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## Techniques for the interruption of tubal patency for female sterilisation (Review)

Lawrie TA, Kulier R, Nardin JM

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[Intervention Review]

# Techniques for the interruption of tubal patency for female sterilisation

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## ABSTRACT

### Background

This is an update of a review that was first published in 2002. Female sterilisation is the most popular contraceptive method worldwide. Several techniques exist for interrupting the patency of fallopian tubes, including cutting and tying the tubes, damaging the tube using electric current, applying clips or silicone rubber rings, and blocking the tubes with chemicals or tubal inserts.

### Objectives

To compare the different tubal occlusion techniques in terms of major and minor morbidity, failure rates (pregnancies), technical failures and difficulties, and women's and surgeons' satisfaction.

### Search methods

For the original review published in 2002 we searched MEDLINE and the Cochrane Central Register of Controlled Trials (CENTRAL). For this 2015 update, we searched POPLINE, LILACS, PubMed and CENTRAL on 23 July 2015. We used the related articles feature of PubMed and searched reference lists of newly identified trials.

### Selection criteria

All randomized controlled trials (RCTs) comparing different techniques for tubal sterilisation, irrespective of the route of fallopian tube access or the method of anaesthesia.

### Data collection and analysis

For the original review, two review authors independently selected studies, extracted data and assessed risk of bias. For this update, data extraction was performed by one author (TL) and checked by another (RK). We grouped trials according to the type of comparison evaluated. Results are reported as odds ratios (OR) or mean differences (MD) using fixed-effect methods, unless heterogeneity was high, in which case we used random-effects methods.

### Main results

We included 19 RCTs involving 13,209 women. Most studies concerned interval sterilisation; three RCTs involving 1632 women, concerned postpartum sterilisation. Comparisons included tubal rings versus clips (six RCTs, 4232 women); partial salpingectomy versus electrocoagulation (three RCTs, 2019 women); tubal rings versus electrocoagulation (two RCTs, 599 women); partial salpingectomy versus clips (four RCTs, 3827 women); clips versus electrocoagulation (two RCTs, 206 women); and Hulka versus Filshie clips (two RCTs, 2326 women). RCTs of clips versus electrocoagulation contributed no data to the review.

One year after sterilisation, failure rates were low (< 5/1000) for all methods. There were no deaths reported with any method, and major morbidity related to the occlusion technique was rare.

Minor morbidity was statistically significantly higher with the tubal ring than the clip (Peto OR 2.15, 95% CI 1.22 to 3.78; participants = 842; studies = 2;  $I^2 = 0\%$ ; *high-quality evidence*), as were technical failures (Peto OR 3.93, 95% CI 2.43 to 6.35; participants = 3476; studies = 3;  $I^2 = 0\%$ ; *high-quality evidence*).

Major morbidity was significantly higher with the modified Pomeroy technique than electrocoagulation (Peto OR 2.87, 95% CI 1.13 to 7.25; participants = 1905; studies = 2;  $I^2 = 0\%$ ; *low-quality evidence*), as was postoperative pain (Peto OR 3.85, 95% CI 2.91 to 5.10; participants = 1905; studies = 2;  $I^2 = 0\%$ ; *moderate-quality evidence*).

When tubal rings were compared with electrocoagulation, postoperative pain was reported significantly more frequently for tubal rings (OR 3.40, 95% CI 1.17 to 9.84; participants = 596; studies = 2;  $I^2 = 87\%$ ; *low-quality evidence*).

When partial salpingectomy was compared with clips, there were no major morbidity events in either group (participants = 2198, studies = 1). The frequency of minor morbidity was low and not significantly different between groups (Peto OR 7.39, 95% CI 0.46 to 119.01; participants = 193; studies = 1, *low-quality evidence*). Although technical failure occurred more frequently with clips (Peto OR 0.18, 95% CI 0.08 to 0.40; participants = 2198; studies = 1; *moderate-quality evidence*); operative time was shorter with clips than partial salpingectomy (MD 4.26 minutes, 95% CI 3.65 to 4.86; participants = 2223; studies = 2;  $I^2 = 0\%$ ; *high-quality evidence*).

We found little evidence concerning women's or surgeon's satisfaction. No RCTs compared tubal microinserts (hysteroscopic sterilisation) or chemical inserts (quinacrine) to other methods.

### Authors' conclusions

Tubal sterilisation by partial salpingectomy, electrocoagulation, or using clips or rings, is a safe and effective method of contraception. Failure rates at 12 months post-sterilisation and major morbidity are rare outcomes with any of these techniques. Minor complications and technical failures may be more common with rings than clips. Electrocoagulation may be associated with less postoperative pain than the modified Pomeroy or tubal ring methods. Further research should include RCTs (for effectiveness) and controlled observational studies (for adverse effects) on sterilisation by minimally-invasive methods, i.e. tubal inserts and quinacrine.

## PLAIN LANGUAGE SUMMARY

### A review of techniques for tubal sterilisation (blocking the fallopian tubes)

#### Background

This is an update of a Cochrane Review that was first published in 2002 and previously updated in 2011.

Tubal sterilisation prevents pregnancy by stopping the woman's unfertilised eggs from passing through the fallopian tubes to be fertilised by sperm. Techniques to close the tubes include cutting and tying them (partial salpingectomy), blocking them mechanically by using clips or rings, or by applying electric current (electrocoagulation) to damage and block them, and blocking them by using chemicals or tubal inserts (inserted via the mouth of the womb) that cause tubal scarring.

#### Methods

We, the Cochrane researchers, wanted to compare the different techniques for tubal sterilisation in terms of:

- how unwell they made women feel in the short and long term, including pain experienced (major and minor morbidity);
- failure rates (pregnancies);
- technical failures and difficulties encountered during the sterilisation procedure; and
- women's and surgeons' satisfaction.

We searched the medical literature up to 23 July 2015 for randomised controlled trials (RCTs) that compared any methods of closing the fallopian tubes; RCTs produce the most reliable results.

#### Findings

We included 19 RCTs involving 13,209 women of childbearing age. The trials compared:

- tubal rings versus clips (six RCTs, 4232 women);
- partial salpingectomy versus electrocoagulation (three RCTs, 2019 women);

- tubal rings versus electrocoagulation (two RCTs, 599 women);
- partial salpingectomy versus clips (four RCTs, 3827 women);
- clips versus electrocoagulation (two RCTs, 206 women); and
- two types of clips, i.e. Hulka clips versus Filshie clips (two RCTs, 2326 women).

We found no RCTs that investigated sterilisation by chemicals or tubal inserts, so all the included studies involved an abdominal operation.

There were no deaths reported with any method, and major and minor morbidity were rare. Pregnancy rates were less than 5/1000 procedures one year after surgery. Complication rates (problems after surgery/minor morbidity) were very low for all methods compared. Minor complications, including pain, and technical failures were more common with rings than clips. Major morbidity and postoperative pain were more common with partial salpingectomy than with electrocoagulation. Postoperative pain was reported twice as often by women sterilised by tubal rings than those sterilised by electrocoagulation. Technical failures were more common with clips than cutting and tying techniques, but operating time was shorter for clips.

We found little evidence concerning women's or surgeon's satisfaction.

### **Conclusions**

Tubal sterilisation by cutting and tying the tubes, or using electric current, clips or rings, is an effective method of contraception with few problems. The choice of method will depend upon the surgeon's experience, availability of equipment, setting, and cost. More research is needed about methods for tubal sterilisation that do not require an abdominal operation.

