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**NHS**
*National Institute for Health and Clinical Excellence*

# Laparoscopic cerclage for prevention of recurrent pregnancy loss due to cervical incompetence

## 1 Guidance

1.1 The evidence on the safety and efficacy of laparoscopic cerclage for prevention of recurrent pregnancy loss due to cervical incompetence is limited, and therefore this procedure should not be used without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to undertake laparoscopic cerclage for prevention of recurrent pregnancy loss due to cervical incompetence should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and that they will require delivery by caesarean section. They should provide patients with clear, written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG228publicinfo).
- Audit and review clinical outcomes of all patients having laparoscopic cerclage for prevention of recurrent pregnancy loss due to cervical incompetence (see section 3.1).

1.3 Selection of patients for this procedure should be carried out in the context of a multidisciplinary team experienced in the management of recurrent pregnancy loss, including a clinician with training in advanced laparoscopic techniques.

## 2 The procedure

### 2.1 Indications

2.1.1 Cervical incompetence may be due to previous obstetric or gynaecological trauma or a congenital weakness of the cervix. It is characterised by painless dilatation of the cervix in the second or third trimester, followed by premature rupture of the membranes and preterm delivery or miscarriage. The condition is usually diagnosed after one or more late second trimester or early third trimester pregnancy losses, and after other causes have been excluded.

2.1.2 Cervical incompetence is traditionally treated by transvaginal cervical cerclage. This involves placing a stitch of strong thread or tape around the cervix, via the vagina, and tightening it to keep the cervix closed. The procedure is typically performed at the end of the first trimester or the beginning of the second trimester, and the stitch is usually removed at around 37 weeks' gestation. Cervical cerclage via a transabdominal approach (either open or laparoscopic) may be necessary if transvaginal cerclage is technically difficult or has proved ineffective.

### 2.2 Outline of the procedure

2.2.1 Laparoscopic cervical cerclage can be performed during pregnancy or in non-pregnant women. Under general anaesthesia, the peritoneal cavity is insufflated with carbon dioxide through a needle inserted into the umbilicus (carbon dioxide is usually, but not always, used during pregnancy), and several small incisions are made to provide

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**This guidance is written in the following context**

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

NHS Quality Improvement Scotland

access for the laparoscope and surgical instruments. In a non-pregnant woman, 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 of tape or mesh is secured around the cervical isthmus, above the cardinal and uterosacral ligaments. As with the open transabdominal approach, delivery has to be carried out by caesarean section.

## 2.3 Efficacy

2.3.1 Two case series of 31 women (32 pregnancies) treated with laparoscopic cervical cerclage reported live birth rates of 95% (19/20) and 83% (10/12). The proportion of term deliveries (defined in one study as 38 weeks or more and not defined in the other study) was 70% (14/20) and 67% (8/12), respectively. In the case series of 20 women, one pregnancy loss occurred after premature rupture of membranes at 19 weeks' gestation. For more details, refer to the 'Sources of evidence' section.

2.3.2 The Specialist Advisers considered this procedure to be novel and expressed uncertainty about its efficacy. They listed key efficacy outcomes of laparoscopic cerclage as live birth rate, 'take-home baby' rate, prolongation of pregnancy, reduction in perioperative morbidity and perinatal morbidity, operating times and blood loss.

## 2.4 Safety

2.4.1 The safety evidence was from three case series, comprising 34 women (35 pregnancies) in total. Uterine vessel injury was reported in two case series, in 33% (1/3) and 5% (1/20) of women. In another case series of 11 women, there was one case of small bowel injury (9%) and subsequent pelvic abscess (9%). No other surgical complications were described.

2.4.2 Mean operating times in the first two studies (n = 3, n = 20) were 68 and 55 minutes, and mean blood loss was estimated to be less than 40 ml and less than 100 ml, respectively. For more details, refer to the 'Sources of evidence' section.

2.4.3 The Specialist Advisers noted that there are special theoretical concerns when the procedure is done during pregnancy. They stated that potential adverse events of the procedure include: premature rupture of membranes; uterine rupture; haemorrhage; intrauterine death of fetus; extreme preterm delivery; maternal infection; bowel and bladder damage; the need to perform laparotomy, hysterotomy or hysterectomy; and difficulties with evacuation of a non-viable pregnancy.

## 2.5 Other comments

2.5.1 It was noted that there is uncertainty about the efficacy of all cervical cerclage techniques as a treatment for recurrent loss of pregnancy due to cervical incompetence.

2.5.2 The Committee noted specific concerns about performing the procedure in women who are not pregnant. These include the difficulty in defining the internal os for correct placement of the suture, and ensuring that the suture is not tied in such a way that there is a risk of it cutting through the cervix during subsequent pregnancy.

# 3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. The Institute has identified relevant audit criteria and developed an audit tool (which is for use at local discretion), available from www.nice.org/IPG228

Andrew Dillon
Chief Executive
August 2007

## Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG228publicinfo

## Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of laparoscopic cerclage for prevention of recurrent pregnancy loss due to cervical incompetence', January 2007

Available from: www.nice.org.uk/ip379overview

**Ordering information**

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1314. 'Understanding NICE guidance' can be obtained by quoting reference number N1315.

The distribution list for this guidance is available at www.nice.org.uk/IPG228distributionlist

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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**National Institute for Health and Clinical Excellence**
MidCity Place, 71 High Holborn, London WC1V 6NA; www.nice.org.uk

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