BJOG An International Journal of Obstetrics and Gynaecology

DOI: 10.1111/1471-0528.14719
www.bjog.org

Safety and effectiveness of female tubal sterilisation by hysteroscopy, laparoscopy, or laparotomy: a register based study

E Jokinen,[a,b] A Heino,[c] T Karipohja,[b] M Gissler,[c] R Hurskainen[a,b]

[a] Obstetrics and Gynaecology, Hyvinkää Hospital, Hyvinkää, Finland [b] Obstetrics and Gynaecology, Helsinki University Hospital, Helsinki, Finland [c] National Institute for Health and Welfare, Helsinki, Finland
Correspondence: Dr E Jokinen, Obstetrics and Gynaecology, Hyvinkää Hospital/University of Helsinki and Helsinki University Hospital, Sairaalankatu 1, 05850 Hyvinkää, Finland. Email ewa.jokinen@hus.fi

Accepted 24 April 2017. Published Online 15 June 2017.

Objective To determine the safety and effectiveness of female sterilisation in the Finnish population.

Design A national register-based study using record linkage.

Setting National data from Finland.

Sample A total of 16 272 female sterilisations performed in 2009–2014.

Methods The Register of Sterilisations was linked with the Hospital Discharge Register, Termination of Pregnancy Register, and the Medical Birth Register in order to investigate the occurrence of re-sterilisations, other surgical operations, and unwanted pregnancies after sterilisation, per method.

Main outcome measures Outcome measures included all pregnancies after sterilisation (births, miscarriages, terminations of pregnancy, and ectopic pregnancies) and operations (repeat sterilisations, other hysteroscopic and laparoscopic procedures, hysterectomies, and re-operations for a complication). The outcomes were presented by method as risk ratio (RR) with 95% confidence intervals (95% CIs).

Results There was no significant difference in all spontaneous pregnancies between the groups. The risk ratio for any pregnancy was 1.27 (95% CI 0.80–2.02) for Filshie® versus Essure® and 1.35 (95% CI 0.92–1.96) for Pomeroy versus Essure®. In total, 1394 (8.6%) selected operations were identified after primary sterilisation. Re-sterilisations and hysteroscopies were most frequent among Essure® patients.

Conclusions Patients undergoing hysteroscopic or laparoscopic sterilisation have a similar risk of unintended pregnancy. All sterilisations are safe, and the risk of re-operations because of complications is low. Women with Essure® have a higher risk of undergoing re-sterilisation compared with patients undergoing laparoscopic sterilisation.

Keywords Female sterilisation, hysteroscopic sterilisation, laparoscopic sterilisation, operations after sterilisation, pregnancy after sterilisation, tubal ligation.

Tweetable abstract Essure®, Filshie®, and Pomeroy sterilisations are equally effective and safe.

Please cite this paper as: Jokinen E, Heino A, Karipohja T, Gissler M, Hurskainen R. Safety and effectiveness of female tubal sterilisation by hysteroscopy, laparoscopy, or laparotomy: a register based study. BJOG 2017; https://doi.org/10.1111/1471-0528.14719.

Introduction

Female sterilisation is a commonly used method of contraception among women who prefer permanent and safe birth control. Bilateral tubal ligation under anaesthesia either via laparoscopy (Filshie® clip method; Cooper Surgical, Lake Forest, CA, USA) or mini-laparotomy (Pomeroy method) has been the primary technique for decades. In 2001 a novel hysteroscopic approach (Essure®; Conseptus, San Carlos, CA, USA) received approval in Europe after short follow-up studies.

Little evidence is available about female sterilisation, despite its wide application. No randomised controlled trial or large comparative cohort study has been conducted to compare the efficacy and safety of the hysteroscopic procedure with the traditional laparoscopic procedure. Reports worldwide are based on small cohorts, case reports, and industry statistics for Essure® kits sold, including kits not implanted.[1]

Much recent debate has focused on the feasibility of hysteroscopic sterilisations: two publications highlighted the concern about the risk of unintended pregnancy, adverse

events, and re-operations.[2,3] The US Food and Drug Administration (FDA) also announced the need for additional actions to provide important information about the risks of using Essure® (FDA News release 29 February 2016).