## SUMMARY OF FINDINGS

### Summary of findings for the main comparison. Summary of findings: ring versus clip

#### Tubal ring compared with tubal clip for interval sterilisation

**Patient or population:** women > 6 weeks postpartum requesting tubal sterilisation

**Settings:** any

**Intervention:** tubal ring

**Comparison:** tubal clip

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Clip	Ring				
<b>Major morbidity: total</b>	<b>Low risk population</b>		<b>OR 0.14</b> (0.00 to 7.05)	545 (1)	⊕⊕⊕⊕ <b>low</b> <sup>1,2</sup>	Only one event occurred in the clip group
	4 per 1000	1 per 1000 (0 to 28)				
<b>Minor morbidity: total</b>	<b>Low risk population</b>		<b>OR 2.15</b> (1.22 to 3.78)	842 (2)	⊕⊕⊕⊕ <b>high</b>	
	57 per 1000	123 per 1000 (70 to 215)				
<b>Minor morbidity: details - procedure-related injuries</b>	<b>Low risk population</b>		<b>OR 1.95</b> (1.36 to 2.78)	3575 (3)	⊕⊕⊕⊕ <b>high</b>	
	21 per 1000	41 per 1000 (29 to 58)				
<b>Technical failures</b>	<b>Low risk population</b>		<b>OR 3.93</b> (2.43 to 6.35)	3476 (3)	⊕⊕⊕⊕ <b>high</b>	
	10 per 1000	39 per 1000 (24 to 63)				
<b>Failure rate: details</b> (12 to 24 months)	<b>Low risk population</b>		<b>OR 0.72</b> (0.33 to 1.57)	3822 (4)	⊕⊕⊕⊕ <b>high</b>	
	4 per 1000	3 per 1000				

		(1 to 6)			
<b>Complaints: Postoperative pain</b> (24 hours)	<b>Low risk population</b>		<b>OR 1.14</b>	922	⊕⊕⊕⊕ <b>high</b>
	<b>477 per 1000</b>	<b>544 per 1000</b> (420 to 706)	(0.88 to 1.48)	(3)	

\*The basis for the **assumed risk** is the median control group (clip) risk across studies. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

<sup>1</sup> Downgraded due to imprecision.

<sup>2</sup> Downgraded due to sparse data.

## Summary of findings 2. Summary of findings: modified Pomeroy partial salpingectomy versus electrocoagulation

### Modified Pomeroy partial salpingectomy compared with tubal electrocoagulation for interval sterilisation

**Patient or population:** women > 6 weeks postpartum requesting tubal sterilisation

**Settings:** any

**Intervention:** modified Pomeroy partial salpingectomy

**Comparison:** electrocoagulation

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Electrocoagulation	Modified Pomeroy				
<b>Major morbidity: total</b>	<b>Low risk population</b>		<b>OR 2.87</b>	1905	⊕⊕○○ <b>low<sup>1,2</sup></b>	
	<b>10 per 1000</b>	<b>29 per 1000</b> (11 to 73)	(1.13 to 7.25)	(2)		



<b>Major morbidity: procedure-related injuries requiring additional operation or blood transfusion</b>	<b>10 per 1000</b>	<b>19 per 1000</b> (19 to 190)	<b>OR 1.90</b> (0.19 to 18.96)	1905 (2)	⊕⊕⊕○ <b>low 1,2</b>	
<b>Major morbidity: rehospitalisation as a consequence of the operation</b>	<b>20 per 1000</b>	<b>115 per 1000</b> (15 to 900)	<b>OR 5.74</b> (0.73 to 45.09)	295 (1)	⊕○○○ <b>very low 1,2</b>	
<b>Minor morbidity: total</b>	<b>Low risk population</b>		<b>OR 1.60</b> (1.10 to 2.33)	1905 (2)	⊕⊕⊕○ <b>low 1,4</b>	The WHO study reported significantly more wound infections in the modified Pomeroy group, where participants underwent minilaparotomy, compared with the electrocoagulation group where laparoscopy was used)
	<b>38 per 1000</b>	<b>61 per 1000</b> (42 to 89)				
<b>Minor morbidity: procedure-related injuries with no additional operation</b>	<b>Low risk population</b>		<b>OR 0.53</b> (0.06 to 5.11)	1610 (1)	⊕⊕⊕○ <b>moderate 1</b>	
	<b>2 per 1000</b>	<b>1 per 1000</b> (0 to 10)				
<b>Failure rate: total</b> (12 months)	<b>Low risk population</b>		<b>OR 4.47</b> (0.07 to 286.78)	295 (1)	⊕⊕⊕○ <b>low 1,3</b>	
	<b>0.5 per 1000</b>	<b>2 per 1000</b> (0 to 143)				
<b>Complaints - postoperative pain</b> (24 hours)	<b>Low risk population</b>		<b>OR 3.85</b> (2.91 to 5.10)	1905 (2)	⊕⊕⊕○ <b>moderate 4</b>	
	<b>95 per 1000</b>	<b>366 per 1000</b> (276 to 485)				
<b>Complaints - persistent pain at follow-up visit</b>	<b>Low risk population</b>		<b>OR 1.09</b> (0.88 to 1.47)	1610 (1)	⊕⊕⊕○ <b>moderate 4</b>	
	<b>117 per 1000</b>	<b>128 per 1000</b> (95 to 172)				

\*The basis for the **assumed risk** is the median control group (electrocoagulation) risk across studies. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence

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**Very low quality:** We are very uncertain about the estimate.

1 Downgraded due to imprecision.

2 Downgraded due to inconsistency.

3 Sparse data.

4 Downgraded due to indirectness (this effect may be due to the abdominal approach (minilaparotomy versus laparoscopy) rather than the tubal technique).

### Summary of findings 3. Summary of findings: tubal ring versus electrocoagulation

#### Tubal ring compared with electrocoagulation for interval sterilisation

**Patient or population:** women > 6 weeks postpartum requesting tubal sterilisation

**Settings:** any

**Intervention:** tubal ring

**Comparison:** electrocoagulation

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Electrocoagulation	Ring				
<b>Major morbidity: total</b>	<b>Low risk population</b>		<b>OR 0.14</b>	596 (2)	⊕⊕⊕⊖ <b>low</b> <sup>1,2</sup>	Unipolar electrocoagulation stated in one study and not specified in the other. Only one event reported in total
	0.5 per 1000	0 per 1000 (0 to 4)	0.00 to 7.01			
<b>Minor morbidity: total</b>	<b>Low risk population</b>		<b>OR 0.97</b>	596 (2)	⊕⊕⊕⊖ <b>moderate</b> <sup>1</sup>	
	66 per 1000	64 per 1000 (33 to 123)	(0.50, 1.87)			
<b>Technical failures: total</b>	<b>Low risk population</b>		<b>OR 3.42</b>	596 (2)	⊕⊕⊕⊖ <b>moderate</b> <sup>1</sup>	
			(0.59 to 19.81)			



	3 per 1000	10 per 1000 (2 to 60)				
<b>Failure rate: total</b>	not estimable	not estimable	Not estimable due to insufficient data	160 (1)	-	No pregnancies reported in one study
<b>Complaints - postoperative pain</b> (24 hours)	<b>Low risk population</b>		<b>OR 3.40</b>	596 (2)	⊕⊕⊕○	<b>low<sup>1,3</sup></b>
	<b>176 per 1000</b>	<b>598 per 1000</b> (206 to 1000)	(1.17 to 9.84)			
<b>Complaints - persistent pain at follow-up visit</b>	<b>Low risk population</b>		<b>OR 1.22</b>	594 (2)	⊕⊕⊕○	<b>moderate<sup>1</sup></b>
	<b>140 per 1000</b>	<b>171 per 1000</b> (105 to 276)	(0.75 to 1.97)			

\*The basis for the **assumed risk** is the median control group (electrocoagulation) risk across studies. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence

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**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

<sup>1</sup> Downgraded due to imprecision.

