

A comparison of the modified Pomeroy tubal ligation and Filshie clips for immediate postpartum sterilisation: A systematic review

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ABSTRACT **Objectives** The modified Pomeroy procedure is currently the most widely used method for postpartum sterilisation. Alternative options are Filshie clips, Hulka-Clemens clips and Falope rings. In this systematic review we pooled the available evidence in order to compare the failure rates, complications, technical difficulties, and reversibility of the Pomeroy method and Filshie clips when resorted to for postpartum sterilisation.

Methods We gathered data from MEDLINE, EMBASE (1970–2010), the Cochrane database, and reference lists of randomised controlled trials (RCTs) and observational studies. We extracted information on study design, sample characteristics, interventions, and outcomes.

Results Our search yielded 294 citations of which 43 were retrieved for detailed evaluation. Fourteen studies were included in the systematic review. One RCT and three observational studies compared failure rates of the Pomeroy method vs. Filshie clips. A random-effects analysis of the pooled studies showed no difference in the failure rates between these two methods (odds ratio 0.76 [95% confidence interval 0.30–1.95]). Complication rates were similar although the Filshie clip technique was reported to be easier.

Conclusions Filshie clip application is easier to perform. The failure and complication rates are comparable to those of the modified Pomeroy method, when performed in the postpartum period.

KEY WORDS Female sterilisation, Tubal occlusion, Postpartum sterilisation, Minilaparotomy, Caesarean section, Pomeroy method, Modified Pomeroy method, Filshie clip

INTRODUCTION

Female sterilisation is a popular method of family planning (FP). It is estimated that, worldwide, about 180 million couples opt for this method of contraception¹.

Around half of all tubal occlusion procedures in the United States are carried out in the postpartum period². In the aforementioned country, the incidence of postpartum sterilisations appears to be stable at 8–9 %

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of all live births, in spite of a decrease in the interval sterilisation rates by 12% over the same time period³. Postpartum sterilisation is ideally done within 48 hours of vaginal delivery⁴, or is performed during caesarean section.

In the postpartum period the Fallopian tubes are mostly approached via a minilaparotomy. This approach continues to be widely used in developing countries. It is relatively quick, relatively free of complications, and requires only basic surgical equipment that is readily available in most centres worldwide.

The main methods currently used for occluding the Fallopian tubes are *tubal ligation* (usually by a modified Pomeroy technique) or the application of *mechanical devices* (e.g., Filshie clips, Hulka-Clemens clips or Falope rings)^{5,6}.

The most commonly performed method of postpartum sterilisation is the modified Pomeroy method⁷⁻⁹, a technique that has not been modified since it was developed in 1930. In this method of tubal ligation, the cut ends of the Fallopian tube separate as the suture material employed for the ligature is resorbed, and the peritoneum grows over to cover the tubal segments. This leaves a gap of up to 3–4 cm between the two ends of the Fallopian tube^{6,10-12}. The familiarity of this procedure among gynaecologists makes it relatively easy to perform. However, there can be a potential risk of bleeding from the blood vessels in the mesosalpinx, which are engorged in the postpartum period, and this may be compounded by tears. Ideally following this method of tubal occlusion, the excised tissue should be submitted to histological examination to confirm that the surgical specimens are segments of Fallopian tubes.

The Filshie clip (Femcare-Nikomed, Hampshire, UK) is made from titanium and silicone rubber. When applied over the isthmic portion of the Fallopian tube, the immediate mechanical effect of compression causes occlusion of the Fallopian tube. As the tube undergoes necrosis, the V-shaped silicone rubber lining expands to keep the tubal lumen blocked. This property of the Filshie clip, as well as its length of 14 mm, allow for its application over the oedematous tubes during caesarean section and in the postpartum period¹³. With further tissue degeneration, the ends of the tubes divide and the stumps heal⁶. Due to the narrow width (4 mm) of the Filshie clip, the length of the Fallopian tube that is destroyed is no more than 4–5 mm. The silicone lining of the Filshie clip prevents clip

migration and reduces the risk of tubal transection or fistula formation around the tubal stump.

