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What has NICE said?

Insertion of <u>a double balloon catheter</u> for <u>induction of labour</u> in pregnant women who have not had a previous caesarean section is safe enough and works well enough for use in the NHS.

What does this mean for me?

Your health professional should fully explain what is involved in having this procedure, and discuss the possible benefits and risks with you. You should also be told how to find more information about the procedure. All of this should happen before you decide whether you want to have this procedure or not.

The condition

Labour is a natural process that usually starts on its own. But sometimes it needs to be started artificially; this is called 'induced labour'. Most commonly, labour is induced because the baby is overdue, or because there are risks to the mother's or baby's health. Induced labour is usually more painful than spontaneous labour, and epidural analgesia and assisted delivery are more likely to be needed.

Various methods are used to encourage the cervix to dilate, and so to induce labour. These include medicines known as prostaglandins (in vaginal gels or tablets), an infusion of a drug called oxytocin, surgical methods and mechanical methods (such as single balloon catheters). Sometimes saline solution is put into the space around the baby in the womb at the same time as a catheter is put in place.

NICE has looked at using a double balloon catheter as another treatment option.

NHS Choices (<u>www.nhs.uk</u>) and <u>NICE's information for the public about induction of labour</u> may be a good place to find out more.

The procedure

The aim of using a double balloon catheter is to help induce labour by causing the cervix to soften and dilate. It is usually done with the mother lying on her back, often with her legs in stirrups. A sterile speculum is put into the vagina, so the cervix can be cleaned using an antiseptic. The catheter is then inserted so that 1 balloon is in the uterus and 1 is in the vagina. The balloons are slowly and alternatively inflated with saline. When the balloons are fully inflated and in place on both sides of the cervix, the speculum is removed. The end of the catheter is loosely taped to the inner thigh.

The device is left in place for up to about 12 hours. Both the mother and baby are monitored during the procedure. If labour begins, the device comes out, the waters break, or the baby seems to be in distress, the balloons are deflated and the device is removed. If labour does not begin, the waters are broken artificially and an oxytocin infusion is started.

Benefits and risks

When NICE looked at the evidence, it decided that inserting a double balloon catheter to

induce labour in pregnant women who have not had a previous caesarean section is safe enough and works well enough for use in the NHS. The 9 studies that NICE looked at involved a total of 2262 patients.

Generally, they showed the following benefits:

- softening of the cervix in 96% of women, which is similar to when a single ballon is used
- no increase in, or fewer, caesarean deliveries
- spontaneous vaginal delivery within 24 hours in 69% of women
- a positive birth experience in almost 90% of women.

The studies showed that the risks of a double balloon catheter included:

- excessive contractions of the uterus in 5% of women, but this was much less than with prostaglandin gel (17%)
- worrying heart rate in 2% of babies, but this was much less than with prostaglandin gel (15%)
- baby presenting the wrong way round in 2 women, 1 of whom needed a caesarean section
- cord prolapse, resulting in a caesarean section in 1 woman
- haemorrhage after delivery in 5% of women, which was no more common than with other methods
- injury to the birth canal in 1 woman compared with 5 women given prostaglandin gel
- fever during labour in 8 women
- infection in 4 babies
- more pain with the double balloon than with a single balloon catheter but less than with prostaglandin gel.

NICE was also told about another possible risk: a delay between the start of induction and delivery of the baby.

If you want to know more about the studies, see the <u>guidance</u>. Ask your health professional to explain anything you don't understand.

Questions to ask your health professional

- What does the procedure involve?
- What are the benefits I or my baby might get?
- How good are my and my baby's chances of getting those benefits? Could having the procedure make us feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I and my baby need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

About this information

NICE <u>interventional procedures guidance</u> advises the NHS on the safety of a procedure and how well it works.

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Accreditation

