Hysteroscopic Metroplasty for Primary Infertility

Description
A septate uterus is a type of congenital uterine anomaly, in which the inside of the uterus is divided by a muscular or fibrous wall, called the septum. The septum may be partial or complete, extending as far as the cervix. It is more common in women with infertility and in women with repeated miscarriage and may therefore be one cause of this problem. Surgical removal of the septum (metroplasty) is usually considered for women who have a septate uterus and repeated adverse reproductive outcomes, including miscarriage and preterm delivery. Metroplasty has also been used to manage primary infertility but the causal relationship between this problem and the presence of a uterine septum is less clear.

Surgery 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.

NICE Interventional procedures guidance [IPG509] Hysteroscopic metroplasty of a uterine septum for primary infertility was published in January 2015 and the pathway follows their recommendations.

1. NICE ipg509 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.

1.2 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. NICE ipg509 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 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 micro scissors, 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 NICE ipg509 Efficacy

The NICE Committee considered the efficacy outcomes from the published literature as part of the evidence about the procedure.

4.1
A non-randomised comparative study of 78 women with a partial septate uterus and a history of recurrent miscarriage reported miscarriage rates of 22% (8/37) after hysteroscopic metroplasty and 50% (9/18) 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% (4/22) after hysteroscopic metroplasty and 64% (9/14) 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% (268/344) of women reached term, 14% (48/344) of women miscarried before 12 weeks’ gestation, 4% (14/344) 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% (332/363) of pregnancies ended in miscarriage compared with 13% (24/186) of pregnancies after hysteroscopic metroplasty (p=0.02), at a mean follow up of 29 months.

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). 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% (71/129) 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% (2/37) of pregnancies in women treated by hysteroscopic metroplasty and 28% (5/18) 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% (1/22) of pregnancies after hysteroscopic metroplasty and 7% (1/14) 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% (22/363) of pregnancies before hysteroscopic metroplasty compared with 8% (14/186) 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% (14/129) 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 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 women 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 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 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.