<sup>2</sup> Downgraded due to sparse data.

<sup>3</sup> Downgraded due to inconsistency.

#### Summary of findings 4. Summary of findings: partial salpingectomy versus clip

##### Partial salpingectomy compared with tubal clips for tubal sterilisation

**Patient or population:** women requesting postpartum or interval sterilisation

**Settings:** any

**Intervention:** partial salpingectomy

**Comparison:** tubal clips

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Clips	Partial salpingectomy				
<b>Major morbidity: total</b>	Low risk population		not estimable	2198 (1)	-	No deaths or major morbidity events reported in one large trial
	0 per 1000	0 per 1000				
<b>Minor morbidity: total</b>	Low risk population		<b>OR 7.39</b> (0.46 to 119.01)	193 (1)	⊕⊕⊕⊕ <b>low</b> <sup>1,2</sup>	
	0.5 per 1000	4 per 1000 (0 to 60)				
<b>Technical failures</b>	Low risk population		OR 0.18 (0.08 to 0.40)	2198 (1)	⊕⊕⊕⊕ <b>moderate</b> <sup>3</sup>	
	20 per 1000	4 per 1000 (2 to 8)				
<b>Failure rate: total</b> (12 months)	Low risk population		<b>OR 0.36</b> (0.08 to 1.59)	3685 (3)	⊕⊕⊕⊕ <b>high</b>	In this analysis, we grouped studies according to whether sterilisation was performed on a postpartum (2) or interval basis (1). Results were similar across these subgroups (Test for subgroup differences: P value 0.58, I <sup>2</sup> = 0%)
	2 per 1000	1 per 1000 (0 to 3)				
<b>Complaints</b> (12 months)	Low risk population		<b>OR 1.30</b> (0.92 to 1.82)	2137 (1)	⊕⊕⊕⊕ <b>moderate</b> <sup>1</sup>	This single study reported data on 'chief complaints' at 3, 6, and 12 months and rates were similar between groups at all assessment points
	59 per 1000	77 per 1000 (54 to 107)				

\*The basis for the **assumed risk** is the median control group (clips) risk across studies. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

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**Very low quality:** We are very uncertain about the estimate.

<sup>1</sup> Downgraded due to imprecision.

<sup>2</sup> Downgraded due to sparse data.

<sup>3</sup> Downgraded due to indirectness (unclear whether silver clips and Filshie clips are similarly effective).

<sup>4</sup> Downgraded due to risk of bias.

### Summary of findings 5. Summary of findings: Hulka clip versus Filshie clip

#### Hulka clips compared with Filshie clips for interval sterilisation

**Patient or population:** women requesting sterilisation

**Settings:** any

**Intervention:** Hulka clips

**Comparison:** Filshie clips

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Filshie clip	Hulka clip				
<b>Minor morbidity: total</b>	Low risk population		<b>OR 0.14</b> (0.00 to 7.32)	197 (1)	⊕⊕⊕⊕ <b>low</b> <sup>1,2</sup>	
	10 per 1000	1 per 1000 (0 to 70)				
<b>Minor morbidity: procedure-related injuries</b>	Low risk population		<b>OR 1.55</b> (0.73 to 3.26)	2322 (2)	⊕⊕⊕⊕ <b>moderate</b> <sup>1</sup>	
	10 per 1000	16 per 1000 (7 to 33)				
<b>Technical failures</b>	Low risk population		<b>OR 1.04</b> (0.10 to 11.33)	2325 (2)	⊕⊕⊕⊕ <b>low</b> <sup>1,3</sup>	
	7 per 1000	7 per 1000 (1 to 79)				
<b>Failure rate: total</b> (12 months)	Low risk population		<b>OR 6.20</b> (0.75 to 51.66)	1441 (1)	⊕⊕⊕⊕ <b>moderate</b> <sup>1</sup>	
	1 per 1000	6 per 1000 (1 to 52)				
<b>Complaints: postoperative pain</b>	Low risk population		<b>OR 1.74</b>	197 (1)	⊕⊕⊕⊕ <b>low</b> <sup>1,4</sup>	

(24 hours)	<b>45 per 1000</b>	<b>78 per 1000</b> (45 to 136)	(0.99 to 3.03)
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\*The basis for the **assumed risk** is the median control group (Filshie clips) risk across studies. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

- 1 Downgraded due to imprecision.
- 2 Downgraded due to sparse data.
- 3 Downgraded due to inconsistency.
- 4 Downgraded due to risk of bias.

## BACKGROUND

This is an updated version of this review. The original version of the review was published in 2002 and the last update was published in *The Cochrane Database of Systematic Reviews, Issue 2, 2011*.

Female sterilisation, also called tubal ligation or tubal occlusion, is the most widely used contraceptive method in the world. Globally, in 2011, sterilisation accounted for approximately 19% of all contraceptive methods used by women between the ages of 15 and 49 years who were married or in a union, with the highest prevalences occurring in developing region (21%), and the lowest prevalences occurring in the least developed countries (3%) (UN 2013). Female sterilisation is most prevalent in Latin America and the Caribbean (26%) (UN 2013). Figures published by the United Nations Population Division estimate prevalence rates for various other countries as follows: India 35.8%, China 28.7%, North America 22%, South Africa 14.3%, Germany 8.3%, United Kingdom 8%, France 3.8%, and Nigeria 0.3% (UN 2013). The increased efficacy and acceptability of long-acting reversible contraceptive methods (LARCs) has contributed in a trend towards declining sterilisation rates in some regions, e.g. the United Kingdom, in favour of LARCs.

### Description of the intervention

Female sterilisation prevents pregnancy by occluding or disrupting tubal patency so that the ovum cannot reach the uterus. In the 1930s, Pomeroy made tubal sterilisation well known, however it was considered a major procedure (Bhiwandiwalla 1980). From 1950 to 1982 voluntary sterilisation increased thirty-fold worldwide, the increase partly being attributed to surgical innovations that made sterilisation a safe and effective outpatient procedure (Bhiwandiwalla 1980).

Sterilisation failures (pregnancies) in the first year post-sterilisation of five per 1000 procedures are comparable with pregnancy rates for women using LARCs; however, tubal sterilisation appears to be a more effective contraceptive method over time (Peterson 2008). This is probably due to high continuation rates compared with LARCs. Sterilisation failures may result from conception occurring before the procedure (so-called luteal phase pregnancy), incomplete tubal occlusion, or the formation of fistulas, and may occur several years after the procedure (Gupta 1980; Peterson 1996; Peterson 2008).

Tubal sterilisation is traditionally achieved by an abdominal operation (either via laparotomy or laparoscopy). Tubal sterilisation techniques employed via the abdominal route include surgically cutting and tying the fallopian tubes (with or without a section of tube being removed), mechanically blocking the tubes using clips or rings, and electrically coagulating the tubes. Tubal sterilisation can also be achieved via the vaginal route by means of chemicals or mechanical tubal inserts that block the tubes by inducing a fibrotic reaction. Interventions such as hysterectomy or ovariectomy also lead to female sterility, but are not considered in this review as these operations are usually performed primarily for other medical reasons.

