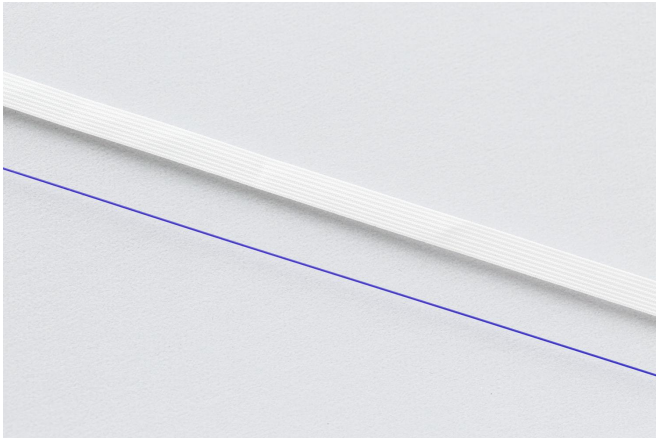


Pregnancy procedure associated with increased risk of preterm birth and neonatal loss

3 August 2016



The thicker thread (top) is the multifilament, while the thinner thread (bottom) is the monofilament. Credit: Imperial College London

Researchers are urging surgeons to reconsider using a particular type of thread for a procedure to prevent premature birth, after new research found this thread was associated with an increased rate of premature birth and baby death compared with a thinner thread.

In a new study, researchers at Imperial College London analysed 671 UK women who received a cervical stitch procedure to prevent miscarriage or premature birth.

The procedure, which is performed on around two million women a year globally, is offered to women deemed at high risk of miscarriage or premature birth. The process involves surgeons placing a stitch in the cervix to hold it closed and delay labour. The closed cervix also acts as a barrier to infection, and so shutting it with a stitch prevents bacteria passing through the cervix and into the womb.

Surgeons use one of two types of thread for the stitch - the majority use a thicker woven thread, and around 20 per cent use a thinner thread.

The study results, published in the journal *Science Translational Medicine*, suggest the thicker thread is associated with a three-fold increase in rate of baby death in the womb when compared to the thinner thread, and is associated with an increased rate of premature birth. It's thought the thicker woven structure of the thread encourages the growth of dangerous bacteria.

The team suggest switching to the thinner thread for all procedures could prevent 170,000 premature births globally every year, and 172,000 intrauterine baby deaths every year across the world.

Professor Phillip Bennett, lead author of the study from the Department of Surgery and Cancer at Imperial, said: "Although the cervical stitch procedure still holds benefits for women overall, our results suggest the thicker thread may encourage the growth of potentially dangerous bacteria in the cervix. This may lead to premature birth or even loss of the baby. We strongly advise that the thicker thread - which is currently used in the majority of procedures - only be used in a research setting whilst we thoroughly investigate the risks this may hold."

Around 50,000 babies are born prematurely every year in the UK. Defined as birth between 24 and 37 weeks of pregnancy, premature birth is the leading cause of neonatal death in the UK. It is triggered by the cervix opening too early in the pregnancy, causing the baby to start moving down the birth canal. The causes are unknown, but infection in the birth canal is thought to be a factor.

Women are recommended to undergo the cervical

stitch procedure if they are deemed at high risk of late miscarriage or premature birth - for instance if they have had a previous miscarriage later in pregnancy or a baby who was born too early.

During the procedure, also called cervical cerclage, surgeons use one of two types of thread to close the cervix. One is a thin nylon thread, around 1mm thick and very similar to fishing line, called monofilament. The other is a thicker thread - around 5mm thick - that is comprised of smaller threads woven together like a shoe lace. The thicker woven thread - called multifilament - is used in around 80 per cent of procedures as surgeons believe it to be stronger, and more efficient at holding the cervix closed.

In the new study, the team looked at 671 women who had the procedure at five UK hospitals over the last ten years. Around half had the thinner 'fishing line' thread, while the other half had the thicker 'shoe lace' thread.

The results revealed the thicker thread was associated with increased rate of intrauterine death compared to the thinner thread (15 per cent compared to 5 per cent). The rate of intrauterine death in a normal pregnancy is around 0.5 per cent.

