



A prospective cohort study of menstrual symptoms and morbidity over 15 years following laparoscopic Filshie clip sterilisation

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ABSTRACT

Objective: To observe the incidence of menstrual symptoms and relevant surgery after sterilisation.

Study design: 1101 women sterilised with Filshie clips between 1983 and 2002 were assessed prospectively comparing menstrual symptomatology documented immediately before surgery and 5–14 years later by questionnaire.

Main outcome measures: Prevalence of menstrual dysfunction and subsequent surgery related to pre-operative menstrual symptoms and contraception.

Results: After excluding 232 (24%) of the 968 eligible women sent questionnaires whose address had changed, 573 of the remaining 735 women (78%) completed the questionnaire, 223 5–6 years after sterilisation, 175 after 7–9 years and 175 after 10–15 years; the respondents were demographically representative of the total population. Heavy periods increased from 9% before to 35% ($P < 0.0001$) after sterilisation, painful periods from 2% to 21% ($P < 0.0001$) and 6% had undergone hysterectomy or endometrial ablation. These findings were not influenced by the pre-sterilisation method of contraception but were inversely related to advancing age ($P < 0.0002$). The lowest rates of menstrual symptoms were reported 10–15 years after sterilisation.

Conclusion: Menstrual symptoms increased following Filshie clip sterilisation irrespective of pre-sterilisation symptoms and contraception. Whatever the causative mechanism, the progestogen-loaded intrauterine system (IUS), with similar efficacy but with improved menstrual symptoms, should be considered before sterilisation.

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1. Introduction

By the early 1980s, laparoscopy had become a common surgical approach for tubal sterilisation, largely replacing a variety of tubal ligation techniques at laparotomy. In 1981, the Filshie titanium and silicone rubber clip [1] was introduced and offered an alternative to tubal diathermy, the spring-loaded clip and tubal banding. From 1983, laparoscopic Filshie clip sterilisations applied under local anaesthesia were offered in a private non-profit-making clinic and a prospective audit of surgical results and long-term outcome was commenced as part of the governance of the clinic [2].

In 2003, the American College of Obstetricians and Gynecologists (ACOG) published its guideline on the benefits and risks of sterilisation [3] and concluded that there was no substantial evidence that tubal sterilisation caused menstrual dysfunction but noted what they described as a non-causative increased risk of hysterectomy compared with control groups of women who had

not been sterilised. The Royal College of Obstetricians and Gynaecologists (RCOG) in London published its guideline on male and female sterilisation in 2004 [4] and reached similar conclusions, based largely on one meta-analysis published in 1997 [5]. It recommended however that further information was collected on menstrual function following mechanical methods of tubal occlusion, especially with the Filshie clip [4].

To date we have not identified any prospective large long-term assessment of the possible impact on menstrual symptoms of sterilisation using the Filshie clip and this study addresses that issue.

2. Methodology

2.1. Study population

Women were self-selected for operation and referred to the clinic by their General Practitioner; the majority were self-funding. From the outset, when possible they were counselled and examined by the gynaecologist who would perform the surgery. An obstetric and gynaecological history was taken by the surgeon including a record of any complaint of heavy or painful periods, current med-

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ication and relevant medical history, particularly gynaecological surgery and the contraception method in use prior to sterilisation.

2.2. Sterilisation procedure

The operative technique changed little during the 20 years involved in the study with all women managed as day-cases; the technique has been described previously [6]. Oral premedication was given to the majority of the patients and operative anaesthesia was provided by 20–30 mL 1% lidocaine with epinephrine (1:200,000) injected at sites identified by the surgeon in the sub-umbilical and suprapubic regions, ensuring that the infiltration reached the peritoneal layer. During the course of the study, the analgesic benefit of 3–5 mL of 5% lidocaine dripped under direct vision on to each Fallopian tube at the proposed site of clip application was convincingly established through a randomized controlled trial [7]. After distension of the abdomen with 1–3 L nitrous oxide, a 7 mm laparoscope was used for all procedures and one Filshie clip [1] was applied to each Fallopian tubes as a routine, with an additional clip applied if the surgeon was concerned about the application of the first clip on either side.

