The feasibility, safety, and effectiveness of hysteroscopic sterilization compared with laparoscopic sterilization

Antoun, Lina; Smith, Paul; Gupta, Janesh; Clark, T. Justin

DOI:
10.1016/j.ajog.2017.07.011

Document Version
Peer reviewed version

Citation for published version (Harvard):
Antoun, L, Smith, P, Gupta, J & Clark, TJ 2017, 'The feasibility, safety, and effectiveness of hysteroscopic sterilization compared with laparoscopic sterilization', *American journal of obstetrics and gynecology*. https://doi.org/10.1016/j.ajog.2017.07.011

The feasibility, safety and effectiveness of hysteroscopic sterilization compared with laparoscopic sterilization

Lina Antoun, MD, Paul Smith, PhD, MRCOG, NIHR, Janesh K. Gupta, MSc, FRCOG, T. Justin Clark, MD, FRCOG

PII: S0002-9378(17)30853-0

DOI: 10.1016/j.ajog.2017.07.011

Reference: YMOB 11766

To appear in: *American Journal of Obstetrics and Gynecology*

Received Date: 18 April 2017

Revised Date: 6 July 2017

Accepted Date: 12 July 2017

Please cite this article as: Antoun L, Smith P, Gupta JK, Clark TJ, The feasibility, safety and effectiveness of hysteroscopic sterilization compared with laparoscopic sterilization, *American Journal of Obstetrics and Gynecology* (2017), doi: 10.1016/j.ajog.2017.07.011.

The feasibility, safety and effectiveness of hysteroscopic sterilization compared with laparoscopic sterilization

Lina Antoun, MD, Specialist Registrar Birmingham Women's NHS Foundation Trust, Birmingham, B15 2TG UK

Paul Smith, PhD, MRCOG, NIHR Clinical Lecturer, Birmingham Women's NHS Foundation Trust, Birmingham, B15 2TG UK and School of Clinical and Experimental Medicine, University of Birmingham, B15 2TT UK

Janesh K Gupta MSc, FRCOG Professor and Honorary Consultant Obstetrician and Gynaecologist, University of Birmingham, B15 2TT UK and Birmingham Women's NHS Foundation Trust, Birmingham, B15 2TG UK

T. Justin Clark, MD, FRCOG Consultant Obstetrician and Gynaecologist and Honorary Professor, Birmingham Women's NHS Foundation Trust, Birmingham, B15 2TG UK and University of Birmingham, B15 2TT UK (corresponding author)

Address for correspondence: Prof. T. Justin Clark, Consultant Obstetrician and Gynaecologist and Honorary Professor, Birmingham Women's NHS Foundation Trust, Birmingham, B15 2TG UK

E-mail: justin.clark@bwnft.nhs.uk

Tel: 0044 121 607 4712

Fax: 0044 121 6272667

Conflict of Interest statement

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf. Prof. Clark reports personal fees for consultancy, lecturing, training, travel and accommodation from

Conceptus (former manufacturers of Essure™) and Bayer (manufacturers of Essure™).

All other authors report no conflicts of interest.

Prof J K Gupta has participated in training courses for Bayer (Mirena, Essure) and Conceptus (Essure) in the past and more recently has been a medical adviser / consultant for Utah Medical who now own Femcare-Nikomed uk, producers of the Filshie clip.

The authors confirm that the manufacturers of either sterilization system were not involved in any aspect of the study, either in study design, analysis, manuscript drafting or providing funding during the conduct of this study.

In condensation: Hysteroscopic sterilization had a similar rate of unintended pregnancies in comparison with laparoscopic sterilization but higher rate of re-operation, failed re-operation and reduced feasibility.

Abstract

***Background*:** In contrast to conventional laparoscopic sterilization, newer hysteroscopic approaches avoid the need for hospital admission, general anesthesia and prolonged recovery. However, there are concerns that the feasibility, safety and efficacy of hysteroscopic sterilization may be lower than established laparoscopic sterilization.

Objectives: To evaluate the outcomes of hysteroscopic sterilization compared with laparoscopic sterilization in routine clinical practice in a comparative observational cohort study.

