasty of a uterine septum for recurrent miscarriage includes some serious but rare complications. Current evidence on efficacy is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- Patient selection and treatment should be done by a multidisciplinary team including specialists in reproductive medicine, uterine imaging and hysteroscopic surgery.
- 1.3 Clinicians undertaking hysteroscopic metroplasty of a uterine septum for recurrent miscarriage should be trained in hysteroscopic surgery in accordance with the Royal College of Obstetricians and Gynaecologists training module.

#### 2 Indications and current treatments

- 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 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 recurrent miscarriage aims to create a normal uterine cavity by removing the septum, and consequently reduce the risk of miscarriage.
- 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.
- 3.3 After a miscarriage, an interval of at least 6 weeks is left before doing a hysteroscopic metroplasty.

# 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 <u>overview</u>.

A non-randomised comparative study of 78 women with a partial septate uterus and a history of recurrent miscarriage reported miscarriage rates of 22% (8 out of 37) after hysteroscopic metroplasty and 50% (9 out of 18) with expectant

management (p<0.05), at a mean follow-up of 11 months. A non-randomised comparative study of 48 women with a septate uterus and a history of recurrent miscarriage reported miscarriage rates for the first pregnancy after enrolment of 18% (4 out of 22) after hysteroscopic metroplasty and 64% (9 out of 14) with expectant management (p<0.001), at a mean follow-up of 36 months. A case series of 973 women with a septate uterus and a history of recurrent miscarriage or infertility reported the pregnancy outcomes of 344 women after hysteroscopic metroplasty: 78% (268 out of 344) of women reached term, 14% (48 out of 344) of women miscarried before 12 weeks' gestation, 4% (14 out of 344) of women miscarried after 12 weeks' gestation and 14 women were still pregnant at the close of the study (follow-up period not reported). A case series of 170 women with a partial or complete septate uterus and a history of recurrent miscarriage, preterm delivery or infertility reported that before hysteroscopic metroplasty, 92% (332 out of 363) of pregnancies ended in miscarriage compared with 13% (24 out of 186) of pregnancies after hysteroscopic metroplasty (p=0.02), at a mean follow-up of 29 months.

- A review of 2,528 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 2,074 women (29 studies) reported a live birth rate of 50% after hysteroscopic metroplasty (95% confidence interval [CI] 43 to 57; 19 studies, n=1,525; follow-up period not reported). A case series of 246 women with a septate uterus and a history of recurrent miscarriage or infertility reported a live birth rate after hysteroscopic metroplasty of 60% (71 out of 129) in women with a history of recurrent miscarriage, at a mean follow-up of 37 months; there were 11 ongoing pregnancies at the close of the study.
- 4.3 The non-randomised comparative study of 78 women with a partial septate uterus and a history of recurrent miscarriage reported preterm delivery in 5% (2 out of 37) of pregnancies in women treated by hysteroscopic metroplasty and 28% (5 out of 18) in women managed expectantly (p<0.05). The non-randomised comparative study of 48 women with a septate uterus and a history of recurrent miscarriage reported preterm delivery in 5% (1 out of 22) of pregnancies after hysteroscopic metroplasty and 7% (1 out of 14) with expectant management, for the first pregnancy after enrolment (p value not stated). The case series of 170 women with a partial or complete septate uterus and a history of recurrent miscarriage, preterm delivery or infertility reported preterm delivery in 6% (22 out

of 363) of pregnancies before hysteroscopic metroplasty compared with 8% (14 out of 186) of pregnancies after hysteroscopic metroplasty (p=0.12). The case series of 246 women with a septate uterus and a history of recurrent miscarriage or infertility reported a preterm delivery rate after hysteroscopic metroplasty of 11% (14 out of 129) of pregnancies in women with a history of recurrent miscarriage.

4.4 The specialist advisers listed the key efficacy outcomes as a normal-sized uterine cavity, pregnancy rate, reduced miscarriage rate and increased live birth rate.

# 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 overview.

- Uterine perforation during hysteroscopic metroplasty was reported in 1% (17 out of 2,167) of women in a review of 2,528 women (37 studies) and in 1% (8 out of 923) of women in a case series of 973 women. Uterine perforation was reported in 1% (2 out of 170) of women in a case series of 170 women; this was managed by laparoscopic bipolar coagulation and both women were discharged the same day. One of these women subsequently had a pregnancy that carried to term, with delivery by caesarean section.
- Uterine rupture during pregnancy or delivery was identified in 18 confirmed reports in the review of 2,528 women; in 10 of the 18 cases, uterine perforation had occurred at the time of the hysteroscopic metroplasty.
- 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 out of 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 out of

2,167) of women in the review of 2,528 women. Difficult dilatation leading to cervical injury (not further described) was reported in 1 woman in the case series of 170 women.

- Pulmonary oedema was reported in 1 woman each in the review of 2,528 women and in the case series of 973 women (no further details reported).
- Uterine synechiae after hysteroscopic metroplasty were reported in 2% (4 out of 181) of women in a case series of 181 women (these synechiae were all treated surgically) and in 1 woman in the review of 2,528 women (treatment not reported). Mild adhesions were reported in 7% (11 out of 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.
- 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.
- 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

The Committee noted that much of the evidence on efficacy of hysteroscopic metroplasty of a uterine septum for recurrent miscarriage did not provide direct evidence that the procedure resulted in pregnancies that would not otherwise have occurred. However, it included large numbers of women with a history of

recurrent miscarriage who subsequently had successful pregnancies that would not otherwise have been expected.

#### 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 <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.