Complications of postpartum sterilisation are rare; they largely arise at the time of surgical abdominal entry or when identifying and grasping the Fallopian tube. These risks have been found to be higher in obese women, those with adhesions and with endometriosis¹⁴.

Sterilisation failures occurring beyond one year after use of Filshie clips are more likely to be due to recanalisation or fistula formation than to malpositioning of a clip. Conversely, partial occlusion with possible tubal patency is a cause for failure within the first year^{15,16}.

As the Hulka-Clemens clip and the Falope rings are not being used for tubal occlusion in the postpartum period, there are very little data to compare their failure and complication rates to those of other methods. The present review, therefore, evaluates the available evidence solely on the two most common types of sterilisation performed in the postpartum period: the modified Pomeroy method and Filshie clips (Mark VI).

METHODS

Identification and assessment of evidence

We excluded all publications that evaluated the Mark IV Filshie clip as this was superseded by the current Mark VI clip in 1981. We searched the MEDLINE and EMBASE from 1970 to 2010 using a combination of MeSH terms, text words and word variants: (sterilis* OR steriliz*) and 'tubal' or 'minilaparotomy' combined with 'postpartum' or 'puerperium' and 'Filshie' or 'Pomeroy'. The Cochrane Controlled Trials Register was searched for related randomised controlled trials (RCTs). We also hand-searched the bibliographies of all relevant reviews and primary studies to identify articles not captured by electronic searches. The search revealed the existence of a paper in Afrikaans which was translated, but no other non-English language papers were identified. We contacted Femcare-Nikomed, manufacturers of the Filshie clip in the United Kingdom, for conference proceedings and abstracts, for unpublished data. For the purpose of this review, only tubal occlusions performed within six days of delivery, including those done during caesarean section were considered.

We classified each paper into a level of evidence according to the Oxford Centre for Evidence-Based Medicine Levels of Evidence (March 2009) criteria¹⁷.

The studies were classified as being of ‘good’ quality if their evidence level was 1-a, b, c, or 2-a, b, c, and of ‘poor’ quality if they were level 3-a, b, c or 4. We also used the papers identified for evidence on complications (minor and major morbidity), technique-related issues (ease of procedure, ease of learning, operation times), long-term complication of ectopic pregnancy, reversibility of the procedure, and cost implications.

All estimates were calculated as odds ratios and statistical data analyses (including funnel plot to analyse publication bias) was carried out using Review Manager Software (version 5.1, Cochrane Collaboration). For combining the evidence across the trials, a Mantel-Haenszel method random effect method was applied, which was based on different treatment effects in the individual studies.

RESULTS

The electronic search yielded 294 citations. On the examination of titles and abstracts, 43 were found to be potentially relevant and their full papers were obtained. Their reference lists brought to light 23 further citations (Figure 1).

Failure rates

The salient features of the studies included in this systematic review for failure rates are summarised in Table 1. Most studies had a retrospective observational cohort design. We identified only one RCT comparing the modified Pomeroy method and Filshie clips that reported failure rates¹⁸. There were two other RCTs but the first one compared the modified Pomeroy tubal ligation with the application of Hulka-Clemens clips¹⁹, and the second one the Filshie clip with the Hulka-Clemens clip²⁰. We used the data from these trials for the pooling of the overall failure rates. The follow-up duration for most studies was for 12 months or 24 months. Only in the Collaborative Review of Sterilisation (CREST) study did the follow-up period extend to between 8 and 14 years²¹.

Although the CREST²¹ study determined the overall ten-year cumulative failure rates for bipolar coagulation, unipolar coagulation, Falope rings, Hulka-Clemens spring clips, interval- and postpartum partial salpingectomy, it did not evaluate the Filshie clip method. Among the 1637 women who underwent postpartum partial salpingectomy, the most commonly used method was the modified Pomeroy method⁶ (Table 1).