Study design: Study was carried out at University of Birmingham, UK NHS Teaching Hospital. Office hysteroscopy clinics and day-case hospital unit**.** 1085 women underwent hysteroscopic sterilization and 2412 women had laparoscopic sterilization. Hysteroscopic sterilization was carried out using the tubal implant permanent Birth Control System in the office setting and laparoscopic sterilization using the Tubal Ligation System™ as a day-case under general anesthesia. Outcome data were collected regarding feasibility (technical completion of the sterilization procedure; satisfactory radiological confirmation at three months – hysterosalpingogram or transvaginal pelvic ultrasound scan), safety events within 30 days of procedures; re-operations and unintended pregnancies within one year of procedures.

Results: Hysteroscopic sterilization was successful in 992/1085 (91.4 %, 95% CI 89.6% to 93.0%) at the first attempt. In comparision bilateral tubal ligation was successfully performed in 2400/2412 (99.5% %, 95% CI 99.2% to 99.8%) of patients who underwent laparoscopic sterilizations (odds ratio 18.8, 95% CI 10.2 to 34.4). 902/1085 (83.1%, 95% CI 80.8% to 85.2%) of successfully performed hysteroscopic procedures who attended for radiological confirmation testing were considered satisfactory. The rate of adverse events within 30 days were similar 2/1085 (0.2%) vs. 3 (0.12%, 95% CI 0.04% to 0. 36%).There were 3/1085 (0.3 %, 95% CI 0.1% to 0.8%) unintended pregnancies after hysteroscopic sterilization compared with 5/2412 (0.2 %, 95% CI 0.1% to 0.5%) laparoscopic sterilization (odds ratio 1.3, 95% CI 0.3 to 5.6). Median length of follow up for pregnancy outcome was 5 years. Hysteroscopic sterilization

was associated with a higher risk of re-operation at one year compared to laparoscopic sterilization (odds ratio 6.2; 95% CI 2.8 to 14.0) and the commonest re-intervention was unilateral salpingectomy (12/22, 54.5%).

Conclusions: Hysteroscopic sterilization has been introduced as a more convenient, office based method of permanent fertility control. However, whilst the small risk of unintended pregnancy is comparable to conventional laparoscopic sterilization, women should also be counselled regarding its lower success rate in successfully completing the procedure and its higher rate of failed re-operation.

Keywords: Hysteroscopic sterilization; laparoscopic sterilization; unintended pregnancy.

Trial registration: N/A

Introduction

Tubal sterilization is a widely-used method of contraception, adopted by 17% of women worldwide and 12% of women in the UK (1–3). Interval sterilization has traditionally required entry into the peritoneal cavity via laparoscopic or laparotomic routes. However, a new, hysteroscopic method of sterilization (Essure™ Permanent Birth Control System (Bayer, Germany) was approved in 2002 by the US Food and Drug Administration (FDA) (4) followed by the UK National Institute for Health and Care Excellence (NICE) in 2009 (5). The Essure™ system involves the transcervical placement of a small, flexible nickel/titanium alloy coil containing polyethylene fibers into each fallopian tube, which induces fibrosis and tubal occlusion after three months. The advantage of the hysteroscopic route for tubal occlusion is the avoidance of abdominal incisions, the need for hospital admission and the use of general or regional anesthesia. Published data highlight the convenience and economic advantages of office based female sterilization with more than 750,000 Essure™ procedures have now been performed worldwide(6,7).

Prospective, uncontrolled, observational data support the short and medium term safety, acceptability and efficacy of hysteroscopic sterilization. Indeed, the hysteroscopic procedure has been considered safer with fewer potentially serious complications (7–10). However, this view has recently been called into question by patient groups and the US Food and Drug Administration (FDA) authority with reports of adverse events such as pain, bleeding, allergies, uterine trauma and unintended pregnancies (4,5). The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) concluded that tubal implant is a safe device but recommended to carry on monitoring side effects following insertion (8).