2.3. Consent and follow-up protocol

All women signed a consent form before the operation was performed and, with her approval, her partner was also invited to sign his agreement with her decision. Following the operation, the patient was asked to return an early recovery questionnaire 4–6 weeks later detailing post-operative progress; at the same time, they were advised that a further questionnaire enquiring about subsequent health would be sent. This approach to follow-up was established before the introduction of current guidelines adopted by research ethics committees in the United Kingdom. Even so, the principles enunciated in the Declaration of Helsinki were adhered to and procedures were used to maintain the confidentiality of the patient. In 1991, a written request for the patient to indicate whether she was agreeable to being contacted in future was added to the early recovery questionnaire. Prior to 1991, follow-up questionnaires were sent only to women who had returned the early recovery questionnaire and whose partner had signed his agreement to the operation. We did not ask whether information could be requested from General Practitioners if personal contact failed and in consequence we had no way of obtaining further information from non-responders to our questionnaire.

Statistical analyses have been performed using χ^2 -test and odds ratios with 95% confidence intervals.

3. Results

1101 women had the operation and Table 1 shows the proportion of women who reported heavy and/or painful periods at routine pre-sterilisation counselling according to the method of contraception used at that time. There was a trend towards more women complaining of heavy periods with increasing age, but a similar trend was not found with dysmenorrhoea. Women using the intrauterine contraceptive device (IUCD) for contraception were more likely to complain of current heavy periods than those using other methods or no contraception (OR 4.9 CI (2.39–10.08)) and those using hormonal contraception complained of dysmenorrhoea less often than those using other methods or no contraception (OR 0.45 CI (0.21–0.93)).

Fig. 1 illustrates the numbers of women and the intervals between surgery and questionnaire completion with the percentage response rates for each year after sterilisation. Table 2 documents the characteristics of all women at the time of operation, separately identifying the 133 not eligible for follow-up, the

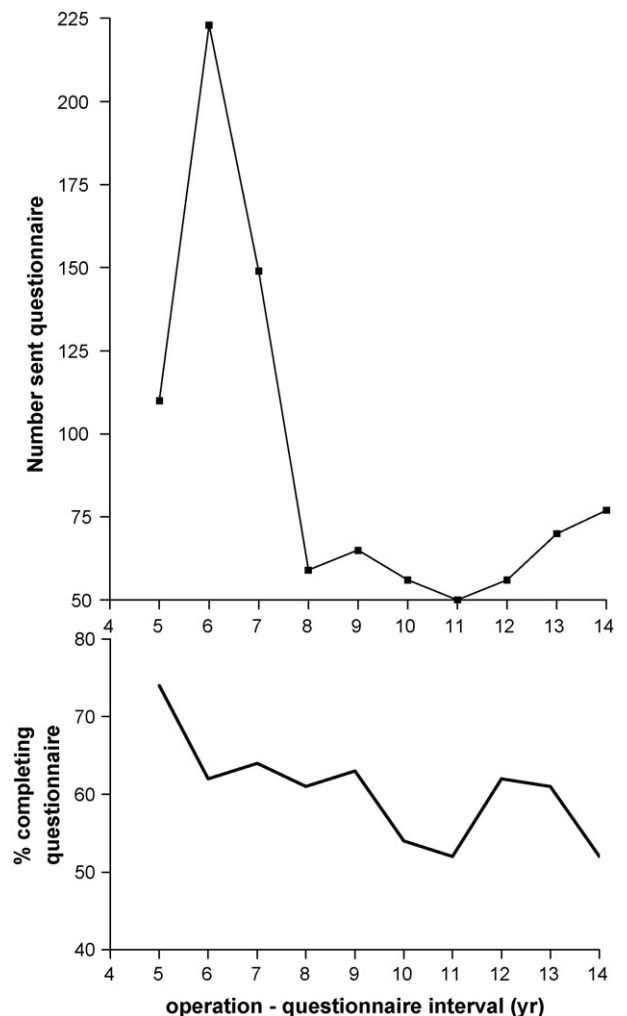


Fig. 1. Response rate for questionnaire completion related to the interval since sterilisation.