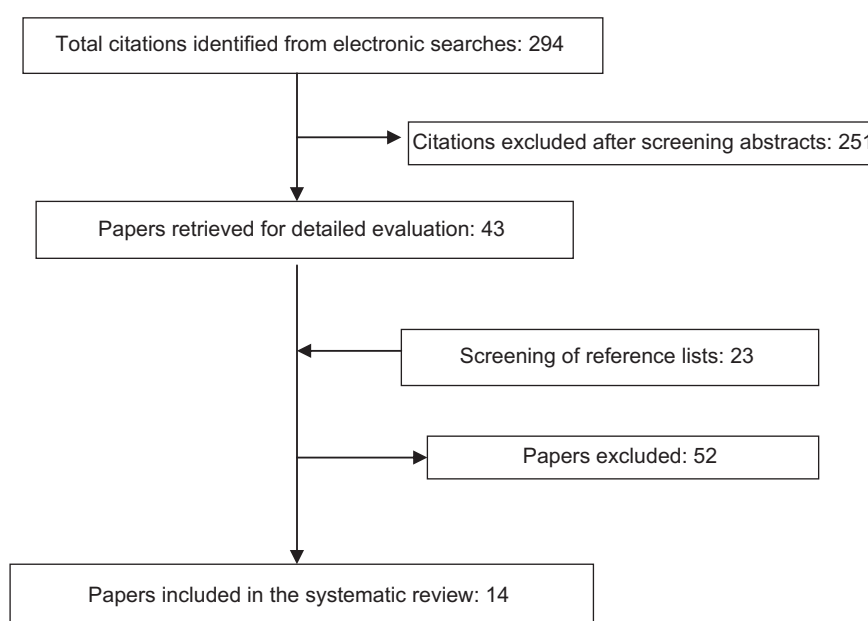


Figure 1 Study selection for the systematic review of failure rates of the modified Pomeroy tubal ligation and Filshie clips for postpartum sterilisation.

Of the procedures whereby Filshie clips were used in the study by Puraviappani *et al.*²², only those ($n = 373$) that were carried out with Mark VI Filshie clips are taken into consideration in this systematic review. The 441 sterilisations performed using Mark IV Filshie clips have been excluded.

Also the results from the earlier studies by DeVillers and co-authors, published in 1983²³ and 1987²⁴, were excluded to avoid duplication of numbers. In the paper DeVillers published in 1992²⁵, data were used from 1971 until 1991, which pertained to postpartum sterilisation by means of the Vienna method (better known as Madlener method: transection of the Fallopian tube at the isthmo-ampullary junction and ligation of each end of the tube with black silk), the modified Pomeroy method, total fimbriectomy, the Filshie clip method, and the Irving method (at caesarean section). The modified Pomeroy method was not used after 1973 and the Filshie Clip Mark VI was used between 1983 and 1985.

Studies varied in population origin, sample size, follow-up, number of centres involved (single or multicentre), time of publication, and level of surgical expertise. Such heterogeneity precludes a reliable meta-analysis; hence we opted to simply pool the studies to generate aggregate frequency data.

We present the data for easy reference in a forest plot, pooling both the good and the poor quality studies (Figure 2). There is no significant difference in the postpartum sterilisation failure rate between the modified Pomeroy tubal ligation and the Filshie clip method, at minilaparotomy.

Procedure-related complications

Irrespective of the sterilisation method chosen, the frequency of complications following postpartum sterilisation is extremely low (less than 1%)³². The 1982 WHO Task Force study³³ reported a major complication rate of 0.3% and a minor complication rate of 4.2%. Major complications included: abandonment of surgery, bleeding from engorged blood vessels (more common with the modified Pomeroy method¹⁸), injuries to viscera, and anaesthetic complications. Minor complications included: the need to enlarge the incision, local infections, and urinary tract infections.