As part of the Managed Uptake of Medical Methods (MUMM) programme, the Finnish Office for Health Technology Assessment at THL (National Institute for Health and Welfare) launched the systematic review about Essure® in 2010.[4] The high-quality registers in Finland provide reliable comparative follow-up data of female tubal sterilisations. The study objective was to evaluate long-term results about the effectiveness and the need for re-operations after three types of sterilisation.

Methods

In Finland, the most used sterilisation methods include the laparoscopic method with Filshie® clips and the hysteroscopic method with Essure® implants. Before either procedure, vaginal ultrasound is carried out to exclude abnormalities. Practically all Pomeroy sterilisations are performed at the time of a caesarean section.

The Finnish Register of Sterilisations was linked with the Finnish Hospital Discharge Register, Register on Induced Abortions, and Medical Birth Register (MBR), in order to investigate the occurrence of repeat sterilisations and other operations, as well as all pregnancies after sterilisation, by method. Cases were linked using the personal identification number (PIN) that is included in all registers. The complication rates were calculated per 1000 follow-up years for each procedure separately, and the comparisons by procedure were made by calculating risk ratios (RRs) and 95% confidence intervals (95% CIs). We calculated unadjusted risk ratios for different sterilisation procedures against other sterilisation procedures as the comparison group. Data linkage and analyses were conducted with SAS 9.3 (SAS Institute, Cary, NC, USA).

The Finnish health registers are considered to be complete, and most of the variables correspond well or very well with the medical records.[5,6] According to Finnish legislation, data collection is mandatory for both the public and private sectors without informed consent from the people registered. Finnish medical authorities have collected data on sterilisations since 1939, and the data are available in electronic form from 1987. The latest revision of the data collection form was completed in 2009, when the procedure classification of female sterilisation was updated. Current classification methods include tubal ligation, hysteroscopic sterilisation, and laparoscopic sterilisation. Tubal ligation and hysteroscopic sterilisation were previously registered in the same category. In this study, only sterilisations with specific information on procedure with the current classification were used.

The research data included all female sterilisations performed in the period 2005–2014: a total of 30 194 cases. Altogether, 12 867 sterilisations could not be allocated to any of the categories for the following reasons: data were collected using the older data collection form (n = 12 776, 42.3%); some other sterilisation method was used (n = 89, 0.3%); information was missing on procedure type (n = 718, 2.4%); or the PIN was either missing or incomplete (n = 123, 0.4%), and these cases were excluded from the data. In addition, 216 women had received two procedures in the register: both sterilisations were included in the data, but for data-linkage purposes, the latter procedure was removed. The final data set thus included 16 272 sterilisations.

The Finnish Hospital Discharge Register has data on patients discharged from hospitals from 1969 onwards. From 1994 onwards the register also contains information on day surgeries, and from 1998 includes care in specialised outpatient care. From 1997 onwards the NOMESCO Classification for Surgical Procedures (NCSP) has been used.[7]

The Termination of Pregnancy register contains information on all legal terminations of pregnancy in Finland. Data on the number of terminations of pregnancy by individual-level data with a PIN are available in electronic form from 1983 onwards. The Medical Birth Register was established in 1987. The register includes data on all live births, and on stillbirths with a gestational age of 22 weeks or more or birthweight of 500 grams or more, as well as data on the mothers. Since 1990, the Medical Birth Register includes information on *in vitro* fertilization (IVF).

We used the tenth revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10; codes O00, O00.1, O00.2, O00.8, O00.9, O03, O04, O30, O60, O80, and O82) and NCSP (codes JAH00, JAH01, JAL11, JAL31, JAP01, LBC20, LBC21, LBE00, LBE01, LBF01, LBF30, LBF31, ULC02, LCA22, LCG22, LCC, LCD, LEF13, LGA00, LGA10, LGA11, LGA20, LGA21, LGA22, LGA96, LGA97, LGA98, and LW) to find pregnancy- or surgery-related episodes in the Hospital Discharge Register (the codes are defined in Appendix S1). A total of 1196 women were identified to have such a diagnoses or procedures after the date of the sterilisation. Altogether 21 women had a reversal of the sterilisation (NCSP codes LBF60, LBF61, LBF70, LBF71, LBF96, and LBF97), and these cases were excluded after the reversal procedure. The final number of hospital episodes was 1394.