### Surgical methods

There are a number of surgical techniques employed for interrupting tubal patency. Possibly the most common method of surgical sterilisation is a partial salpingectomy using the Pomeroy or 'modified' Pomeroy technique in which a chromic

tie is placed around a loop of fallopian tube, and a 1 cm to 2 cm portion is then excised. The Parkland method involves separating a mid-portion of the tube from mesosalpinx and twice ligating the tube; the intervening segment between the ties is then resected, achieving immediate separation of the tubal ends. Alternatively, the Irving method double ties and divides the tube, then buries the proximal stump of the tube into the myometrium through an incision in the posterior uterine wall near the utero-tubal junction. The Uchida method involves infiltration of the serosa of the tube with a vasoconstricting solution with subsequent dissection of the subserosa and resection of a 2 cm portion of the muscular part of the tube; the proximal stump retracts into the mesosalpinx, which is closed, and the distal stump is exteriorised to the peritoneal cavity (Peterson 2008). Other methods and modifications include fimbriectomies and salpingectomies, e.g. Kroener, Madlener and Aldrich techniques. In a large, prospective cohort study (CREST) conducted in the United States between 1978 and 1992, interval (not within 42 days of pregnancy) and postpartum partial salpingectomy were associated with cumulative 10-year probabilities of pregnancy of 20.1 per 1000 and 7.5 per 1000 procedures, respectively (Peterson 1996).

### Mechanical methods

Bands or rings made of silicone and rubber (e.g. Yoon, Falope) are placed around a loop of fallopian tube, using a cone-shaped applicator. When the ring is released onto the loop of tube, it contracts and constricts the base of the loop, thereby blocking the tube. The 2 cm to 3 cm loop undergoes necrosis and the healthy ends of the tube separate. Hinged clips (e.g. Filshie, Hulka) can also be used to block the fallopian tubes mechanically. Filshie clips are made of titanium and silicone rubber, while Hulka clips are made of plastic with a gold spring lock. Only a small portion of the tube is damaged when these devices are used (Chi 1994; Kaplan 1990; Lipscomb 1992), therefore their use might increase the chance of reversibility among women who experience regret (Hillis 1999). In the CREST study, tubal rings and clips were associated with cumulative 10-year probabilities of pregnancy of 17.7 per 1000 and 36.5 per 1000 procedures, respectively (Peterson 1996).

### Electrical methods

The standard laparoscopic technique for tubal occlusion by electrocoagulation originally used unipolar forceps, however, since the risk of burns to the bowel and other organs is decreased with the use of bipolar forceps, the latter are preferred (Kessel 1976). With bipolar coagulation, the tube is grasped with the forceps, and electrical current passes between the two ends of the forceps, damaging the tube. To achieve successful occlusion it is recommended that at least 3 cm of the isthmic portion of the tube is coagulated (Peterson 2008). Unipolar coagulation damages a wider segment of tube, which is often cut after coagulation. In the CREST study, unipolar and bipolar electrocoagulation were associated with cumulative 10-year probabilities of pregnancy of 7.5 per 1000 and 24.7 per 1000 procedures, respectively (Peterson 1996).

### Chemical methods

Licensed as an antimalarial and in use for more than 70 years, quinacrine's use in sterilisation in low- and middle-income countries has been fraught with ethical issues (Bhattacharyya 2003). However, a report on 40,252 cases of quinacrine sterilisation (QS) from Chile, Indonesia, Pakistan, India, Egypt, Libya, Syria, China, Costa Rica and the USA concluded that this is a safe

and effective method (IJOG 2003). The method, involving the interuterine device-like insertion of quinacrine pellets transcervically into the uterus, leads to chemical irritation and scarring of the fallopian tubes (Suhadi 1998). QS does not immediately result in sterilisation, which can take up to 12 weeks, and failure rates appear to vary depending on dosage and the number of insertions (Agoestina 2003). Two insertions one month apart seems to be the most common and effective method of QS, and results in reported gross pregnancy rates of 1.2% to 4.3% in 10 years (Lu 2003; Suhadi 2003).

### Tubal inserts

Essure<sup>®</sup> inserts are 4 cm devices consisting of a stainless steel inner coil coated with PET (polyethylene terephthalate), and a nickel titanium outer coil. According to the manufacturer, approximately 750,000 women have undergone Essure<sup>®</sup> sterilisation to date (Bayer 2015). To achieve sterilisation, these inserts are introduced bilaterally into the proximal fallopian tubes via hysteroscopy and expand on insertion. The PET fibres induce a tissue response that causes fibrosis of the tubes (Valle 2001). Bilateral occlusion must be verified, usually by hysterosalpingogram (HSG), three months postinsertion (Veersema 2015). Although other inserts have been developed (Adiana, Ovabloc), Essure<sup>®</sup> is currently the only tubal insert on the market. Successful bilateral placement varies from between 80% to 99% of first attempts (Arjona 2008; Connor 2009; Cooper 2003; Duffy 2005; Panel 2010; Savage 2009; Shavell 2009), and placement failure has been attributed mainly to related to poor visualisation of the tubal ostia or tubal spasm/stenosis on hysteroscopy, and operator experience (Mino 2007). Sterilisation failures may be mainly attributed to misinterpretation of the HSG and non-adherence to the follow-up protocol (Veersema 2015), although evidence from controlled studies is lacking.

### Why it is important to do this review

Contraception plays a vital role in reducing maternal morbidity and mortality, and the acceptability and satisfaction of women with contraceptive methods is increased when users are well-informed (Blumenthal 2011). This review considers the different techniques for tubal interruption, regardless of the method used to access the fallopian tubes, and evaluates them for their safety and effectiveness. Previous versions of this review identified no eligible studies of chemical or hysteroscopic methods that could be included in the review. Given the evolving nature of sterilisation methods, and contraception in general, it is important that we keep this review updated.

### OBJECTIVES

To compare the different tubal occlusion techniques in terms of major and minor morbidity, failure rates (pregnancies), technical failures and difficulties, and women's and surgeons' satisfaction.

### METHODS

#### Criteria for considering studies for this review

##### Types of studies

Randomised controlled trials (RCTs) comparing different occlusion techniques for tubal sterilisation. Quasi-RCTs are excluded.

##### Types of participants

Women requesting tubal sterilisation.

##### Types of interventions

Interventions include interrupting tubal patency by partial salpingectomy, clips, silicone rings, electrocoagulation, chemicals and tubal inserts.

Interventions may be performed as:

- postpartum sterilisation: sterilisation performed during caesarean section or within 42 days of delivery (it is usually performed during the first 48 to 72 hours postpartum);
- postabortion sterilisation: sterilisation performed immediately after termination of pregnancy; or
- interval sterilisation: sterilisation performed at least six weeks after delivery.

##### Types of outcome measures

###### Primary outcomes

- Failure rate (yearly incidence of unintended pregnancy) including extrauterine pregnancy.
- Operative mortality, major and minor morbidity (procedure-related intestinal, vascular or bladder injuries, injury to other pelvic organ, blood transfusion, re-admission).
- Failure of technical approach (e.g. clip converted to partial salpingectomy).

Other outcomes included:

- operative time;
- changes in menstrual bleeding pattern;
- postoperative pain: pain scores or use of analgesics;
- postoperative complications: wound infection, reoperation, urinary tract infection, pelvic inflammatory disease;
- length of hospital stay;
- difficulty of procedure;
- persistent pain;
- women's satisfaction;
- surgeons' satisfaction.

###### Definitions

Postoperative pain: defined whenever possible as localised physical suffering related to the tubal occlusion technique.

Postoperative complication: any disease or condition developed as a direct consequence of the procedure.

Changes in menstrual pattern: any changes in frequency or quantity of menstrual bleeding.

