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**Safety concerns over new female sterilization** **device**

Women who undergo implant based female sterilization have a significantly heightened risk of reoperation following complications, suggests a large study published in **The BMJ** this week.

Female sterilization is one of the most common contraception methods worldwide. Laparoscopic sterilization has been the primary method for decades. It is a surgical procedure that clips, stitches or burns the fallopian tubes to prevent pregnancy.

Hysteroscopic sterilization was developed more recently and involves implanting the "Essure" device to block the fallopian tubes. It does not require general anaesthetic or surgery unlike laparoscopic sterilization.   
  
The “Essure” device received approval in Europe in 2001 and was approved by the US Food and Drug Administration (FDA) in 2002. Since its approval, thousands of concerns have been received by the FDA, and device failure became a subject of litigation in 2014.

So a team of researchers carried out the first study to compare the performance, safety and other outcomes of these two widely used forms of female sterilization.  
  
They analysed data from 8,048 women who underwent hysteroscopic sterilization, and 44,278 who underwent laparoscopic sterilization in outpatient settings between 2005 and 2013 in the New York State.  
  
They looked at complications within 30 days of the initial sterilization procedure, and investigated unintended pregnancies and reoperation up to three years after the initial sterilization procedure.

Hysteroscopic sterilization was associated with over 10-fold higher risk of reoperation, equivalent to around 21 additional reoperations per 1,000 patients undergoing surgery. The authors warn that this is a “serious safety concern."  
  
Women were eight times more likely to undergo a reoperation at two years and six times more likely at three years following the initial sterilization procedure.   
  
Women who underwent hysteroscopic sterilization were more likely to be older (more than 40 years), have a history of pelvic inflammatory disease and cesarean section. Nevertheless, the higher risk of reoperation persisted in the various age groups and women with history of pelvic inflammatory disease.  
  
The risk of unintended pregnancy was comparable in the “Essure’ and laparoscopic sterilization groups, and the overall chance of unintended pregnancy was found to be approximately one in 100 after use of the “Essure” device; higher than reported in previous studies.   
  
The authors also found that the use of laparoscopic sterilization decreased from 7,852 cases in 2005 to 3517 cases in 2013. Meanwhile, the use of hysteroscopic sterilization significantly increased from 45 cases in 2005 to 1,231 cases in 2013.  
  
"With an estimated 600,000 sterilization procedures performed in the US every year, the device based hysteroscopic sterilization has a major public health impact" write the authors. They conclude that the "benefits and risks of both procedures should be discussed with patients for informed decisions making.”  
  
**This was an observational study which means that some unmeasured factors may have influenced the relationship between use of the  "Essure" device and the increased risk of reoperation.**  
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