Whilst the focus of recent safety concerns has concentrated on hysteroscopic procedures, there has been less data comparing hysteroscopic and laparoscopic methods of sterilization and no randomized controlled trials (RCTs). One recently published comparative cohort study from the US reported

comparable contraceptive efficacy at one year with unintended pregnancies rates of 1.1-1.2%. The prevalence of iatrogenic surgical complications and major medical morbidity were also similar, estimated to be under 0.5%. Whilst this study confirmed the safety and efficacy of both methods of female sterilization, it did find a 10-fold higher likelihood of re-operation on the fallopian tubes after hysteroscopic sterilization amounting to one re-operation in every 40 hysteroscopic procedures (6). The convenience of outpatient hysteroscopic sterilization may therefore have to be offset against the potential need for further surgical intervention to ensure tubal sterilization, remove fallopian tubes and / or tubal implant micro inserts.

In order to better inform clinical practice and patient decision making regarding choice of female sterilization, we conducted a controlled cohort study to compare both methods of female sterilization to see if current comparative data pertaining to the safety, feasibility, efficacy and need for surgical re-intervention were consistent.

Methods

An observational cohort study comparing peri- and post-operative outcomes associated with two contrasting methods of female sterilization was undertaken at the Birmingham Women's Hospital (BWH), a UK University Teaching Hospital. Data were collected over 10 years from January 2005 and to November 2015 for the two types of female sterilization utilized; office hysteroscopic sterilization using the Essure^{TM} permanent birth control system (Bayer, Germany) and day-case laparoscopic sterilization using the Filshie clip tubal ligation system (Cooper Surgical, USA). Both procedures were conducted in accordance with the relevant instructions for use and as have been previously described (4–6). Hysteroscopic procedures were conducted in an office setting with either no anesthesia or direct cervical, local anesthesia whereas all laparoscopic procedures were conducted under general anesthesia apart from one case that was performed under spinal anesthesia. Hysteroscopic sterilization procedures were

performed by senior operators (consultants) trained in operative hysteroscopy (TJC, and JKG), whilst laparoscopic sterilization procedures were performed by both senior operators (Consultants) and Obstetrics and Gynaecology residents (trainees).

Peri-operative data pertaining to feasibility defined as technical completion of the sterilization procedure (successful bilateral micro-insert placement) and satisfactory radiological confirmation at three months with either hysterosalpingogram or transvaginal pelvic ultrasound scan, and safety (complications) were collected prospectively for office hysteroscopic sterilization on a specifically designed electronic database. Outcomes of confirmatory radiology at three months i.e. results of transvaginal ultrasound scan (TVS) and / or hysterosalpingogram (HSG) required in accordance with the tubal implant permanent birth control system instructions for use and recommendations from the UK National Institute for Health and Care excellence (NICE) (5) were also entered into the database. Between 2005 and 2007, HSG was undertaken as the first-line confirmatory test. Thereafter (2007-2015), TVS was the first line confirmatory test according to the protocol used at the BWH (uncomplicated hysteroscopic procedures defined as taking less than 15 minutes, minimal pain, easy passage of devices and 1-8 trailing device coils visible in the uterine cavity) with HSG reserved for complicated procedures or in cases where the TVS findings were equivocal). Laparoscopic sterilization procedures were retrospectively identified over the same 10-year period using the BWH data coding for gynecological operative procedures. Case notes were then scrutinized to record whether procedures were successfully completed (clips correctly applied in keeping with the instructions for use to both fallopian tubes or one in the case of a prior salpingectomy) and the occurrence of intra-operative complications.

Intra-operative complications for both types of female sterilization were defined as haemorrhage > 200mLs, damage to a viscus (uterus, bladder, bowel, ureter, ovary and major blood vessel) and major medical complications (acute myocardial infarction, stroke, pulmonary embolism, perioperative shock, and respiratory complications). Post-operative complications up to 30 days following the index procedure were defined as unplanned overnight stay in hospital and iatrogenic complications (hemorrhage or

hematoma; damage to an abdominal viscus and major medical complications) requiring hospital re-admission. These events were identified from BWH coding and relevant case note examination of identified cases.

The BWH operative coding system and ICD-9-CM (international classification of diseases, ninth revision, clinical modification codes) were used to identify women undergoing further surgical procedures considered to re-operations arising from the initial hysteroscopic or laparoscopic sterilization procedure i.e. as a result of failed or sub-optimal procedures or complications. Re-operations were defined as surgery to the fallopian tube (salpingectomy –Q35.4; tubal ligation / sterilizations – Q35.2; diagnostic laparoscopy – Z30.2; clipping/blocking the remaining fallopian tube Q36.1; hysterectomy Q122).