The data on all women sterilised were also linked with the Termination of Pregnancy register (n = 138) and the Medical Birth Register (n = 128). If one person had several end-point outcomes (e.g. termination of pregnancy) or

births in the data, only the first occurrence after sterilisation was included in the analyses.

Results

The final data comprise 16 272 sterilisations, 4425 of which were performed laparoscopically by Filshie® clips, 5631 of which were performed hysteroscopically by Essure®, and 6216 of which were performed by the Pomeroy method. The mean age at sterilisation was 37.8, 38.0, and 35.5 years, respectively. The age difference was statistically significant between Pomeroy patients and both Filshie® and Essure® patients. In both Filshie® and Essure® groups, 3% of the women were under 30 years of age, and 39% of women were aged 40 years or older. In the Pomeroy group, 9% were under 30 years of age and 20% were aged 40 years or older ($P < 0.001$ in both age groups). Three or more previous births were reported by 41% of women in the Filshie® group, 46% of women in the Essure® group, and 74% of women in the Pomeroy group, with statistical significance between all the groups ($P < 0.001$).

Numbers, percentages, numbers per 1000 follow-up years, and risk ratios for any pregnancy are shown in Table 1. The incidence of all spontaneous pregnancies was lowest in the Essure® group (1.97 per 1000 follow-up years), compared with the Filshie® and Pomeroy groups (2.50 and 2.65 per 1000 follow-up years, respectively), with no statistically significant difference. All births and births after spontaneous pregnancies were more common in the Filshie® and Pomeroy groups than in the Essure® group, but the difference was statistically significant only between the Pomeroy and Essure® groups (RR 2.42, 95% CI 1.36–4.33). In the whole study group, 0.20% of the women underwent a reversal of the sterilisation and 0.08% ($n = 24$) delivered after assisted fertility treatment. The total numbers of assisted fertility treatments are unknown, as only pregnancies ending into a birth are registered in Finland. For terminations of pregnancy, there was no statistical difference between the study groups: we found 1.24 terminations per 1000 follow-up years in the Essure® group, and 0.96 and 0.75 per 1000 follow-up years in the Filshie® and Pomeroy groups, respectively. In both the Essure® and Filshie® groups about 30% of pregnancies leading to termination began during the first 3 months, whereas after the first year this incidence was 33% (Essure®) and 23% (Filshie®). None of these pregnancies began within 3 months in the Pomeroy group, and 60% began after the first year.

In the whole study group, 1394 selected operations were reported after primary sterilisation, representing 8.6% of the cases. The numbers and risk ratios for the operations reported are presented in Table 2, according to sterilisation method used. All reported operations were performed more frequently in the Essure® group: the risk ratio between the Filshie and Essure group was 0.81 (95% CL 0.71–0.93), and between the Pomeroy and Essure® group 0.48 (95% CI 0.43–0.54). After disregarding re-sterilisations, the statistical difference between the Filshie® and Essure® group disappeared. Hysterectomies were performed more often in women with Filshie® sterilisation (RR 1.41, 95% CI 1.10–1.82) compared with women with Essure® sterilisation. In salpingectomies a significant difference was detected only between the Pomeroy and Essure® groups (RR 0.65, 95% CI 0.45–0.94). Reported re-sterilisations were more common in the Essure® group: the risk ratios between the Filshie® and Essure® groups, and between the Pomeroy and Essure® group, were 0.51 and 0.13, respectively. Similarly, for all hysteroscopies there was a statistical difference in favour of Filshie® and Pomeroy sterilisations (i.e. fewer hysteroscopies were performed after these procedures).

Discussion

Main findings

No statistical difference between the sterilisation groups was evident when compared by method for all spontaneous pregnancies per 1000 follow-up years. Operations after index sterilisation were reported in 8.6% of cases in the whole study group. Re-sterilisations and hysteroscopies were more common in the Essure® group, but no differences were observed in other operations between the sterilisation groups.