232 who had moved from their last known address, the 573 of the remaining 735 (78%) who provided long-term follow-up data and 163 for whom a response was not received. Of the 573 completed questionnaires, 223 (39%) were completed 5–6 years after the operation, 175 (30%) after 7–9 years and 175 (30%) after 10–15 years.

Of the 573 responses, 200 (35%) women reported their periods were heavy. This compares with 50 in that cohort who had reported heavy periods at the time of sterilisation; 21 (42%) of this group reported still having heavy periods at follow-up. A total of 120 of the 573 (21%) reported that their periods were painful. Within the cohort 41 reported painful periods at the time of sterilisation and 13 (32%) again reported painful periods at follow-up. Table 3 illustrates the relationship between these symptoms before and after sterilisation according to the method of contraception used immediately before sterilisation. Significantly increased rates of heavy periods were reported for all groups of women except those who had been using an IUCD and of painful periods for all except the IUCD and 'other' contraception groups.

The relationship between the age at the time of questionnaire completion and recorded heavy or painful periods is shown in Table 4 and Fig. 2. There was a strong inverse association with advancing age and menstrual symptoms ($P < 0.0001$ χ^2 -test for Trend). This association persisted if only women aged 49 years or younger were analysed to reduce the potential impact of the menopause (heavy periods $P = 0.0002$; painful periods $P < 0.0001$).

Table 1
Total numbers of women and the percentage reporting heavy periods and/or painful periods according to last contraceptive method in use prior to sterilisation related to age at sterilisation.

Age range (year)	Contraceptive practice pre-sterilisation				All women
	Barrier ^a	Hormonal	IUCD ^c	Other ^b	
Heavy periods					
20–29	29 (3%)	42 (5%)	3 (0%)	4 (50%)	78 (6%)
30–34	115 (12%)	120 (4%)	20 (20%)	22 (5%)	280 (9%)
35–39	176 (9%)	172 (9%)	44 (27%)	33 (3%)	425 (10%)
40–44	110 (14%)	96 (4%)	26 (38%)	30 (7%)	262 (12%)
45–54	20 (5%)	15 (0%)	10 (0%)	8 (0%)	53 (4%)
All ages	450 (10%)	445 (6%)	103 (25%)	101 (7%)	1099 ^a (10%)
Painful periods					
20–29	29 (3%)	42 (7%)	3 (33%)	4 (0%)	78 (6%)
30–34	115 (10%)	120 (6%)	20 (15%)	22 (16%)	280 (9%)
35–39	176 (10%)	172 (2%)	44 (5%)	33 (9%)	425 (6%)
40–44	110 (11%)	96 (5%)	26 (4%)	30 (13%)	262 (8%)
45–54	19 (5%)	15 (0%)	10 (20%)	8 (0%)	53 (6%)
All ages	450 (10%)	445 (4%)	103 (8%)	101 (11%)	1099 ^a (7%)

13 of 275 (5%) using the combined oral contraceptive pill had heavy periods. 9 of 275 (3%) using the combined oral contraceptive pill had painful periods; IUCD: intrauterine contraceptive device.

^a Two women with unrecorded ages have not been included in this analysis.

^b Includes 96 women using coitus interruptus, rhythm method, abstinence, breast feeding or no contraception, five for whom no method was recorded and one woman relying on her partner's vasectomy.

^c One woman was using a progestogen-releasing IUS.