Pregnancies were identified correlating the unique BWH patient identifying code with inpatient and outpatient admission codes for pregnancy and pregnancy related care; antenatal clinic attendance; early pregnancy unit attendance (care of miscarriage and ectopic pregnancy); termination of pregnancy. Case notes were inspected if pregnancy was identified.

In the main analyses, follow-up was limited to one year to avoid loss of follow-up because of relocation of patients. Longer-term analysis was conducted to evaluate unintended pregnancy and reoperation at any point thereafter (between one and 10 years according to the date of the index sterilization procedure)

Statistical analyses

Use of hysteroscopic sterilization and laparoscopic sterilization over time were inspected graphically and the relationship between the number of laparoscopic sterilizations and time was analysed using Poisson regression. Baseline characteristics, successful procedures, radiological testing and complications were compared between patients undergoing hysteroscopic and laparoscopic sterilization. Categorical variables were presented as frequencies and percentages. The categorical outcomes were analyzed using regression analysis and presented as unadjusted odds ratios. Analysis of plots and summary statistics guided which statistical analysis was performed on continuous variables. As data was normally

distributed continuous variables were presented as a mean with standard deviation and compared using students t test.

Results

Between 2005 and 2015, 1085 women underwent hysteroscopic sterilization and 2412 had a laparoscopic sterilization. Over this ten-year study period, the use of laparoscopic sterilization remained fairly constant whereas hysteroscopic sterilization increased from 14.2% (40/280) of all female sterilization procedures in 2005 to 40.5% in 2015 (150/350) (P = < 0.001) (Figure1). Poisson regression analysis showed a significant relationship between increasing year and an increase in the number of hysteroscopic sterilisations (p = <0.001). The women who underwent hysteroscopic sterilization had a significantly higher mean age (36.1 years), and higher parity (2.6) compared to the women in the laparoscopic sterilization group who had a mean age of (35.6 years), and parity of (2.4) (Table 1). Women undergoing hysteroscopic sterilization were nearly three times more likely to have had a caesarean section (199/1085 (18.4%) versus 160/2412 (6.6%), P = <0.001). They also had a significantly higher body mass index (BMI) (Table 1).

Hysteroscopic sterilization was successful in 992/1085 (91.4%, 95% CI 89.6% to 93.0%) at the first attempt compared with 2400/2412 (99.5% %, 95% CI 99.2% to 99.8%) laparoscopic sterilizations (odds ratio 18.8, 95% CI 10.2-34.4). Of the 93/1085 (8.6%) failed hysteroscopic sterilizations, six (6.5%) were due to device failure, 32/93 (34.4%) because of difficulty in visualizing one or both tubal ostia and 15/93 (16.1%) of women were unable to tolerate the procedure, 40/93 (43%) were due to tubal stenosis. Initial unilateral device placement requiring a second stage procedure to complete the hysteroscopic sterilization was required 2/1085 (0.2%) women. Overall, we had 12/2412 (1.5%) patients with failed laparoscopic sterilization. The reasons for failed laparoscopic procedures were mesosalpingeal tear in 1/12 (8.3%) of patients and pelvic adhesions in 11/12 (91.7%) of patients. Of the 992 completed hysteroscopic

sterilization procedures, 958 (97%) attended for a confirmatory radiological testing data out of which 902 (91%) patients had satisfactory confirmatory testing and so could rely on the sterilization for contraception. Where TVS was used as a first-line confirmatory radiological modality, 13.4% (63/471) required further imaging with a HSG.

There were five adverse events reported within 30 days of the sterilization and these all occurred peri- or immediately post-operatively (Table 1). Two peri-operative complications occurred during hysteroscopic sterilization; uterine perforation during insertion of the hysteroscope and perforation of the uterine cornea whilst placing a tubal implant micro insert. The three immediate post-operative complications recorded after laparoscopic sterilization included three overnight admissions; two because of post-operative urinary retention requiring an indwelling catheter and one because of abdominal pain requiring narcotic analgesia.