The thicker thread was also associated with an increased rate of preterm birth rate compared to the thinner thread - 28 per cent compared to 17 per cent. The rate of preterm birth among the general population is around 7 per cent, but the cervical stitch procedure is only performed on women already deemed at high risk of [premature birth](#).

To understand the difference in outcomes between procedures using the two threads, the team conducted a second study with 50 women who were due to have the cervical stitch procedure. Half received the thinner thread, while half received the thicker thread.

The team then monitored the women at 4, 8 and 16 weeks after the procedure through ultrasound scans and analysis of bacteria collected using vaginal swabs.

The results suggested that women who received

the thicker thread had increased inflammation around the cervix. There was also increased blood flow, which is associated with the cervix opening before labour.

Crucially, the team also found women who received the thicker thread had more potentially harmful bacteria in the vagina and around the cervix.

Dr David MacIntyre, scientific lead of the study, also from the Department of Surgery and Cancer at Imperial explained: "At the beginning of the trial, all women had similar types of naturally-occurring bacteria, called Lactobacillus, in their birth canal and around their cervix. However four weeks after the procedure 45 per cent of the women who received the thicker thread had these harmless bacteria replaced with potentially dangerous bacteria that have previously been associated with poor outcomes during pregnancy, like [preterm birth](#) and infection in babies. Women who received the thinner thread maintained normal levels of harmless Lactobacillus bacteria in the birth canal or [cervix](#)."

The team also performed lab-based experiments to examine how easily bacteria grew on the two types of thread. Dr MacIntyre added: "We found potentially dangerous bacteria grew more easily on the thicker thread. This may be because bacteria can latch onto the woven structure of the thick thread more easily than the smooth thin thread."

There is a randomised clinical trial of 900 patients currently underway, organised by University of Birmingham, which is looking at the comparative risks of the two threads.

Professor Bennett added: "Our current study suggests the thick multifilament thread is associated with increased risk of complications. Even after factoring in the age and overall health of the patient, this effect still existed. However there are other factors that may influence the risks, such as surgical technique. Only by performing a large randomised clinical trial can we confirm whether the thicker thread itself is triggering complications, to ensure this procedure is as safe and effective as possible for the mother and baby."

Professor Bennett added that anyone concerned about the cervical stitch procedure should speak to their healthcare team.

Provided by Imperial College London

Professor Jeremy Nicholson, head of the Department of Surgery and Cancer at Imperial, explained the research also provides insights into how a women's naturally occurring bacteria may influence pregnancy: "This research showed that all 50 women in the second part of the study had a higher level of potentially dangerous bacteria in their birth canal than a healthy pregnant woman - even before undergoing the cervical stitch procedure. This links to our ongoing work that suggests a woman's bacterial mix in the [birth canal](#) - called the microbiome - has an important role in pregnancy. It also shows, for the first time, that treatments that change the bacteria in the vagina may lead to bad outcomes in pregnancy. We need to further investigate the role of a woman's vaginal microbiome in pregnancy to help ensure more babies are born healthy, and at the right time.

"This is part of a much broader work programme in our department aimed to understand the normal microbial composition of the body, and how changes to this may link to a range of non-infectious diseases."

Jane Brewin, chief executive of the charity Tommy's, added: "The really good news is that a safe and proven treatment to prevent pre-term birth has just been made safer by this new finding. A treatment which has been around for many years has been shown to prevent pre-term birth but no-one really understood why it seemed so effective in some people but not in others; now we have a plausible explanation and success rates should improve as a result of this work. It's important that [women](#) who have this procedure ask their obstetrician about what stitch they will receive because clinical practice can take time to catch up with research findings."

More information: "Relationship between vaginal microbial dysbiosis, inflammation, and pregnancy outcomes in cervical cerclage," *Science Translational Medicine*, stm.sciencemag.org/lookup/doi/...scitranslmed.aag1026

APA citation: Pregnancy procedure associated with increased risk of preterm birth and neonatal loss (2016, August 3) retrieved 12 October 2022 from <https://medicalxpress.com/news/2016-08-pregnancy-procedure-preterm-birth-neonatal.html>

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