Strengths and limitations

The key strengths of this study are the mandatory and high-quality national registers and comprehensive record linkage. Some problems occurred, however, when analysing the current data. There were several cases with two sterilisations in the register. These may be double notifications of the same procedure, in which case the duplicate should be removed; however, the register is routinely checked for this and cases with the same procedure data, for example, are removed. Double PIN numbers could also be a result of a sterilisation performed in two parts (e.g. first one tube and then the other), which is supported by the number of second sterilisations by Essure® after Essure® ($n = 127$). According to the instructions, the register notification should only be made after the second procedure, when the sterilisation is complete, but some clinicians appear to ignore this instruction. Double PIN numbers could also mean an unsuccessful first sterilisation attempt. For eight cases, however, it was clear from the register information that the sterilisation was performed in two parts, and the first report was removed.

Table 1. Pregnancies according to sterilisation method*

	Filshie	Essure	Pomeroy	Filshie vs essure RR (95% CI)	Pomeroy vs essure RR (95% CI)	Filshie vs pomeroy RR (95% CI)
Total-*n*	4425	5631	6216			
Deliveries, *n*	14	14	61			
Deliveries, %	0.32	0.25	0.98			
Deliveries, per 1000 follow up-years	1.03	0.72	1.76	1.42 (0.68–2.98)	**2.42 (1.36–4.33)**	0.59 (0.33–1.05)
Deliveries after assisted fertility treatments (IVF), *n*	2	1	7			
Deliveries after assisted fertility treatments (insemination), *n*	0	1	0			
Deliveries after assisted fertility treatments (ovulation induction), *n*	0	0	0			
Deliveries after assisted fertility treatments, all, *n*	2	2	7			
Deliveries after assisted fertility treatments, all, %	0.05	0.04	0.11			
Deliveries after assisted fertility treatments, all, per 1000 follow up-years	0.15	0.10	0.20	1.42 (0.20–10.09)	1.95 (0.40–9.36)	0.73 (0.15–3.52)
Deliveries after spontaneus pregnancy, *n*	12	12	54			
Deliveries after spontaneus pregnancy, %	0.27	0.21	0.87			
Deliveries after spontaneus pregnancy, per 1000 follow up-years	0.88	0.62	1.55	1.42 (0.64–3.16)	**2.50 (1.34–4.67)**	0.57 (0.3–1.06)
Re-anastomosis of Fallopian tube, *n*	3	0	16			
Re-anastomosis of Fallopian tube, %	0.07	0	0.26			
Re-anastomosis of Fallopian tube, per 1000 follow up-years	0.22	0	0.46			
Miscarriages, *n*	4	2	3			
Miscarriages, %	0.09	0.04	0.05			
Miscarriages, per 1000 follow up-years	0.29	0.10	0.09	2.84 (0.52–15.52)	0.83 (0.14–4.99)	3.41 (0.76–15.24)
Terminations of pregnancy, *n*	13	24	26			
Terminations of pregnancy, %	0.29	0.43	0.42			
Terminations of pregnancy, per 1000 follow up-years	0.96	1.24	0.75	0.77 (0.39–1.51)	0.60 (0.35–1.05)	1.28 (0.66–2.49)
Ectopic pregnancies, *n*	5	0	9			
Ectopic pregnancies, %	0.11	0	0.14			
Ectopic pregnancies, per 1000 follow up-years	0.37	0	0.26			
All pregnancies, *n*	36	40	99			
All pregnancies, %	0.81	0.71	1.59			
All pregnancies, per 1000 follow up-years	2.65	2.07	2.85	1.28 (0.82–2.01)	1.38 (0.95–1.99)	0.93 (0.64–1.36)
All spontaneus pregnancies, *n*	34	38	92			
All spontaneus pregnancies, %	0.77	0.67	1.48			
All spontaneus pregnancies, per 1000 follow up-years	2.50	1.97	2.65	1.27 (0.80–2.02)	1.35 (0.92–1.96)	0.95 (0.64–1.4)

*Statistically significant results with bolded numbers.