Women undergoing hysteroscopic sterilization were six times more likely to undergo a reoperation at one year after initial surgery (22/1085 [2%] vs. 8/2412 [0.3%] odds ratio 6.2 [95% CI 2.8 to 14.0]). Indications for re-operation were failed hysteroscopic sterilization including additional procedures to remove incorrectly placed devices (3/22, 13.6%) or pelvic pain (14/22, 68.2%). Of the failed sterilizations, five (5/22, 23%) patients had a second-stage hysteroscopic procedure to achieve bilateral occlusion to the fallopian tubes, and twelve (12/22, 54.5%) a laparoscopic sterilization (including the one case of device perforation). Of the twenty-two women who underwent reoperation at one year following hysteroscopic sterilization, fourteen were complaining of chronic pelvic pain out of which none had a prior history of pelvic pain, 9/14 (64%) had a unilateral salpingectomy due to chronic pelvic pain, 4/14 (29%) a bilateral salpingectomy and 1/14 (7%) woman had a laparoscopic hysterectomy because of concomitant menstrual problems.

There were eight unintended pregnancies; three (0.3 %, 95% CI 0.1% to 0.8%) following hysteroscopic sterilization and five (0.2 %, 95% CI 0.1% to 0.5%) after laparoscopic sterilization (OR 1.3, 95% CI 0.3-

5.6). Two out of three pregnancies following hysteroscopic sterilization occurred despite the confirmation test (1st pregnancy occurred five months following hysteroscopic sterilization, and 2nd pregnancy eight months following hysteroscopic sterilization. Both women proceeded to have a termination of pregnancy); the third pregnancy occurred within three months of hysteroscopic sterilization procedure as the patient did not comply with post-procedural instructions to use contraception until a satisfactory confirmatory test was secured, and the patient proceeded to have a normal vaginal delivery. All five pregnancies following laparoscopic sterilization occurred within one year of the procedure.

Discussion

Hysteroscopic tubal implant sterilization and laparoscopic tubal ligation sterilization are comparably safe, feasible and effective. In this series, hysteroscopic sterilization procedures were completed successfully in 83.1% of cases and the rate of unintended pregnancy was 0.3% in keeping with other observational cohorts (11–13). However, women desiring permanent birth control need to weigh the advantages of a convenint office based hysteroscopic procedure against the six-fold increase in the need for further tubal surgery to complete sterilization or remove devices and / or fallopian tubes. Previous observational series have shown that whilst hysteroscopic sterilization is successfully completed in most women, bilateral tubal placement of Essure™ devices will fail in 3 - 10% of procedures (11,12). In such cases, a further attempt at hysteroscopic sterilization or alternative laparoscopic approaches should be considered. The chance of potential failure and the need for repeat procedures to complete sterilization should be discussed with women prior to undergoing office based hysteroscopic sterilization. Women need to be aware of this small chance of requiring further tubal surgery to remove incorrectly sited devices or to treat symptoms such as pelvic pain, thought to be attributable to tubal implant device placement.

In total there were eight unintended pregnancies in the cohort. In contrast to laparoscopic tubal occlusion,

hysteroscopic occlusion with the tubal implant system is not immediate. Women should be advised to continue with other methods of contraception for at least three months until a confirmatory radiological test is completed. One of the three hysteroscopic pregnancies could be attributed to patient non-compliance with follow up radiological testing. Non-compliance with radiological follow up is well recognized with rates varying between 12.7% and 78% (14–16) but in our series less than 4% of women failed to do so. Moreover, unsatisfactory confirmation testing in compliant patients is reported to be between 4.9% and 5% and in keeping with our series where 3% of tests were not satisfactory. This means that 94% of the cohort of women undergoing hysteroscopic sterilization could be advised to rely upon it for permanent contraception in contrast to 99% of women undergoing laparoscopic sterilization, where confirmatory testing is not required. Unintended pregnancy rates were comparable between methods of sterilization. The reason for all other pregnancies, which occurred beyond three months of the index procedure, could not be elucidated and so may represent true method failures.