Major morbidity: any morbidity occurring as a result of the intervention that lead to an additional intervention (e.g. additional surgical procedure, blood transfusion) or to re-admission.

Minor morbidity: any morbidity occurring as a result of the intervention and which does not lead to major additional interventions.

Technical failure or failure of technical approach: failure to apply the intended method with the consequent need to switch to another technique.



Technical difficulties: any difficulty in applying the selected method and which does not lead to change to another procedure.

### Search methods for identification of studies

For the original review, the Cochrane Central Register of Controlled Trials (CENTRAL) and MEDLINE were searched; the electronic search strategy included the following terms: (tubal OR female OR contracep\*) AND (sterilis\* OR steriliz\* OR laparo\* OR culdoscopy OR colpotomy OR Filshie OR Hulka OR Yoon OR Pomeroy OR Irving OR Parkland OR (Rocket and Clips) OR (tubal and ring) OR (silastic and ring) OR (Quinacrine AND tubal) OR (chemical AND instillation AND tubal)).

For the 2010 and 2015 updates, PubMed, POPLINE and LILACS were also searched and the following search strategy was used:

PubMed: sterilisation, tubal AND (technique\* OR method OR methods OR methodology OR procedure\*) AND clinical trial.

POPLINE: (female sterilisation/female sterilisation/((tubal & (ligat\*/occlud\*/occlus\*)) & female)) & clinical trial.

LILACS: sterilisation, tubal or esterilizacion tubaria or esterilizacao tubaria [Words] AND method OR metodo OR methods OR metodos OR technique OR techniques OR tecnica OR technicas OR procedure OR procedures OR procedimiento.

Searches were conducted by Carol Manion of FHI 360 (formerly Family Health International). In addition, we searched reference lists of identified trials and used the 'related articles' feature of PubMed to search for other possible trials.

### Data collection and analysis

#### Selection of studies

For the original 2002 review, two reviewers (RK, JMN) selected the trials for inclusion (Nardin 2002; Nardin 2003). For the update, TL and RK sifted the searches and selected trials.

#### Data extraction and management

For this update, we designed a Microsoft Excel® spreadsheet based on a Microsoft Word® form that was previously designed and used for this review. Data extraction for the original review was performed by RK and JMN. For the updates, this was performed by TL and checked by RK. TL entered data into Review Manager software and RK checked them (RevMan 2014).

In addition to outcome data, we also extracted information about the following:

- setting (country, level of the healthcare institution, year);
- details of surgery: type of surgical procedure, type of anaesthesia, timing of procedure (postpartum, interval, postabortion);
- interventions compared;
- types and numbers of participants;
- risk of bias criteria including, method of randomisation, concealment of allocation, loss to follow-up and postrandomisation exclusions.

Whenever possible, we extracted outcome data according to 'intention to treat'.

### Assessment of risk of bias in included studies

The 2002 and 2010 versions of this review utilised older Cochrane methodology for assessing risk of bias that involved an A, B, C system of assessing bias and excluded studies with poor allocation concealment (Appendix 1). For this updated review we reviewed previous exclusions and, where possible, updated the 'Risk of bias' assessment of previously included studies. For this version of the review (and future versions), risk of bias has been assessed according to the following criteria:

#### 1. Random sequence generation (checking for possible selection bias)

For each study we assessed the method used to generate the allocation sequence as:

- low risk of bias (any truly random process, e.g. random-number table; computer random-number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); though quasi-randomised studies are not eligible for inclusion in the review;
- unclear risk of bias (if the process of sequence generation was not described).

#### 2. Allocation concealment (checking for possible selection bias)

For each included study, we assessed the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias (if the process of was not described).

#### 3. Blinding of participants, personnel and outcome assessors (checking for possible performance and detection bias)

For each included study, we assessed the methods used, if any, to blind study participants, personnel and outcome assessors from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded.

We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel;
- low, high or unclear risk of bias for outcome assessors.

#### 4. Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We assessed the completeness of data including attrition and exclusions from the analyses. We recorded whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomized participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias (e.g. withdrawals not stated, denominators not given).

### 5. Selective reporting (checking for reporting bias)

We assessed the possibility of selective outcome reporting bias as:

- low risk of bias (where it was clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so could not be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

### 6. Other bias (checking for bias due to problems not covered by 1 to 5 above)

We assessed whether there were other possible sources of bias, for example, imbalances in important baseline characteristics, and judged these to be at low, high or unclear risk.

### 7. Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). With reference to points 1 to 6 above, we attempted to assess the likely magnitude and direction of the bias and whether we considered it likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - see [Sensitivity analysis](#).

### Measures of treatment effect

#### Dichotomous data

For dichotomous data, we used summary odds ratios (OR) with 95% confidence intervals (CI).

#### Continuous data

We used the mean difference (MD) with 95% CIs if outcomes were measured in the same way between trials, which was the case for this version of the review. Had they not been measured in the same way, we would have used the standardised mean difference (SMD), provided pooling these data was considered meaningful.

#### Unit of analysis issues

We did not anticipate unit of analysis issues.

#### Dealing with missing data

For included studies, we noted levels of attrition. We did not impute data. For all outcomes, as far as possible, we performed analyses on an intention-to-treat basis, that is, we attempted to

include all participants randomized to each group in the analyses. The denominator for each outcome in each trial was the number randomized minus any participants whose outcomes were known to be missing.

### Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the  $Tau^2$ ,  $I^2$  and  $Chi^2$  statistics. We regarded heterogeneity as substantial if  $I^2$  was greater than 30% and, either  $Tau^2$  was greater than zero, or there was a low P value (less than 0.10) in the  $Chi^2$  test for heterogeneity.

### Assessment of reporting biases

There were insufficient studies to assess publication bias using funnel plots; however, in future versions, this may be possible if there are 10 or more studies in a meta-analysis.

### Data synthesis

We carried out statistical analysis using Review Manager software (RevMan 2014). We used fixed-effect methods to produce an overall summary of effect if heterogeneity was low ( $I^2 < 30\%$ ), otherwise we used random-effects methods. The random-effects summary was treated as the average of the range of possible treatment effects.

### Quality of evidence

The quality of the evidence was assessed using the GRADE approach for the following key outcomes (GRADE 2014):

- failure rate (yearly incidence of unintended pregnancy);
- major morbidity;
- minor morbidity;
- failure of technical approach;
- postoperative pain.

We considered evidence from RCTs to be high quality in the first instance, and downgraded the evidence quality for imprecision, inconsistency, indirectness, risk of bias, and publication bias when present. We also downgraded for sparse data when few events occurred (equivalent to downgrading twice for imprecision).

### Sensitivity analysis

If there were sufficient trials, we carried out sensitivity analyses to explore the effect of trial quality by excluding studies at high risk of bias from the analyses in order to assess whether this made any difference to the overall results.

## RESULTS

### Description of studies

#### Results of the search

We included nine RCTs in the original 2002 review, and 12 trials in the 2011 version. For this latest review, we ran the searches on 23 July 2015, which produced a list of 62 references. After screening these references for title and abstract, we identified three eligible studies; two of which we included (Qui 2011; Rodriguez 2013), and one that we excluded (Chapa 2015). We also identified two additional studies that we included using the 'related articles' feature of PubMed (Dominik 2000; Siegle 2005).

We reviewed all previously excluded RCTs according to our updated methodology, and included three that had previously been excluded due to risk of bias concerns, bringing the total number of included RCTs in the review to 19.

### Included studies

Trials evaluated the following comparisons.