A study of 445 women who underwent Filshie clip sterilisation²⁷ in the postpartum period within 48 hours or between 49 hours and six days, revealed

no significant differences in surgical difficulties, tubal injuries, complications/complaints, technical failures or length of hospitalisation (calculated after the procedures). Procedure-related complications are few; however, the ones most reported with the Filshie clip are transection of the tube, improper application of the clip, and the clip falling into the peritoneal cavity^{34,35}. These procedure-related complications were not observed by Yan *et al.*¹⁸ or by Graf *et al.*, in a prospective study of 300 women undergoing Filshie clip sterilisation in the postpartum period¹³.

Technical difficulties and operation times

There has been only one randomised controlled pilot study of 32 obstetric patients comparing surgeon's preference and operative time between the modified Pomeroy and Filshie clip methods³⁶. This small study showed that the Filshie clip was the preferred method of postpartum sterilisation due to the ease of application of the clip. The time taken for the Filshie clip procedure was shorter compared to that taken to perform the modified Pomeroy procedure (Table 2). The authors also stated that the Filshie clip technique did not require tubal exteriorisation for carrying out its occlusion, which was also described by Yan *et al.*¹⁸. This may be an advantage in morbidly obese patients and in those with extensive tubal adhesions from previous surgical procedures (e.g., caesarean sections) or endometriosis.

Ectopic pregnancies

Data from the 10-year CREST study³⁷ on cumulative probability of ectopic pregnancy following different methods of female sterilisation showed that postpartum salpingectomy has an ectopic pregnancy rate of 1.5/1000. The Filshie clip application is associated with an ectopic pregnancy rate of 0.1/1000 (4%³⁸ of the total failure rate of 2–3/1000³⁹).

Reversibility

Sterilisation reversal is easier after Filshie clips were used because with this technique a much smaller portion of the Fallopian tube is destroyed (up to 4–5 mm) than with the modified Pomeroy method (up to 2–4 cm)^{18,40}. In a study by Nwagbara *et al.*¹², the

Table 1 Modified Pomeroy tubal ligation and Filshie clips for postpartum sterilisation: available evidence regarding failure rates

Authors	Place Duration of study Type of study	Sample size	Intervention	Outcome-failures		Duration of follow-up	Quality assessment
				Pomeroy method	Filshie clips		
Good quality studies							
Chi et al. 1987 ²⁶	International data set (1978–1984) Retrospective	1862	Pomeroy vs. Filshie clip	0/297	3/302	12 months	2b
Yan et al. 1990 ¹⁸	Taiwan (1984–1986) RCT	200	Pomeroy vs. Filshie clip	1/70	0/78	24 months	1b
Chi et al. 1991 ²⁷	Panama & Philippine (1984–1987) RCT	445	Filshie clip 48 hours vs. 49 hrs to 6 days		5/445	24 months	2b
Lee et al. 1991 ¹⁹	US RCT	50	Pomeroy vs. Hulka clip	0/28		Unclear	1b
Graf et al. 1996 ¹³	UK (1987) Prospective cohort	300	Filshie clip		0/209	24 months	2b
CREST 1996 ^{21*}	Multicentric US (1978 – 1986) Prospective cohort	10685	Pomeroy	12/1637		14 years	2b
Dominick 2000 ²⁰	Multicentric (1990) RCT	878	Filshie vs. Hulka		0/296	12 months	1b
Subtotal				13/2032 6.4/1000	8/1330 6.0/1000		
Poor quality studies							
Rozier JR 1973 ²⁸	US (1965–1970) Retrospective	392	Pomeroy's	0/392		6 years	4
Filshie GM 1987 ²⁹	UK Retrospective	593	Filshie clip	3/593		12 months	4
Puraviappani 1987 ²²	Malaysia (1980–1986) Retrospective	796	Filshie clip		0/373	Unclear	4
De Villiers 1992 ²⁵	Paarl (1971–1991) Prospective cohort	7811	Pomeroy vs. Filshie clip	19/892	18/808	17 years	4
Dao et al. 1997 ³⁰	Burkina Faso (1995–1996) Retrospective	63	Pomeroy	0/63		15 months	4
Salim 2003**	UK (1989– 2003) Prospective cohort	110	Filshie clip		0/50	5 years	4
Oligbo et al. 2010 ³¹	UK (1994–2007) Retrospective	290	Pomeroy vs. Filshie clip	0/203	1/87	7 years	3b
Subtotal				22/2143 10.2/1000	19/1318 14.4/1000		
Overall total				8.4/1000	10.2/1000		

*Most of the partial salpingectomy procedures that were evaluated for their failure rates were modified Pomeroy tubal ligations.