Comparison with other studies

Two recently published, US registry based studies have compared efficacy, adverse events and re-intervention rates between hysteroscopic and laparoscopic methods of tubal occlusion, although not restricted to tubal implant and tubal ligation procedures (17,18). Both studies also found unintended pregnancy rates to be comparable between hysteroscopic and laparoscopic methods of sterilization albeit the reported rates of around 1% are higher than in our series (0.3% 95% CI 0.1%-0.8%). One of these studies reported a higher tubal surgery re-intervention rate following hysteroscopic sterilization consistent with our findings although the magnitude was much higher; a 10-fold increase compared with a six-fold increase in the current study (17). In contrast, no enhanced risk of tubal surgical re-intervention arising from hysteroscopic sterilization. The US observational cohorts reflected general gynecological practice and this may explain the higher unintended pregnancy rates as our study was limited to a single center with expertise in ambulatory hysteroscopic interventions. The possible explanation for the conflicting study findings regarding the magnitude and indeed presence of any difference in the need for surgical re-

intervention directly arising from tubal sterilization is unclear and may reflect the way data was coded and recorded. It is intuitive however, that re-intervention post hysteroscopic sterilization would be higher because of its higher failure rate compared with laparoscopic sterilization It is an established part of counseling women about choices of permanent birth control that the convenience of office-based, non-incisional hysteroscopic sterilization is balanced against the increased likelihood of failure to complete the procedure. Indeed, women during the consenting process should be encouraged to consider other methods of contraception with similar efficacy (19) such as an intrauterine contraceptive device, other long-acting reversible contraceptives, laparoscopic sterilization or male sterilization should the procedure fail. In addition, the role of laparoscopic salpingectomy as opposed to laparoscopic tubal ligation should be discussed in light of new evidence that serous adenocarcinoma, the most common ovarian cancer, may originate in the Fallopian tube and removal of the tubes may mitigate against this risk (20).

Strengths and limitations

The hysteroscopic sterilization data were collected prospectively from consecutive women on a bespoke electronic database whereas the laparoscopic data were collected retrospectively over the same time period. Whilst the approach to data collection would suggest that the completeness of the hysteroscopic data is likely to be better, the inpatient operating theatre coding system was rigorous with data entered prospectively for all operations, including laparoscopic sterilization, so it is unlikely that missing or inaccurate data is pervasive. Women undergoing further surgery arising from their sterilization procedure would have been missed if undertaken at another hospital. However, it is unlikely that re-intervention procedures were missed given that the timescale for follow up was restricted to one year, the actual re-intervention rate recorded was low and the Birmingham Women's Hospital (BWH) was the only health care provider for hysteroscopic sterilization procedures over the study time period making re-presentation to other regional hospitals less likely. Similarly, the risk of missing unintended pregnancies should be negligible because (i) one would expect women to contact their health care provider and (ii) the BWH would provide the antenatal / gynecological care to local women so that the coding employed to identify

pregnancy related health encounters should be robust.

We did not adjust our analyses for potential confounding variables because extensive clinical and demographic data were not electronically recorded over the study period for day-case hospital procedures. Women undergoing hysteroscopic sterilization were likely to be significantly older, have a significantly higher BMI and were three times more likely to have undergone a caesarean delivery. This may suggest that when a difficult laparoscopic procedure is anticipated women are being guided towards a hysteroscopic procedure. Our hysteroscopic bilateral device placement rates were over 91.4% which compares favorably with published rates (89-90%) (21,22) it is unlikely that the higher prevalence of caesarean delivery would have impacted adversely upon the outcomes for hysteroscopic sterilization. The only two observational series (17,18) to compare female methods of sterilization also observed a higher rate of caesarean delivery but did not find this biased against hysteroscopic outcomes. One of these studies (17) also found a higher prevalence of major abdominal surgery and pelvic inflammatory disease in women undergoing hysteroscopic procedures adding credence to the contention that the likelihood of pelvic adhesions is influencing choice of sterilization method. Again, on adjusted analysis these observations did not appear to influence the comparative results. It should also be noted that all hysteroscopic sterilizations were performed by senior surgeons with expertise in hysteroscopic surgery whereas the more established laparoscopic procedures were conducted by a wider range of surgeons with more variable experience. However, this observation is unlikely to bias against laparoscopic sterilization because it is a simple technique familiar to most gynecologists and the feasibility rate of over 99% and low complication rate observed in this study is testimony this.