Table 2
Demographic and symptom details at the time of surgery analysed by completion of follow-up questionnaires.

	All women	No FU data available				FU data available	P value
		Not circulated	Moved away	No response	Total		
N women	1101	133	232	163	528	573	FU v no FU
Age (year)							
20–29	78 (7%)	7 (5%)	25 (11%)	15 (9%)	47 (9%)	31 (5%)	P=0.10 ^a
30–39	705 (64%)	80 (60%)	152 (66%)	102 (63%)	334 (63%)	371 (65%)	
40–49	315 (29%)	45 (34%)	54 (23%)	46 (28%)	146 (27%)	170 (30%)	
n/r	2 (0%)	1 (1%)	1 (0%)	0 (0%)	1 (0%)	1 (0%)	
Civil state							
Married	933 (85%)	69 (52%)	201 (87%)	136 (83%)	406 (77%)	527 (92%)	P<0.0001 ^b
Previously married	112 (10%)	57 (43%)	19 (8%)	11 (7%)	87 (16%)	25 (4%)	
Single	56 (5%)	7 (5%)	12 (5%)	16 (10%)	35 (7%)	21 (4%)	
Nulliparae	126 (11%)	18 (14%)	28 (12%)	22 (13%)	68 (13%)	58 (10%)	P=0.03 ^a
Reported menstrual symptoms							
Heavy periods	106 (10%)	20 (15%)	21 (9%)	15 (9%)	56 (11%)	50 (9%)	P=0.30 ^b
Painful periods	83 (8%)	7 (5%)	15 (6%)	20 (12%)	42 (8%)	41 (7%)	P=0.65 ^b

FU: follow-up. Note: Significant difference in marriage status was expected, given the follow-up policy described prior to 1991 (follow-up only of women whose partners had signed the surgical consent form).

^a χ^2 -test for Trend.

^b χ^2 -test.

Table 3
Percentage women reporting heavy and painful periods before and after sterilisation according to contraceptive method used immediately prior to sterilisation.

	Contraception used immediately before sterilisation								All women	
	Barrier		Hormonal		IUCD ^{**}		Other ^{**}		Before	After
Number of respondents	253		233		47		40		573	
Relationship to sterilisation	Before	After	Before	After	Before	After	Before	After	Before	After
Heavy periods	9%	34%	6%	36%	28%	32%	3%	38%	9%	35%
OR (95% CI)	5.0 (3.05–8.20)		9.34 (5.04–17.42)		1.23 (0.51–2.97)		26.00 (3.24–208.91)		5.49 (3.93–7.67)	
Painful periods	9%	19%	4%	24%	9%	17%	9%	23%	9%	21%
OR (95% CI)	2.28 (1.34–3.89)		7.06 (3.50–14.23)		2.21 (0.62–7.90)		2.26 (0.73–9.33)		3.44 (2.36–5.01)	

^{**} Includes 35 women using coitus interruptus, rhythm method, abstinence or no contraception, four for whom no method was recorded and one woman whose partner had a vasectomy.

Table 4
Relationship between age at questionnaire completion and menstrual symptoms.

Age (year)	Total respondents ^a	N (%) reporting heavy periods	N (%) reporting painful periods
<35	6	32 (50%)	1 (17%)
35–39	69	37 (54%)	29 (42%)
40–44	169	72 (43%)	43 (25%)
45–49	214	64 (30%)	35 (16%)
50–54	94	21 (22%)	11 (12%)
55+	20	3 (15%)	0
Total	572	200 (35%)	120

^a The woman with no recorded age who was also symptomless has not been included in the analysis.

Table 5
Relevant gynaecological symptoms and operations performed since sterilisation and before questionnaire completion. Results illustrated are numbers (%) or mean ± SD.