**Unpublished data: Post partum female sterilization-oral presentation XII ISGE, Cancun, Mexico.

RCT: randomised controlled trial. Quality assessment based on Oxford Centre for Evidence-Based Medicine Levels of Evidence (March 2009) criteria: 1b: Individual RCT; 2b: Individual Cohort study (including low quality RCT); 3b: Individual Case-Control study; 4: Case-series (including poor quality cohort and case control studies).

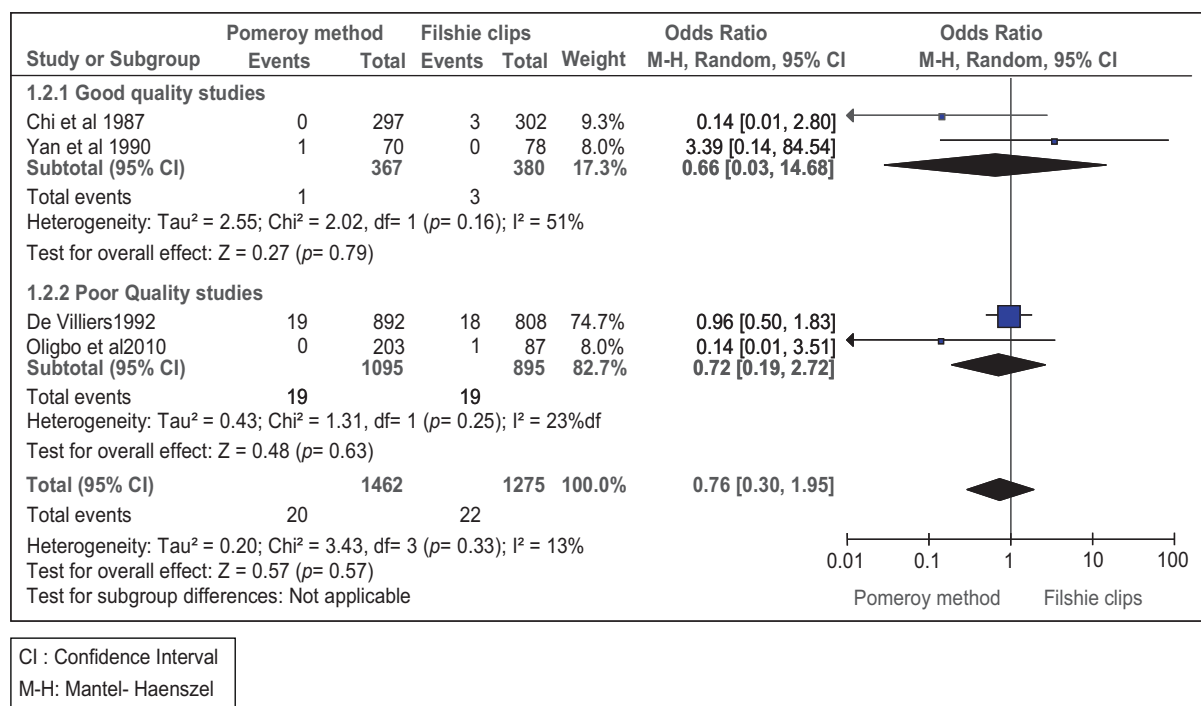


Figure 2 Pooled analysis of postpartum sterilisation failure rates (Pomeroy tubal ligation vs. application of Filshie clips).

intrauterine pregnancy rate following reversal of sterilisation was 6/6 following Filshie clips application as compared to 0/5 following the modified Pomeroy method.