- Sterilisation (interval) using tubal ring compared with tubal clip: six trials, including a total of 4232 women (Aranda 1985; Argueta 1980; Geirsson 1985; Pymar 2004; Sokal 2000; Stovall 1991).
- Sterilisation (interval) with partial salpingectomy (modified Pomeroy technique) compared with electrocoagulation: three trials, including 2019 women (Siegle 2005; Sitompul 1984; WHO 1982).
- Sterilisation (interval) using tubal ring compared with electrocoagulation: two trials, including a total of 599 women (Aranda 1976; Koetsawang 1978).
- Postpartum sterilisation by partial salpingectomy (Pomeroy and Modified Pomeroy techniques) compared with Filshie clip: three trials, including 1629 women (Kohaut 2004; Rodriguez 2013; Yan 1990).
- Interval or postabortion sterilisation by partial salpingectomy (modified Uchida technique) compared with silver clip: one trial, including 2198 women (Qui 2011).
- Interval sterilisation by Hulka clip compared with Filshie clip: two trials, including 2326 women (Dominik 2000; Toplis 1988).
- Interval sterilisation by clip compared to electrocoagulation: two trials, including 206 women (Gentile 2006; Goynumer 2009).

Electrocoagulation was specified as unipolar in Koetsawang 1978, and bipolar in Gentile 2006, Goynumer 2009 and Siegle 2005, but type was not specified in three other trials that used electrocoagulation.

### Design and settings

Most of the studies were single-centre RCTs, with six exceptions: WHO 1982 involved eight centres, four in industrialised countries and four in non-industrialised countries; Aranda 1976 was conducted in three low- and middle-income country centres (Costa Rica, El Salvador, Egypt); Qui 2011 was conducted in 20 clinics in China; Rodriguez 2013 was conducted in centres in Thailand, Taiwan, Panama and the Phillipines; Sokal 2000 was conducted in centres in Panama, Peru, Kenya, Brazil, Mexico, Indonesia, Thailand and the Dominican Republic; and Dominik 2000 was conducted in centres in Malaysia, Panama, the Dominican Republic, Mexico, Venezuela, Guatemala, and Haiti.

### Surgical approach

Access to the abdomen was achieved by different approaches. Ten studies used laparoscopy (Aranda 1976; Argueta 1980; Geirsson 1985; Gentile 2006; Goynumer 2009; Koetsawang 1978; Pymar 2004; Siegle 2005; Stovall 1991; Toplis 1988); three used laparotomy (Aranda 1985; Qui 2011; Yan 1990); two used minilaparotomy (Kohaut 2004; Rodriguez 2013); three used minilaparotomy or laparoscopy (Dominik 2000; Sokal 2000; WHO 1982), and one study compared three different approaches to enter the abdominal cavity (Sitompul 1984).

Procedures were performed by experienced surgeons in five trials (Dominik 2000; Sitompul 1984; Sokal 2000; Toplis 1988; WHO 1982), and by trainee third year residents in two trials (Siegle 2005; Stovall 1991); in the remainder, the surgeon's experience was not explicitly stated.

The type of anaesthesia used varied among participating institutions according to institutional standards or at the surgeons' discretion for certain multicentre studies (Rodriguez 2013; Sokal 2000; WHO 1982). For other studies, procedures were performed under general anaesthesia (Geirsson 1985; Goynumer 2009; Siegle 2005), local anaesthesia (Aranda 1976; Argueta 1980; Koetsawang 1978; Qui 2011; Sitompul 1984) epidural anaesthesia (Yan 1990), general or local (Aranda 1985), general or spinal (Kohaut 2004), or was not clearly stated (Dominik 2000; Gentile 2006; Pymar 2004; Stovall 1991; Toplis 1988).

### Participants and outcomes

#### 1. Tubal ring versus clip trials

Aranda 1985 randomized 663 women to tubal ring or Rocket clip. Women had similar socio-demographic characteristics, and a similar percentage of interval and post-spontaneous abortion procedures (about 55% and 45% respectively) was performed in each group. Main outcomes were major and minor morbidity, technical failures and difficulties, failure rates and complaints.

Argueta 1980 randomized 299 women to interval sterilisation by tubal ring or spring-loaded clip. Selected socio-demographic characteristics of the subjects were similar in both groups. Main outcomes were operative morbidity, technical failures and difficulties, failure rates, and complaints. A total of 114 women were lost to follow-up at 24 months; 54 from the clip group (36% of group) and 60 from the ring group (40% of group).

Stovall 1991 randomized 365 women to interval sterilisation by tubal ring (189 women) or the spring-loaded clip (176 women). All women had urine tests for human chorionic gonadotropin (hCG) 72 hours before their planned surgical procedure. Both groups had similar socio-demographic characteristics. The primary outcome was failure rate. An average of 16 months (range, 6 to 24 months) of follow-up was reported. Chromopertubation was performed on all the women after application of the occluding devices and confirmed successful tubal occlusion in all women.

Geirsson 1985 randomized 79 women to interval sterilisation by tubal ring or Filshie clip. Mean age and parity were similar between the two groups. Primary outcomes were postoperative pain and analgesic requirements.

Pymar 2004 included 40 women who had a Filshie clip and a ring applied to opposite tubes. The side of application and type of device was randomized. Pain during the first 24 hours postoperatively was the primary outcome based on evidence that women can discriminate between pain on each side of the abdomen. The method of anaesthesia was not stated.

Sokal 2000 randomized 2746 women to a Filshie clip (1381 women) or tubal ring (1365 women). The report combined data from two studies, one utilising a minilaparotomy approach, the other utilising laparoscopy. Outcomes evaluated included pregnancy, adverse events, hospital admissions, and further surgery with follow-up conducted at one, six, and 12 months.

## 2. Partial salpingectomy versus electrocoagulation

[Sitompul 1984](#) randomized 300 women to interval sterilisation in three groups (100 each for minilaparotomy, laparoscopy and culdoscopy). The modified Pomeroy technique was performed for all women in the minilaparotomy and the culdoscopy group, while electrocoagulation was the sterilisation method used in the laparoscopy group. Outcomes included operative time, hospitalisation, postoperative complications, and failure rates.

[WHO 1982](#) randomized 1827 women to interval sterilisation by Pomeroy partial salpingectomy via minilaparotomy (912 women) or electrocoagulation via laparoscopy (915 women). Main outcomes were major and minor morbidity, technical failures, and postoperative complaints.

[Siegle 2005](#) randomized 109 women to interval partial salpingectomy (Pomeroy) or bipolar electrocoagulation. The primary outcome was postoperative pain up to two weeks after surgery. There was little usable data from this study.

## 3. Tubal ring versus electrocoagulation

In [Aranda 1976](#), 299 women who were at least six weeks postpartum were randomly assigned to electrocoagulation or tubal ring groups via laparoscopy (interval sterilisation). Women in the two groups were similar with respect to socio-demographic characteristics. Outcomes included surgical and early postoperative complications, and complaints.

[Koetsawang 1978](#) randomized 300 women in equal numbers to electrocoagulation (unipolar) or the tubal ring. All operations were performed on an outpatient basis for women who had not recently been pregnant (interval sterilisation). The two groups had similar socio-economic characteristics. All women completed the six month follow-up. Outcomes included operative morbidity, technical failures and difficulties, failure rates, operative time, and complaints.

## 4. Postpartum partial salpingectomy versus clip

[Yan 1990](#) randomized 200 women postpartum: 100 to Pomeroy partial salpingectomy and 100 to Filshie clip, and followed them up for 24 months after sterilisation. Socio-demographic characteristics (age, total live births and previous contraceptive use) were reported to be similar between groups.

