GYNECOLOGY

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

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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.

OBJECTIVE: We sought to evaluate the outcomes of hysteroscopic sterilization compared with laparoscopic sterilization in routine clinical practice in a comparative observational cohort study.

STUDY DESIGN: This study was carried out at University of Birmingham, United Kingdom, National Health Service teaching hospital, office hysteroscopy clinics, and day-case hospital unit. In all, 1085 women underwent hysteroscopic sterilization and 2412 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 3 months—hysterosalpingogram or transvaginal pelvic ultrasound scan), safety events within 30 days of procedures, reoperations, and unintended pregnancies within 1 year of procedures.

RESULTS: Hysteroscopic sterilization was successful in 992/1085 (91.4%; 95% confidence interval, 89.6—93.0%) at the first attempt. In comparison, bilateral tubal ligation was successfully performed in 2400/2412 (99.5%; 95% confidence interval, 99.2—99.8%) of patients who underwent laparoscopic sterilizations (odds ratio, 18.8; 95% confidence interval, 10.2—34.4). In all, 902/1085 (83.1%; 95% confidence interval, 80.8—85.2%) of successfully performed hysteroscopic procedures 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% confidence interval, 0.04—0.36%). There were 3/1085 (0.3%; 95% confidence interval, 0.1—0.8%) unintended pregnancies after hysteroscopic sterilization compared with 5/2412 (0.2%; 95% confidence interval, 0.1—0.5%) laparoscopic sterilization (odds ratio, 1.3; 95% confidence interval, 0.3—5.6). Median length of follow-up for pregnancy outcome was 5 years. Hysteroscopic sterilization was associated with a higher risk of reoperation at 1 year compared to laparoscopic sterilization (odds ratio, 6.2; 95% confidence interval, 2.8—14.0) and the commonest reintervention was unilateral salpingectomy (12/22, 54.5%).

CONCLUSION: Hysteroscopic sterilization has been introduced as a more convenient, office-based method of permanent fertility control. However, while 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 reoperation.

Key words: hysteroscopic sterilization, laparoscopic sterilization, unintended pregnancy

Introduction

Tubal sterilization is a widely used method of contraception, adopted by 17% of women worldwide and 12% of women in the United Kingdom.[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; Bayer, Germany) was approved in 2002 by the US Food and Drug Administration (FDA)[4] followed by the United Kingdom 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 3 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 and >750,000 Essure procedures have now been performed worldwide.[6,7]

Prospective, uncontrolled, observational data support 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 was recently called into question by patient groups and the US FDA with reports of adverse events such as pain, bleeding, allergies, uterine trauma, and unintended pregnancies.[4,5] The United Kingdom's Medicines and Healthcare Products Regulatory Agency concluded that tubal implant is a safe device but recommended to continue monitoring side effects following insertion.[8]

While the focus of recent safety concerns concentrated on hysteroscopic procedures, there were fewer data comparing hysteroscopic and laparoscopic methods of sterilization and no randomized controlled trials. One recently published comparative cohort study from the United States reported comparable contraceptive efficacy at 1 year with unintended pregnancy rates of 1.1-1.2%. The prevalence of iatrogenic surgical complications and major medical morbidity was also similar, estimated

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to be <0.5%. While this study confirmed the safety and efficacy of both methods of female sterilization, it found a 10-fold higher likelihood of reoperation on the fallopian tubes after hysteroscopic sterilization amounting to 1 reoperation 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 microinserts.

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 reintervention were consistent.

Materials and Methods

An observational cohort study comparing perioperative and postoperative outcomes associated with 2 contrasting methods of female sterilization was undertaken at the Birmingham Women's Hospital (BWH), a United Kingdom university teaching hospital. Data were collected over 10 years from January 2005 through November 2015 for the 2 types of female sterilization utilized; office hysteroscopic sterilization using the Essure permanent birth control system and day-case laparoscopic sterilization using the Filshie clip tubal ligation system (Cooper Surgical; Trumbull, CT). Both procedures were conducted in accordance with the relevant instructions for use and as 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 1 case performed under spinal anesthesia. Hysteroscopic sterilization procedures were performed by senior operators (consultants) trained in operative hysteroscopy (T.J.C. and J.K.G.), while laparoscopic sterilization procedures were performed by both senior operators (consultants) and obstetrics and gynecology residents (trainees).

Perioperative data pertaining to feasibility defined as technical completion of the sterilization procedure (successful bilateral microinsert placement) and satisfactory radiological confirmation at 3 months with either hysterosalpingogram (HSG) or pelvic transvaginal ultrasound scan (TVS), and safety (complications) were collected prospectively for office hysteroscopic sterilization on a specifically designed electronic database. Outcomes of confirmatory radiology at 3 months, ie, results of TVS and/or HSG required in accordance with the tubal implant permanent birth control system instructions for use and recommendations from the United Kingdom NICE[5] were also entered into the database. From 2005 through 2007, HSG was undertaken as the first-line confirmatory test. Thereafter (2007 through 2015), TVS was the first-line confirmatory test according to the protocol used at BWH (uncomplicated hysteroscopic procedures defined as taking <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 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 intraoperative complications.

Intraoperative complications for both types of female sterilization were defined as hemorrhage >200 mL, 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). Postoperative 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 readmission. These events were identified from BWH coding and relevant case note examination of identified cases.

The BWH operative coding system and *International Classification of Diseases, Ninth Revision, Clinical Modification* codes were used to identify women undergoing further surgical procedures considered to reoperations arising from the initial hysteroscopic or laparoscopic sterilization procedure, ie, as a result of failed or suboptimal procedures or complications. Reoperations 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); and termination of pregnancy. Case notes were inspected if pregnancy was identified.

In the main analyses, follow-up was limited to 1 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 1-10 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 analyzed 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

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