	Sterilisation—follow-up interval (year)			Total
	5–6	7–9	10–15	
Total respondents	223	175	175	573
Age (years) at questionnaire completion	43.6 ± 6.1	44.6 ± 4.8	48.1 ± 4.7	45.3 ± 5.6
Menstrual symptoms				
Heavy periods	76 (34%)	74 (42%)	50 (29%)	200 (35%)
Painful periods	49 (22%)	37 (21%)	34 (19%)	120 (21%)
Endometrial examination				
All cases	6 (3%)	8 (5%)	11 (6%)	25 (4%)
For menstrual problems	3 (1%)	5 (3%)	4 (2%)	12 (2%)
Hysterectomy				
All cases	7 (3%)	11 (6%) ^a	17 (10%)	35 (6%)
For menstrual problems	4 (2%)	4 (2%)	11 (6%)	22 (4%)
Endometrial resection				
No relevant surgery	1 (0.5%)	6 (3%)	2 (1%)	9 (2%)
	209 (94%)	150 (86%)	14 (83%)	504 (88%)

^a Includes two women on the waiting list for hysterectomy, one because of heavy periods.

At the time of completing the questionnaire a number of women had already undergone a gynaecological operation as shown in Table 5, which correlates the operation to the follow-up interval. In 12 of 25 (48%) cervical dilatation and uterine curettage

(D&C) was performed for heavy periods, as were 22 of 35 (63%) hysterectomies; a further nine (2%) women underwent endometrial ablation. In addition to these gynaecological operations, eight women reported having breast tumours of which four were malignant; five had cervical dysplasia; one had vulvar dyskariosis; and five had other tumours. One of the five women reporting an ‘other’ tumour had died from a brain tumour by the time of follow-up 7 years post-operatively; no further details were provided and this patient does not feature in the other analyses.

4. Discussion

This study has the strengths of being prospective and following a large number of women sterilised by a consistent surgical technique at a single centre. The pre-sterilisation menstrual symptoms and contraceptive use were recorded at pre-sterilisation counselling, thus avoiding the vagaries of symptom recall at a later date, often many years later in some studies. Although the response rate for those who had not changed address was 78%, for all eligible women the response to the questionnaire was 59%, raising the possibility that those responding were unrepresentative; demographically, women completing the questionnaire were very similar to the whole group. It is possible that those less tolerant of menstrual symptoms are more likely to take the opportunity to record their discomfort by postal questionnaire completion. Moreover we acknowledge that, as in similar studies, an unknown proportion of the 293 women (Table 3) using barrier or ‘other’-methods at the time of counselling might have recently switched from hormonal contraception and as a consequence recall their periods as lighter and/or less painful. The possibility cannot be excluded for those recent users, as well as the 233 known users of hormonal contraception, that the reported deterioration in symptoms after sterilisation might be due to method-discontinuation with the consequent loss of hormonal suppression of symptoms.

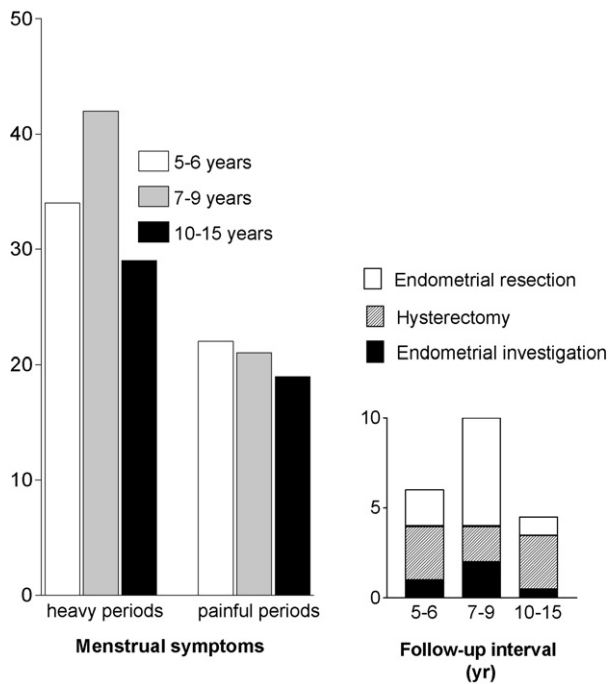


Fig. 2. Percentage of women reporting menstrual symptoms and those who had undergone surgery for menstrual dysfunction by the time since surgery of questionnaire completion. (Note the different Y-axis scales.) [Endometrial investigation includes diagnostic uterine curettage and hysteroscopy.]