Interpretation (in light of other evidence)

On average, 4400 sterilisations are performed in Finland each year, which represents 2.1 sterilisations per 1000 persons aged 25–54 years. During 2002, Essure® sterilisation became available in Finland and has become the most common method (49% of all female sterilisations in 2014). The number of female sterilisations has decreased by 79% from the maximum recorded for one year (12 080 procedures in 1987 compared with 2480 procedures in 2014), and the proportion of all sterilisations has declined from over 80% to 56% in 2014. The main reason for this tendency comes from the high number of levonorgestrel intrauterine system (LNG-IUS) users and from the postponement of childbearing in general. In 2014, the average age for sterilisation was 37.2 years (National Institute of Health and Welfare 2015).

Pregnancy rates have been compared among women who had either laparoscopic or hysteroscopic sterilisation.

Table 2. Operations according to sterilisation method*

	Filshie	Essure	Pomeroy	Filshie vs essure RR (95% CI)	Pomeroy vs essure RR (95% CI)	Filshie vs pomeroy RR (95% CI)
Total-*n*	4425	5631	6216			
Salpingectomy, open (LBE00)	3	6	10			
Salpingectomy, laparoscopic (LBE01)	46	47	52			
Salpingectomy, open and laparoscopic, *n*	49	53	62			
Salpingectomy, open and laparoscopic, %	1.11	0.94	1.00			
Salpingectomy, open and laparoscopic, per 1000 follow-up years	3.61	2.74	1.78	1.31 (0.89–1.94)	**0.65 (0.45–0.94)**	**2.02 (1.39–2.94)**
Hysterectomy (LCC, LCD)	117	115	208			
Hysterectomy (LEF13)	2	5	9			
Hysterectomy, all, *n*	119	120	217			
Hysterectomy, all, %	2.69	2.13	3.49			
Hysterectomy, all, per 1000 follow-up years	8.76	6.21	6.25	**1.41 (1.10–1.82)**	1.01 (0.80–1.26)	**1.40 (1.12–1.75)**
Hysteroscopy, diagnostic (ULC02)	33	112	83			
Hysteroscopy, removal of a foreign body (LCA22)	0	17	1			
Hysteroscopy, removal of adhesions (LCG02)	1	0	0			
Hysteroscopy, all, *n*	34	129	84			
Hysteroscopy, all, %	0.77	2.29	1.35			
Hysteroscopy, all, per 1000 follow-up years	2.50	6.68	2.42	**0.37 (0.26–0.55)**	**0.36 (0.28–0.48)**	1.04 (0.70–1.54)
Laparotomy, diagnostic (JAH00)	5	3	14			
Laparoscopy, diagnostic (JAH01)	30	28	48			
Diagnostic procedures, all, *n*	35	31	62			
Diagnostic procedures, all, %	0.79	0.55	1.00			
Diagnostic procedures, all, per 1000 follow-up years	2.58	1.61	1.78	1.52 (0.91–2.55)	0.95 (0.60–1.52)	**1.60 (1.01–2.52)**
Sterilisation (binding) open (LGA00)	1	2	2			
Sterilisation (cuting or coagulation), open (LGA10)	2	3	12			
Sterilisation (cuting or caogulation), laparocopic (LGA11)	14	22	7			
Sterilisation (clips), open (LGA20)	2	2	12			
Sterilisation (clips), laparoscopic (LGA21)	52	70	18			
Sterilisation, hystreoscopic (LGA22)	10	127	1			
Sterilisation, other laparoscopic (LGA97)	0	1	1			
Sterilisation, other hysteroscopic (LGA98)	1	2	0			
Sterilisation (LGA), *n*	82	229	53			
Sterilisation (LGA), %	1.85	4.07	0.85			
Sterilisation, per 1000 follow-up years	6.04	11.86	1.53	**0.51 (0.40–0.65)**	**0.13 (0.10–0.17)**	**3.96 (2.80–5.59)**
Salpingolysis, laparoscopic (LBF31)	1	0	0			
Sectio tubae, laparoscopic (LBC21)	0	0	0			
Removal of foreign body, laparoscopic (JAL11)	0	5	2			
Omentectomy, laparoscopic (JAL31)	0	2	1			
Other laparoscopic procedures, *n*	1	7	3			
Other laparoscopic procedures, %	0.02	0.12	0.05			
Other laparoscopic procedures, per 1000 follow-up years	0.07	0.36	0.09	0.20 (0.02–1.65)	**0.24 (0.06–0.92)**	0.85 (0.09–8.20)
Re-operation due to a complication (LW), *n*	6	4	14			
Re-operation due to a complication (LW), %	0.14	0.07	0.23			
Re-operation due to a complication (LW), per 1000 follow-up years	0.44	0.21	0.40	2.13 (0.60–7.56)	1.95 (0.64–5.91)	1.10 (0.42–2.85)
Total, *n*	326	573	495			
Total, %	7.37	10.18	7.96			
Total, per 1000 follow-up-years	24.00	29.67	14.25	**0.81 (0.71–0.93)**	**0.48 (0.43–0.54)**	**1.68 (1.47–1.93)**
Total without sterilisations, *n*	244	344	442			
Total without sterilisations, %	5.51	6.11	7.11			
Total without sterilisations, per 1000 follow up-years	17.96	17.81	12.72	1.01 (0.86–1.19)	**0.71 (0.62–0.82)**	**1.41 (1.21–1.65)**