[Rodriguez 2013](#) randomized 1400 postpartum women to partial salpingectomy or Filshie clip. All women had undergone a vaginal delivery. Follow-up was performed at one, six, 12, and 24 months following sterilisation.

[Kohaut 2004](#) randomized 32 women to postpartum or intraoperative (after caesarean section) sterilisation by the Filshie clip or the Pomeroy method. Main outcomes concerned the ease of procedure and the surgeons' satisfaction. There was little usable data from this study.

## 5. Interval partial salpingectomy versus clip

[Qui 2011](#) randomized 2198 women to partial salpingectomy (Uchida technique) or silver clips. The participants were mostly more than six weeks postpartum (interval sterilisation), with less than 2% being postabortion. Approximately 63% of sterilisations were performed in lactating women in whom menses had not resumed. Outcomes were pregnancy rates, morbidity, operative time, and women's satisfaction. Women were followed up at one week, and three, six, and 12 months following sterilisation.

## 6. Comparison of different clip methods for interval sterilisation

[Toplis 1988](#) randomized 200 women to Filshie clip or Hulka clip (spring-loaded clip). Main outcomes were operative morbidity, operative time, and complaints.

[Dominik 2000](#) reported the combined results of two multicentre RCTs comparing Filshie and Hulka clips, one using a minilaparotomy approach (878 women), the other using a laparoscopic approach (1248 women). Outcomes were failure rates, technical failure and difficulties, and morbidity.

## 7. Clips versus electrocoagulation

[Gentile 2006](#) randomized 118 women to Hulka clips or bipolar electrocautery for interval sterilisation and conducted a series of urine and serum oestradiol and progesterone tests for two years poststerilisation. Unpublished data on secondary outcomes, including women's satisfaction, were not available.

[Goynumer 2009](#) randomized 88 women to a mechanical clip or bipolar electrocoagulation for interval sterilisation. Outcomes were ovarian reserve indicators (hormones and ovarian volume). These two trials contributed no data that could be used in the review analyses.

## Risk of bias in included studies

The risk of bias of included studies is summarised in [Figure 1](#). Most studies were older studies with an unclear risk of bias as information about study methods was often missing from trial reports. Randomisation and allocation concealment was inadequately described in 50% of the studies. Blinding of the outcome assessor was described in nine studies ([Aranda 1976](#); [Aranda 1985](#); [Argueta 1980](#); [Gentile 2006](#); [Koetsawang 1978](#); [Pymar 2004](#); [Rodriguez 2013](#); [Sokal 2000](#); [Yan 1990](#)).

**Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Aranda 1976	?	?	+	?	?	+
Aranda 1985	+	?	+	-	?	?
Argueta 1980	?	?	+	?	?	+
Dominik 2000	+	+	+	-	?	+
Geirsson 1985	?	?	?	-	?	-
Gentile 2006	+	+	+	?	?	?
Goynumner 2009	+	?	?	?	?	?
Koetsawang 1978	?	?	+	?	?	+
Kohaut 2004	+	+	?	?	?	?
Pymar 2004	+	+	+	?	?	?
Qui 2011	?	?	?	?	?	?
Rodriguez 2013	+	+	+	-	-	?
Siegle 2005	+	+	?	?	?	?
Sitompul 1984	?	?	?	?	?	?
Sokal 2000	+	+	+	+	?	?
Stovall 1991	+	?	?	?	?	?
Toplis 1988	?	+	?	?	?	?
WHO 1982	+	+	?	?	?	-
Yan 1990	?	+	+	?	?	+

Attrition bias was serious in two studies: in [Geirsson 1985](#), nine women were excluded post-procedure "due to intra-operative difficulties" that were not described in detail, while in [Aranda 1985](#), 30 cases of technical failure (5% of total) were excluded from the analyses. It was not clear from which groups these women came, and we were unable to include these data on technical failures in the review. Postrandomisation exclusions due to protocol violations occurred with similar frequency in the [WHO 1982](#) trial (about 12% in the Pomeroy group and about 10% in the electrocoagulation group); however, there were also important differences in baseline characteristics and methods of accessing the tubes between arms of this trial, which may have had an impact on the results. We took the assessment of risk of bias into consideration when grading the quality of the evidence. For more details, see [Characteristics of included studies](#).

## Effects of interventions

See: [Summary of findings for the main comparison Summary of findings: ring versus clip](#); [Summary of findings 2 Summary of findings: modified Pomeroy partial salpingectomy versus electrocoagulation](#); [Summary of findings 3 Summary of findings: tubal ring versus electrocoagulation](#); [Summary of findings 4 Summary of findings: partial salpingectomy versus clip](#); [Summary of findings 5 Summary of findings: Hulka clip versus Filshie clip](#)

### 1. Tubal ring versus clip

Six trials evaluated this comparison for interval sterilisation. Only one trial reported major morbidity (one event in the clip arm; Peto OR 0.14, 95% CI 0.00 to 7.05; participants = 545; studies = 1; [Analysis 1.1](#)) and no deaths were reported in any of the trials. Overall minor morbidity was more frequent in the ring group (Peto OR 2.15, 95% CI 1.22 to 3.78; participants = 842; studies = 2;  $I^2 = 0\%$ ; [Analysis 1.2](#)) and there were significantly more procedure-related injuries in the ring group compared with the clip group (Peto OR 1.95, 95% CI 1.36 to 2.78; participants = 3575; studies = 3;  $I^2 = 0\%$ ; [Analysis 1.3.1](#)). Failure of technical approach occurred more often in the ring group (Peto OR 3.93, 95% CI 2.43 to 6.35; participants = 3476; studies = 3;  $I^2 = 0\%$ ; [Analysis 1.4](#)). Technical difficulties were not statistically significantly different between tubal ring and clip groups (Peto OR 1.13, 95% CI 0.87 to 1.46; participants = 3590; studies = 3;  $I^2 = 28\%$ ; [Analysis 1.5](#)).

There was no statistically significant difference in failure (pregnancy) rates between the tubal ring and clip groups (Peto OR 0.72, 95% CI 0.33 to 1.57; participants = 3822; studies = 4;  $I^2 = 0\%$ ; [Analysis 1.6](#)). Follow-up in these studies was between 12 and 24 months. There were no statistically significant differences in postoperative pain complaints (Peto OR 1.14, 95% CI 0.88 to 1.48; participants = 922; studies = 3;  $I^2 = 0\%$ ; [Analysis 1.10.1](#)) or analgesic use; however, one study reported more complaints of cramping pain during the first week after surgery with the tubal ring compared with the clip (Peto OR 5.24, 95% CI 1.52 to 18.00; participants = 70; studies = 1; [Analysis 1.10.3](#)). There was no difference in the frequency of menstrual irregularities between groups (Peto OR 1.61, 95% CI 0.75 to 3.49; participants = 612; studies = 2;  $I^2 = 0\%$ ; [Analysis 1.11](#)).

