

Laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg639

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.

This guidance replaces IPG228.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Patient selection should be done by a multidisciplinary team experienced in the management and prevention of preterm delivery.

2 The condition, current treatments and procedure

The condition

- 2.1 Cervical incompetence may be caused by a congenital weakness of the cervix, or previous obstetric or gynaecological trauma. It is characterised by painless dilatation of the cervix in the second or third trimester, followed by second

trimester miscarriage or premature rupture of the membranes and preterm delivery. The condition is usually diagnosed after 1 or more late second trimester pregnancy losses or early third trimester delivery, and after other causes have been excluded.

Current treatments

- 2.2 Cervical incompetence is traditionally treated by transvaginal cervical cerclage. This involves placing a strong suture or tape around the cervix, via the vagina, and tightening it to keep the cervix closed. The procedure is typically done at the end of the first trimester or the beginning of the second trimester. The suture or tape is then usually removed at around 37 weeks of gestation to allow delivery.
- 2.3 Cervical cerclage using a transabdominal approach may be needed if transvaginal cerclage is technically difficult or has proved ineffective. With this approach, caesarean section is necessary to deliver the baby.

The procedure

- 2.4 Laparoscopic cervical cerclage can be done during pregnancy or in women who are not pregnant. Under general anaesthesia, the peritoneal cavity is insufflated with carbon dioxide through a needle inserted into the umbilicus. Several small incisions are made to provide access for the laparoscope and surgical instruments. In women who are not pregnant, a dilator may initially be inserted into the cervix through the vagina for uterine manipulation. The bladder is dissected away from the uterus and a suture or tape is secured around the cervical isthmus, above the cardinal and uterosacral ligaments. As with the open transabdominal approach, caesarean section is necessary to deliver the baby. The suture or tape may be left in place for future pregnancies.

3 Committee considerations

The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 2 systematic reviews, 4 non-randomised comparative studies (2 of which were also included in 1 of the systematic reviews), 4 case series (1 of which was also included in 1 of the systematic reviews) and 1 case report (1 article reported both a case series and a systematic review), and is presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: live birth rate, gestational age at delivery and reduced pain compared with open surgery.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: pregnancy loss, bleeding, infection, unintentional damage to adjacent organs and gas embolus.
- 3.4 No patient commentary was sought.

Committee comments

- 3.5 Different materials are used for this procedure, including sutures and tapes.
- 3.6 For both laparoscopic and open transabdominal cerclage, there is uncertainty about the optimal timing of the procedure.
- 3.7 The committee was told that there is a potential risk of uterine rupture if labour starts when the suture or tape is in place.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).