*Statistically significant results with bolded numbers.

In a French retrospective cohort study of 109 277 women (39 169 Essure® and 70 108 laparoscopic sterilisations), pregnancy rate was significantly lower after Essure® than after laparoscopic tubal ligation (0.36 versus 0.46%).[8] In a worldwide analysis of 748 pregnancies reported after Essure® sterilisation from 2001 through 2010, a pregnancy rate of 0.15% was calculated on the basis of reported pregnancies and number of distributed kits.[9] These data come from follow-ups mostly of non-complicated insertions, but are in line with our study. In a study by Munro et al.,[9] the main causes of failure were patient noncompliance (4.5%), misreading of the confirmation test (42%), and doctor noncompliance (7%). The possibility of recanalisation also increases the failure risk of Pomeroy sterilisation. None of the pregnancies leading to a termination in the Pomeroy group began in 3 months after the procedure, but 60% of these pregnancies began after the first year.

The successful bilateral coil placement at first attempt varies from 76 to 96%.[1] Compared with other sterilisation techniques, hysteroscopic sterilisation is not immediately effective: a confirmation test is required to ensure tubal occlusion 3 months after the procedure, and patients are advised to use additional contraception until then.[10] Based on a mathematical model it has been estimated that the higher pregnancy rate over 10 years with hysteroscopic sterilisation is primarily driven by failures in the first year.[1] This is in line with our study: 30% of terminations of pregnancy occurred during the first 3 months after Essue® sterilisation, which suggests insufficient contraception or that the women were pregnant before the sterilisation. After that, the cause of pregnancy can be malpositioning of the device (i.e. perforation, expulsion, or migration), incomplete adhesion mechanism, or misinterpretation of imaging.[11] Very few pregnancies occur among women with confirmed bilateral tubal occlusion. In 11 articles on almost 60 000 women who underwent Essure® placement, 102 pregnancies were reported, of which 15 occurred after imaging confirmation of correct placement or tubal occlusion.[12] These data support the need for follow-up confirmation of tubal occlusion before the sterilisation method can be relied upon for permanent contraception. The confirmation test is necessary even though the hysteroscopic procedure was easy and uneventful.

In a recently published study, hysteroscopic sterilisation was associated with an over ten-fold occurrence of re-operations, compared with laparoscopic sterilisation.[3] Additional surgeries were mainly re-sterilisations or other procedures performed to reveal complications (device perforation or migration). The reason for higher re-operation risk may be in the protocol-required follow-up visit 3 months after the Essure® procedure, when the device failure might be detected or suspected. After the Essure® procedure 449 hysterectomies were also reported to the Manufacturer and User Facility Device Experience (MAUDE) database.

