NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

Late miscarriages and preterm births can be caused by a weak (sometimes called an incompetent) cervix that shortens or opens too early in pregnancy. Cervical cerclage involves placing a stitch around the upper part of the cervix. In this procedure, the stitch is placed through the abdomen using a laparoscopic ('keyhole') approach. The aim is to keep the cervix closed to prevent late miscarriages and preterm births.

The National Institute for Health and Care Excellence (NICE) is looking at laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide.

Issue date: September 2018

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 18 October 2018

Target date for publication of guidance: January 2019

1 Draft 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.

1.2 Patient selection should be done by a multidisciplinary team, which should include a midwife, obstetrician and a gynaecologist with training in laparoscopic surgery.

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 is then usually removed at around 37 weeks of gestation to allow delivery.

2.3 Cervical cerclage via a transabdominal approach may be necessary 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 ligature 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.

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 This guidance is a review of NICE's interventional procedures guidance on laparoscopic cerclage for prevention of recurrent pregnancy loss due to cervical incompetence.

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.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
September 2018

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