Conclusion

Hysteroscopic sterilization offers women a convenient, office based method of permanent birth control. When women decide upon their choice of sterilization method they need to understand the comparable effectiveness and safety but be aware that whilst the chance of surgical re-intervention for failed

procedures, misplaced devices and other clinical symptoms such as chronic pain, following office based hysteroscopic sterilization is low, it is higher than conventional laparoscopic approaches.

References

1. MacKay AP, Kieke BA, Koonin LM, Beattie K. Tubal sterilization in the United States, 1994-1996. Fam Plann Perspect. 2001 Aug;33(4):161–5.

2. Rowlands S, Hannaford P. The incidence of sterilisation in the UK. BJOG Int J Obstet Gynaecol. 2003 Sep;110(9):819–24.

3. Jones J, Mosher W, Daniels K. Current contraceptive use in the United States, 2006-2010, and changes in patterns of use since 1995. Natl Health Stat Rep. 2012 Oct 18;(60):1–25.

4. Premarket Approval (PMA) [Internet]. [cited 2017 Jun 6]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014

5. Hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implants | Guidance and guidelines | NICE [Internet]. [cited 2017 Jun 6]. Available from: https://www.nice.org.uk/guidance/ipg315

6. Jansen FW, Kapiteyn K, Trimbos-Kemper T, Hermans J, Trimbos JB. Complications of laparoscopy: a prospective multicentre observational study. Br J Obstet Gynaecol. 1997 May;104(5):595–600.

7. Essure® HCP |Homepage | Official Website [Internet]. [cited 2017 Jun 6]. Available from: http://www.hcp.essure-us.com/index.php

8. Roberts M. Essure implant study finds safety concerns. BBC News [Internet]. 2015 Oct 14 [cited 2017 Jun 6]; Available from: http://www.bbc.co.uk/news/health-34519021

9. Palmer SN, Greenberg JA. Transcervical sterilization: a comparison of essure(r) permanent birth control system and adiana(r) permanent contraception system. Rev Obstet Gynecol. 2009;2(2):84–92.

10. Jansen FW, Kolkman W, Bakkum EA, de Kroon CD, Trimbos-Kemper TCM, Trimbos JB. Complications of laparoscopy: an inquiry about closed- versus open-entry technique. Am J Obstet Gynecol. 2004 Mar;190(3):634–8.

11. Chudnoff SG, Nichols JE, Levie M. Hysteroscopic Essure Inserts for Permanent Contraception: Extended Follow-Up Results of a Phase III Multicenter International Study. J Minim Invasive Gynecol. 2015 Oct;22(6):951–60.

12. Fernandez H, Legendre G, Blein C, Lamarsalle L, Panel P. Tubal sterilization: pregnancy rates after hysteroscopic versus laparoscopic sterilization in France, 2006-2010. Eur J Obstet Gynecol Reprod Biol. 2014 Sep;180:133–7.

13. Hitzerd E, Schreuder HWR, Vleugels MPH, Veersema S. Twelve-year retrospective review of unintended pregnancies after Essure sterilization in the Netherlands. Fertil Steril. 2016 Apr;105(4):932–7.

14. Kerin JF, Levy BS. Ultrasound: an effective method for localization of the echogenic Essure sterilization micro-insert: correlation with radiologic evaluations. J Minim Invasive Gynecol. 2005 Feb;12(1):50–4.

15. Veersema S, Vleugels MPH, Timmermans A, Brölmann HAM. Follow-up of successful bilateral placement of Essure microinserts with ultrasound. Fertil Steril. 2005 Dec;84(6):1733–6.

16. Ultrasound detection of the Essure permanent birth control device: a case series. - PubMed - NCBI [Internet]. [cited 2017 Jun 6]. Available from: https://www.ncbi.nlm.nih.gov/pubmed/?term=Teoh+M%2C+Meagher+S%2C+Kovacs+G.+Ultrasound+detection+of+the+ESSURE+permanent+birth+control+device%3A+a+case+series

17. Mao J, Pfeifer S, Schlegel P, Sedrakyan A. Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study. BMJ. 2015;351:h5162.