The most significant finding of this study is the large number of reported re-sterilisations in the Essure® group (11.86 per 1000 follow-up years). There may be double notifications concerning the same patient (e.g. Essure® performed in two different sessions, or an Essure® device placed on one side and then Filshie® performed later because of a failure of bilateral placement). It is also possible that the Essure® attempt failed and that the procedure was coded on the Essure® code (LGA22). A confirmation test 3 months after the hysteroscopic sterilisation may reveal a device failure, which might contribute to the higher re-sterilisation risk as well as the insecurity in confirming the success of the sterilisation. Outpatient hysteroscopies were more common in the Essure® group as well. The reason for post-procedure hysteroscopy might be device expulsion, suspected uterine perforation, or abnormal uterine bleeding. The number of hysteroscopies after Essure® sterilisation can also reflect coding the second session of placement as a diagnostic hysteroscopy; however, hysterectomies were more common in the Filshie® group. Re-operations for a complication were very rare in all sterilisation groups.

Conclusion

Our study shows that Essure, Filshie and Pomeroy are safe and effective methods of sterilisation. Patients undergoing hysteroscopic sterilisation have a higher risk for re-sterilisation compared with patients undergoing laparoscopic or Pomeroy sterilisation. The high failure rate with Essure® during the first months following the procedure underlines the importance of pre-procedure counselling. Effective contraception during the first 3 months after Essure® sterilisation could decrease one-third of pregnancies. The confirmation test is necessary even though the hysteroscopic procedure is easy and uneventful. Benefits and risks for all contraceptive methods must be discussed with patients for informed decision-making.

Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

Contribution to authorship

RH and EJ were responsible for the conception and design of the study, AH and MG for data acquisition, and RH, EJ, and TK for analysis and interpretation of the data. All authors contributed to the writing of the manuscript and revised it critically, approved the final version, and agreed to be accountable for all aspects of the work.

Details of ethics approval
No ethical conflicts (register-based study).

Funding
None.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. The codes of selected diagnoses and operations. ■

References

1 Gariepy AM, Creinin MD, Smith KJ, Xu X. Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization. *Contraception* 2014;90:174–81.
2 Dhruva S, Ross J, Garieby A. Revisiting Essure – towards safe and effective sterilization. *N Engl J Med* 2015;373:e17.
3 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.
4 Hurskainen R, Hovi SL, Gissler M, Grahn R, Kukkonen-Harjula K, Nord-Saari M, et al. Hysteroscopic tubal sterilization: a systematic review of the Essure system. *Fertil Steril* 2010;94:16–9.
5 Gissler M, Ulander V-M, Hemminki E, Rasimus A. Declining induced abortion rate in Finland: data-quality of the Abortion Register. *Int J Epidemiol* 1996;25:376–80.
6 Gissler M, Haukka J. Finnish health and social welfare registers in epidemiological research. *Norsk Epidemiologi* 2004;14:113–20.
7 Sund R. Quality of the finnish hospital discharge register: a systematic review. *Scand J of Public Health* 2012;40:505.
8 Fernandez H, Legendre G, Blein C, Lamarsalle L, Panel P. Tubal sterilization: pregnancy rates after hysterosopic versus laparoscopic sterilization in France, 2006–2010. *Eur J Obstet Gynecol Reprod Biol* 2014;180:133–7.
9 Munro MG, Nichols JE, Levy B, Vleugels M, Veersema S. Hysteroscopic sterilization: 10-year retrospective analysis of worldwide pregnancy reports. *J Minim Invasive Gynecol* 2014;21:245–51.
10 Hitzerd E, Schreuder HW, Vleugels MP, Veersema S. Twelve-year retrospective review of unintended pregnancies after Essure sterilization in the Netherlands. *Fertil Steril* 2016;105:932–7.
11 Adelman MR, Dassel MW, Sharp HT. Management of complications encountered with Essure hysteroscopic sterilization: a systematic review. *J Minim Invasive Gynecol* 2014;21:733–43.
12 Cleary TP, Tepper NK, Cwiak C, Whiteman MK, Jamieson DJ, Marchbanks PA, et al. Pregnancies after hysteroscopic sterilization: a systematic review. *Contraception* 2013;87:539–48.