However, as in almost all similar studies, there remains the inbuilt problem of dependence on the woman's subjective assessment of her symptoms and the potential bias of different observers recording these assessments. Objective measurements of the volume of the menses, though of value scientifically, should not detract from the woman's perception of her symptoms. The pre-sterilisation questions were asked verbally in a clinic setting primarily by three consultant gynaecologists while the follow-up information was obtained using a postal questionnaire completed by the woman at home; the impact of using these two different methods of data collection is uncertain. We did not use a control group, such as the partners of men who had undergone vasectomy to address the potential impact of factors other than contraception method on menstrual symptoms: to adequately address this requires a prospective randomized study which is not tenable, and requires collecting menstrual symptom data 'pre-operatively' to be meaningful.

The ACOG [3] and RCOG[4] guidance concluded there is no convincing evidence for a causative increased risk of heavy periods following sterilisation, although the RCOG expressed some reservations for women under 30 years of age when sterilised. Both bodies agree there is an increased risk of hysterectomy for all ages for which sterilisation may perhaps have a causative link. Menstrual pain as a possible sequel to tubal sterilisation was not specifically addressed in these guidelines. The evidence-base for these guidelines relied on case-control or cohort studies published more than 15 years ago involving women sterilised more than 25 years ago before the evolution of current surgical techniques or the opinions of respected authorities.

A number of the earlier studies assessing heavy periods after sterilisation included operations performed during the 1950s and 1960s [8–11] before the widespread use of the combined oral contraceptive pill, yet these studies generally reported an increased frequency following sterilisation. Studies of sterilisations during the 1970s [12,13] included those by laparotomy and laparoscopy and these also reported increased rates. Four studies used the partners of men who had undergone vasectomy as controls and they reported an increased risk of heavy periods [8,10,12], one of which only found a non-significant increased risk in women with heavy periods before sterilisation [11]. One study reported a similar rate of heavier periods in both the study and control groups, attributed in each instance to discontinuing the oral contraceptive pill; this study however relied on retrospective recall of the nature of periods before sterilisation as the comparison with those at the time of questionnaire completion [14].

The United States Collaborative Review of Sterilisation (CREST), the largest prospective study observing women for up to 14 years after tubal sterilisation during 1976–1986 has spawned a number of reports relating to menstrual function with some contradictory findings. Based on transitional modelling, a significant increase in heavy periods was observed more than 5 years after sterilisation [15], with the increase being 3.9-fold at 3 years, 10.0-fold at 7 years and 22.4-fold at 14 years; for women not troubled by heavy periods before sterilisation, the figures were 2.4, 6.3 and 13.7, respectively [16]. A further study based on these data [17] however in contrast found there was no impact on menstrual flow during the first 5 years after sterilisation irrespective of pre-sterilisation menstrual symptoms.

Harlow et al. [18] concluded that there was no impact on menstrual symptoms except for women who had previously been delivered by caesarean section and had been sterilised at some time at least 5 years earlier. However, in this study, women were asked to recall their menstrual symptoms during the first 5 years after the menarche as the baseline for menstrual function. Since only 97 women for whom information relating to contraceptive use prior to sterilisation were studied and the year and method

of sterilisation were not provided, these results are of doubtful value.

