

Insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section

Information for the public
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What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. It should only be used if extra care is taken to explain the risks and extra steps are put in place to record and review what happens.

More research on this procedure is needed and NICE may look at it again if more evidence is published.

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. In particular, they should explain the

uncertainty about the evidence on how likely it is to help the delivery of your baby and its possible complications. You should only be asked if you want this procedure after having this discussion. Your health professional should ask you if details of your procedure can be collected.

Other comments from NICE

NICE has said that research on this procedure is being done. The procedure could become widely used if the research shows that it works well and is safe.

In an emergency, healthcare professionals may give treatment immediately, without obtaining your informed consent, when it is in your best interests.

The condition

During a caesarean the baby is delivered through an opening that is cut in the mother's abdomen and womb.

It can be difficult to do a caesarean if the baby's head has moved down into the mother's pelvis (that is, when the baby's head is engaged). The [obstetrician](#) or midwife may put their hand in the woman's vagina and push the baby's head back up the pelvis so that it may be delivered head first through the opening made in the mother's abdomen. Another option is that during the caesarean the obstetrician delivers the baby feet first through the opening. Both of these options have risks including injury to the baby, and damage to blood vessels and tissues and severe bleeding in the mother. Problems moving the baby's head may mean that delivery is delayed, which is also a risk to mother and baby.

NICE has looked at using insertion of a balloon device to disimpact an engaged fetal head before an emergency [caesarean section](#) as another treatment option.

NHS Choices (www.nhs.uk) and NICE's [information for the public about caesarean section](#) may be a good place to find out more.

The procedure

The aim of the procedure is to raise the baby's head out of the mother's pelvis, so that an

emergency caesarean can be done.

During the procedure a disposable soft silicone balloon device with a base plate is inserted into the vagina using a lubricant. The device is placed so that the balloon surface touches the baby's head. With the mother's legs flat on the operating table (to stop the device slipping out) the balloon is inflated with sterile saline through a tube. The base plate stops the balloon inflating downwards. As the balloon inflates it pushes the baby's head up out of the pelvis by a few centimetres. The surgeon can then make the opening to deliver the baby where it will avoid damaging surrounding tissue and make the delivery as easy as possible.

After the baby has been delivered the balloon is deflated by draining away the saline and the device is removed.

Benefits and risks

When NICE looked at the evidence, it decided that there wasn't enough information about how well the procedure works or how safe it is. The study that NICE looked at involved a total of 174 women, including 50 who had the procedure.

Generally, the study showed the following benefits for women who had the procedure:

- no deaths
- quicker delivery of the baby
- shorter time to finish the caesarean section
- fewer caesarean section cuts that needed to be enlarged (causing longer operating time, blood loss, or damage to arteries or other organs)
- fewer blood transfusions
- less blood loss of more than 1 litre.

The benefits for the babies of mothers who had the procedure were:

- no deaths
- fewer babies kept in intensive care for more than 24 hours

- no babies needed a breathing tube inserting
- no injury or infection in babies.

Slightly more babies of women who had the procedure (4%) did not do as well 5 minutes after birth (an [Apgar score](#) of less than 3) as the babies of women who did not have the procedure (3%). Seizures were reported in 2% of babies in each group, no details were given.

The study did not report any risks of using the balloon device.

NICE was also told about another possible risk: rupture, or tearing of the womb.

If you want to know more about the studies, see the [guidance](#). 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 might get?
- How good are my chances of getting those benefits? Could having the procedure make my health or my baby's health 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 need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Medical terms explained

Apgar score

The Apgar score is measured by a doctor, midwife, or nurse. They check the baby's breathing, heart rate, muscle tone, reflexes and skin colour 1 and 5 minutes after birth. A score lower than 7 means that the baby needs medical attention.

Obstetrician

A doctor who has had specialised training and experience in the care of women during pregnancy and childbirth.

About this information

NICE [interventional procedures guidance](#) advises the NHS on the safety of a procedure and how well it works.

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Accreditation