18. Perkins RB, Morgan JR, Awosogba TP, Ramanadhan S, Paasche-Orlow MK. Gynecologic Outcomes After Hysteroscopic and Laparoscopic Sterilization Procedures. Obstet Gynecol. 2016 Oct;128(4):843–52.

19. Stoddard A, McNicholas C, Peipert JF. Efficacy and safety of long-acting reversible contraception. Drugs. 2011 May 28;71(8):969–80.

20. Creinin MD, Zite N. Female tubal sterilization: the time has come to routinely consider removal. Obstet Gynecol. 2014 Sep;124(3):596–9.

21. Shavell VI, Abdallah ME, Diamond MP, Kmak DC, Berman JM. Post-Essure hysterosalpingography compliance in a clinic population. J Minim Invasive Gynecol. 2008 Aug;15(4):431–4.

22. Guiahi M, Goldman KN, McElhinney MM, Olson CG. Improving hysterosalpingogram confirmatory test follow-up after Essure hysteroscopic sterilization. Contraception. 2010 Jun;81(6):520–4.

1

1

Table 1

Outcomes following hysteroscopic and laparoscopic sterilization, including odds for failure of sterilization for hysteroscopic compared to laparoscopic sterilization

	Hysteroscopic sterilization (Essure™)(1085)	**Laparoscopic sterilization (Filshie clip™) (2412)**	**Statistical comparison[6]**
Patient characteristics			
Mean Age in years (SD)	36.1 (4.2)	35.6 (3.0)	P = <0.001
Mean Body mass index (SD)	32.8 (4.0)	27.1 (3.0)	P = <0.001
Mean Parity (SD)	2.6 (0.5)	2.4 (0.5)	P = <0.001
Caesarean section	199 (18.4%)	160 (6.6%)	P = <0.001
Procedural outcomes			
Successful procedures[1]	992 (91.4%, 95% CI 89.6% to 93.0%)	2400 (99.5%, 95% CI 99.2% to 99.8%)	Odds ratio 18.8, 95% CI 10.2 to 34.4)
Satisfactory confirmatory test[2]	902 (90.9% 95% CI 89.0 to.92.6%)	Not applicable	-
Successfully completed sterilization (reliance)[3]	902 (83.1% 95% CI 80.8% to 85.2%)	2400(99.5%, 95% CI 99.2% to 99.8%)	Odds ratio 40.6, 95% CI 22.5 to 73.1)
Adverse events <30 days[4]	2 (0.2%, 95% CI 0.05% to 0.7%)	3 (0.12%, 95% CI 0.04% to 0.36%))	Odds ratio 1.48, 95% CI 0.25 to 8.89)
Re-operation[5] < one year	22 (2.0%, 95% CI 1.3% to 3.1%)	8 (0.3%, 95% CI 1.7% to 6.5%)	Odds ratio 6.2 (95% CI 2.8 to 14.0).
Unintended pregnancy	3 (0.3 %, 95% CI 0.1% to 0.8%)	5 (0.2 %, 95% CI 0.1% to 0.5%)	(Odds ratio 1.3, 95% CI 0.3 to 5.6).

1 Defined as correct placement of sterilization devices according to the respective instructions for use.
2 Satisfactory radiological confirmatory testing with transvaginal ultrasound scan and / or hysterosalpinogram; denominator = 992 women attending for confirmatory testing
3 Successfully completed procedure and satisfactory confirmatory radiology at >/= 3 months for hysteroscopic sterilization procedures hysteroscopic sterilization
4 See methods for definitions of adverse events (peri- and post-operative complications)
5 Further surgical procedures considered to re-operations arising from the initial hysteroscopic or laparoscopic sterilization procedure i.e. as a result of failed or sub-optimal procedures or complications.

6 $\chi 2$ tests for categorical variables and student t tests for normally distributed continuous variables to compare differences in baseline characteristics and unadjusted outcomes between groups

Number of hysteroscopic and laparoscopic sterilization at BWH