Cost

There are no studies that have compared the cost-effectiveness of the two methods. The costs for the modified Pomeroy method would include that of a possibly longer hospital stay as well as the cost of histopathological examination of the excised segment of Fallopian tube. For the Filshie clip procedure, the cost of the clips and that of the applicator would have to be considered.

Overview

An overview of the advantages and disadvantages between these methods of postpartum sterilisation is given in Table 2.

DISCUSSION

Tubal sterilisation procedures include a wide range of methods. In the postpartum period, the modified Pomeroy procedure is the most commonly performed

method and the evidence is from studies that were carried out before the advent of laparoscopic procedures. This limits the available comparative evidence on partial salpingectomy to other mechanical occlusive methods. Therefore, we believe that this review may be the most comprehensive study to date based on the best available evidence we have in the literature for comparing the modified Pomeroy and Filshie clip methods applied in the postpartum period.

Our systematic review, whereby data from all studies were cumulated, shows no difference in failure rates between the current Mark VI Filshie clip- and the modified Pomeroy method of tubal occlusion when applied postpartum. Of the two randomised studies included in the systematic review for failure rates, only one was sufficiently powered with adequate strategies to conceal allocation for outcome measures. The data should therefore be interpreted with caution as comparisons of the efficacy of the two different methods of postpartum sterilisation vary considerably because of heterogeneity of the populations, the various techniques employed and lack of long-term follow-up.

Operator- and technique-related factors such as the expertise of the surgeon, approach to the Fallopian

Table 2 Advantages and disadvantages of modified Pomeroy's and Filshie methods of postpartum sterilisation

	<i>Modified Pomeroy method</i>	<i>Filshie clip</i>
Failure rates	Failure rate: 7.5/1000 ²¹ Failure rates from good quality studies reviewed in this paper: 6.4/1000	Failure rates from good quality studies reviewed in this paper: 6.0/1000
Complications <ul style="list-style-type: none"> • Procedure related complications 	Lacerations of tube or ligaments ¹⁸	Lesser incidence of complications seen with Filshie clips than at laparoscopy ¹⁸ Most common: improper application ^{34,35}
Technique related issues <ul style="list-style-type: none"> • Ease of procedure • Ease of learning • Operative times 	Familiarity, widely used ^{5,40} 26.6 ± 10.0 min ³⁶	Superior to modified Pomeroy method ³⁶ Simple procedure to learn and carry out ³⁶ Quick to perform 19.9 ± 4.2 min ³⁶
Ectopic pregnancy rates	Ectopic pregnancy rate – 1.5/1000 ³⁷	Low ectopic pregnancy rate in failures 0.1/1000 ^{38,39}
Reversibility	More difficult as 3-4 cm of tube missing ^{6,10-12}	Easier as 4-5 mm of tube missing ^{10,12}
Cost implications	Relatively inexpensive but extra costs are involved for histological examination of tubal fragments	Cost of Filshie clips and applicator but no pathology costs

tubes and occlusive methods used for postpartum sterilisation have an important role in determining the ease of the procedure. The type of anaesthesia, the timing of the procedure, and the characteristics of the women are equally important for minimising the risks. Data from sufficiently large samples are lacking which would allow identifying reliably differences between the two methods with regard to surgeons' preference for one or the other technique.

We found no studies that compared the cost of the two methods. However, there are expenses for histopathological examination of the fragments of tubes excised during a modified Pomeroy tubal ligation, and there is an initial expenditure for acquiring the Filshie clip equipment and, subsequently, costs for meeting the calibration requirements.

CONCLUSIONS

According to the evidence presented, the efficacy and the complication rates of the Filshie clip- and the modified Pomeroy methods of postpartum sterilisation are similar. However, the Filshie clip application was found to be quicker and easier than the performance of the modified Pomeroy ligation³⁶. The Filshie clip method can be used as an alternative to the modified Pomeroy method at minilaparotomy or caesarean section.

Declaration of interest: The authors alone are responsible for the content and the writing of the paper. J.K. Gupta has received honoraria from Femcare-Nikomede for training workshops.

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