A causative relationship to post-sterilisation menstrual symptoms has largely been dismissed since studies measuring ovarian steroid concentrations in the peripheral circulation immediately [19] or 5 years [20] after sterilisation, have failed to demonstrate any changes from normal—as might theoretically be mediated by occlusion of the tubes causing ischaemic changes in the ovary. Such studies do not however necessarily negate the suggestion of a physical consequence of sterilisation on menstrual function. There have been few objective assessments of menstrual loss before and after sterilisation to support or refute the subjective reports of a change apart from one frequently cited study involving only 25 women during 6 or 12 months after sterilisation [21]. However, as a number of studies have shown, heavy periods are often not reported until more than 5 years have elapsed since sterilisation [4,10,21,22].

Very few studies have investigated dysmenorrhoea, despite the well recognised relationship between the reduction in symptoms with the combined oral contraceptive pill and the increase with the non-hormone containing IUCD. Two studies [8,12] reported an increase in painful periods after sterilisation compared with the results for vasectomy partners acting as controls, even when controlled for previous contraception. Two groups reported increased frequency of painful periods only for women reporting painful periods before sterilisation [11,16].

Most studies addressing post-sterilisation hysterectomy have found an increased risk of hysterectomy for menstrual problems when compared with a control group of non-sterilised women [10,23,24] or the partners of men who have undergone vasectomy [10,12,25]. One study found the increase was limited to women under 30 years of age when sterilised [26] and one limited to women with pre-existing menstrual symptom at the time of sterilisation [11]. The increased risk varied between 0.5- and 5-fold, with the risk doubling between 5 [25] and 14 years post-sterilisation [16]. A complaint of heavy periods and a request for hysterectomy, even if there was no objective change, is thought may reflect the woman's dissatisfaction with continuing menstruation: perceiving it to have little value after the possibility of childbearing has been removed [3,4,10,21,22,25].

With the introduction of newer strategies for treating menstrual dysfunction during the 1990s, including endometrial surgery [27] the levonorgestrel-releasing IUS [28,29] and radiographic uterine artery embolisation [30], enquiry about hysterectomy and these newer strategies should be included in the assessment of post-sterilisation morbidity. As our results show, of 15 women having a surgical intervention for menstrual symptoms 5–9 years after sterilisation, 47% had endometrial resection and 53% hysterectomy compared to 15% and 85%, respectively 10–14 years after sterilisation. We did not enquire about the post-sterilisation use of the levonorgestrel-releasing IUS or uterine artery embolisation.

Tubal sterilisation may offer some protection against ovarian, cervical, endometrial and breast cancers [31,32], though if real the mechanisms are unknown. The numbers and duration of follow-up in our study do not permit useful conclusions regarding tumour development between sterilisation and questionnaire completion. For the record we observed one death from a brain tumour, four cases of breast malignancy and no cases of invasive cervical, ovarian or endometrial cancer.

5. Conclusion

The changes in menstrual symptoms following sterilisation using Filshie clips are broadly similar to those observed for other sterilisation techniques and were not influenced by pre-

sterilisation menstrual symptoms or the contraception used immediately before the operation. While the rate of post-sterilisation hysterectomy for heavy and/or painful periods is similar to that reported in earlier studies, future investigation in this area should expand the enquiry to specifically include other strategies for managing menstrual symptoms including ablative endometrial surgery and the levonorgestrel-releasing IUS. While the mechanism responsible for heavier and more painful menses following sterilisation that we and others have reported remains speculative and include a local physical disturbance or loss of previous hormonal suppression of menstrual dysfunction, these symptoms warrant a woman-centred conclusion. A recommendation for the long-acting levonorgestrel-releasing IUS, with similar contraceptive efficacy but with demonstrable relief of menstrual symptoms and maintained reversibility, should be considered before contemplating sterilisation.

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Contributors

All authors were involved in the design of the study, contributed to clinical care during the course of the study, the analysis and interpretation of the data and the production and final submission of the manuscript.

Competing and financial interests

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