**Hysteroscopic sterilisation is a 'serious safety concern,' researchers say**

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A “serious safety concern” has been raised by researchers over a form of sterilisation for women, which involves blocking the fallopian tubes with a titanium metal implant.

Around 1,500 women a year in the UK undergo the procedure, known as hysteroscopic sterilisation, or HS in which permanent birth control implants are inserted using local anaesthetic. The implant, known as an Essure device, causes the fallopian tube to form scar tissue around it, which eventually blocks the tube.

Essure was first developed by a firm called Conceptus and won ‘pre-market approval’ (PMA) by the US Food and Drug Administration (FDA) in 2002. The device has been dogged by controversy ever since Conceptus was taken over by German pharmaceutical firm Bayer two years ago with a campaign initially led by environmental activist Erin Brockovich.

The FDA is now investigating allegations from several women who say their reports of severe pain were buried by researchers and thousands of women have registered complaints about discomfort and internal injuries they say are related to the device.

Now a team of researchers has carried out the first study to compare the performance, safety and other outcomes of hysteroscopic sterilisation with laparoscopic sterilisation, also known as tubal occlusion when the fallopian tubes are blocked using clips or rings.

Under HS a narrow tube with a telescope at the end, called a hysteroscope, is passed through the patient’s vagina and cervix. A guidewire is used to insert a tiny piece of titanium metal into the hysteroscope, then into each of the fallopian tubes meaning the surgeon does not need to cut into the body.

They are the two most common forms of female sterilisation used by millions of women worldwide.

The study, [published in the *BMJ*](http://www.bmj.com/cgi/doi/10.1136/bmj.h5162)this week, found that women who use HS have a significantly higher risk of needing repeat operations compared to those using the alternative method.

The study looked at more than 8,000 women undergoing HS and more than 44,000 women undergoing laparoscopic sterilisation between 2005 and 2013 in New York State.

Researchers discovered that women choosing HS have a similar risk of unintended pregnancy but a more than 10-fold higher risk of undergoing reoperation, defined as repeated sterilisation, in the first year following surgery - equivalent to around 21 additional reoperations per 1,000 patients undergoing surgery.

Women were eight times more likely to undergo a reoperation at two years and six times more likely at three years following the initial sterilisation procedure. Reported complications related to inserting Essure included pelvic pain, haemorrhage, and device migration or incompatibility.

Art Sedrakyan, the study’s lead researcher and Professor of Healthcare Policy and Research at the Weill Medical College of Cornell University, told *The Independent*: “We hope women will take to time and weigh the benefits and harms of the two procedures, discuss their specific situation and comorbid conditions with their physician and make informed decisions.”

A spokeswoman for the Medicines and Healthcare products Regulatory Agency (MHRA) said: “We currently have no information to suggest that Essure devices used in the UK are unsafe to use.”

A statement from Bayer said: “Essure is a highly effective birth control option with a positive benefit-risk profile for women who have completed their families and want permanent contraception with a non-surgical procedure.

“Over a decade of research and development and a decade of real world experience supports the safety and efficacy of Essure.”