### 2. Modified Pomeroy partial salpingectomy versus electrocoagulation

Three trials evaluated this comparison for interval sterilisation. There were no cases of operative mortality in the one study that

reported this outcome ([WHO 1982](#)). Major morbidity was more frequent in the Pomeroy group than the electrocoagulation group (Peto OR 2.87, 95% CI 1.13 to 7.25; participants = 1905; studies = 2;  $I^2 = 0\%$ ; [Analysis 2.2](#)); with one case of a burn to the small bowel reported in the electrocoagulation group. Minor morbidity was also more frequent in the Pomeroy group (Peto OR 1.60, 95% CI 1.10 to 2.33; participants = 1905; studies = 2;  $I^2 = 0\%$ ; [Analysis 2.4](#)), mainly due to wound infections. There were no data on technical failures and difficulties. One pregnancy was reported (in the Pomeroy group) in the only trial that reported this outcome ([Sitompul 1984](#); Peto OR 4.47, 95% CI 0.07 to 286.78; participants = 295; studies = 1; [Analysis 2.6](#)). This intrauterine pregnancy occurred between one and two years of follow-up ([Analysis 2.7](#)). There was no difference in the proportion of women hospitalised for more than 24 hours (OR 0.48, 95% CI 0.08 to 2.74; participants = 108; studies = 1; [Analysis 2.8](#)). Significantly more women in the Pomeroy group reported postoperative abdominal pain (Peto OR 3.85, 95% CI 2.91 to 5.10; participants = 1905; studies = 2;  $I^2 = 0\%$ ; [Analysis 2.9](#)). Single studies found no statistically significant difference in rates of analgesic use (Peto OR 2.05, 95% CI 0.40 to 10.56; participants = 109; studies = 1; [Analysis 2.9.2](#)), or rates of persistent pain at follow-up visit between the groups (Peto OR 1.09, 95% CI 0.81 to 1.47; participants = 1610; studies = 1; [Analysis 2.9.3](#)).

### 3. Tubal ring versus electrocoagulation

Two trials evaluated this comparison for laparoscopic interval sterilisation ([Aranda 1976](#); [Koetsawang 1978](#)). Electrocoagulation was unipolar in [Koetsawang 1978](#) and not specified in [Aranda 1976](#). No deaths were reported. Major morbidity was not statistically significantly different between the groups with only [Aranda 1976](#) reporting an adverse event due to a burn of the small intestine in the electrocoagulation group (Peto OR 0.14, 95% CI 0.00 to 7.01; participants = 596; studies = 2;  $I^2 = 0\%$ ; [Analysis 3.1](#) and [Analysis 3.2](#)). There were no statistically significant differences in minor morbidity (Peto OR 0.97, 95% CI 0.50 to 1.87; participants = 596; studies = 2;  $I^2 = 0\%$ ; [Analysis 3.3](#)), technical failures (Peto OR 3.42, 95% CI 0.59 to 19.81; participants = 596; studies = 2;  $I^2 = 0\%$ ; [Analysis 3.5](#)) or technical difficulties (Peto OR 0.14, 95% CI 0.01 to 1.33; participants = 298; studies = 1; [Analysis 3.6](#)) between the groups. No pregnancies were reported. More women in the ring group reported postoperative abdominal pain (OR 3.40, 95% CI 1.17 to 9.84; participants = 596; studies = 2;  $I^2 = 87\%$ ; [Analysis 3.9](#)). There was no difference between groups in either operative time ([Analysis 1.8](#)) or menstrual irregularities ([Analysis 1.11](#)).

### 4. Partial salpingectomy versus clip

Four trials evaluated this comparison, three used the modified Pomeroy technique for partial salpingectomy ([Kohaut 2004](#); [Rodriguez 2013](#); [Yan 1990](#)) versus titanium (Filshie) clips, one using the modified Uchida technique for interval sterilisation versus silver clips ([Qui 2011](#)). Two studies contributed little data ([Kohaut 2004](#); [Rodriguez 2013](#)). There were no cases of operative mortality or major morbidity in the only study that reported these outcomes ([Qui 2011](#); [Analysis 4.1](#) and [Analysis 4.2](#)). Minor morbidity was not statistically significantly different between treatment groups (Peto OR 7.39, 95% CI 0.46 to 119.01; participants = 193; studies = 1; [Analysis 4.3](#)). Technical failures were significantly more common in the clip group (Peto OR 0.18, 95% CI 0.08 to 0.40; participants = 2198; studies = 1; [Analysis 4.5](#)), but not technical difficulties (Peto OR 0.97, 95% CI 0.42 to 2.24; participants = 2198; studies = 1; [Analysis 4.6](#)). There were no significant differences between groups with regard

to pregnancy rates at 12 months (OR 0.36, 95% CI 0.08 to 1.59; participants = 3685; studies = 3;  $I^2 = 17%$ ; [Analysis 4.7](#)).

Operative time was statistically significantly longer for partial salpingectomy procedures than for clips (MD 4.26, 95% CI 3.65 to 4.86; participants = 2223; studies = 2;  $I^2 = 0%$ ; [Analysis 4.8](#)). Neither patient complaints (Peto OR 1.30, 95% CI 0.92 to 1.82; participants = 2137; studies = 1; [Analysis 4.9](#)) nor menstrual irregularities were statistically significantly different between groups (OR 1.43, 95% CI 0.73 to 2.79; participants = 2283; studies = 2;  $I^2 = 49%$ ; [Analysis 4.10](#)). Patient complaints were reported by [Qui 2011](#) at three, six, and 12 months and rates were similar at all assessment points. Women's satisfaction, reported in this study favoured the partial salpingectomy group (Peto OR 1.27, 95% CI 0.99 to 1.64; participants = 2110; studies = 1; [Analysis 4.11](#)); authors of this Chinese trial linked this to historical preferences.

## 5. Filshie clip versus Hulka clip

Two trials evaluated this comparison ([Dominik 2000](#); [Toplis 1988](#)). There was no statistically significant difference in minor morbidity overall (Peto OR 0.14, 95% CI 0.00 to 7.32; participants = 197; studies = 1; [Analysis 5.1](#)), or in procedure-related injuries (OR 1.57, 95% CI 0.73 to 3.36; participants = 2322; studies = 2;  $I^2 = 0%$ ; [Analysis 5.2.1](#)), urogenital tract infections (OR 2.40, 95% CI 0.62 to 9.30; participants = 1910; studies = 1; [Analysis 5.2.2](#)), or minor wound complications (OR 0.86, 95% CI 0.63 to 1.17; participants = 1910; studies = 1; [Analysis 5.2.3](#)). There was no statistically significant difference in technical failures (OR 1.04, 95% CI 0.10 to 11.33; participants = 2325; studies = 2;  $I^2 = 55%$ ; [Analysis 5.3](#)); however, technical difficulties occurred more frequently with the Hulka clip (Peto OR 1.51, 95% CI 1.09 to 2.10; participants = 2323; studies = 2;  $I^2 = 0%$ ; [Analysis 5.4](#)). There was no statistically significant difference between groups in the failure rate at one year poststerilisation (OR 6.20, 95% CI 0.75 to 51.66; participants = 1441; studies = 1; [Analysis 5.5](#)). Cumulative two-year failures rates in the largest study, [Dominik 2000](#), were 11.7 and 28.1 pregnancies per 1000 procedures for Filshie and Hulka clips, respectively.

## DISCUSSION

### Summary of main results

Altogether we included 19 RCTs involving 13,209 women requesting sterilisation. Sterilisation was performed on an interval basis in most trials, apart from three RCTs of postpartum sterilisation involving 1632 women. RCTs compared tubal rings versus clips (six RCTs, 4232 women), partial salpingectomy versus electrocoagulation (three RCTs, 2019 women), tubal rings versus electrocoagulation (two RCTs, 599 women), partial salpingectomy versus clips (four RCTs, 3827 women), clips versus electrocoagulation (two RCTs, 206 women) and Hulka versus Filshie clips (2 RCTs, 2326 women). The RCTs of clips versus electrocoagulation contributed no data to analyses. Studies of postpartum sterilisation compared partial salpingectomy with clips. No RCTs compared tubal inserts (hysteroscopic sterilisation) to other methods.

The main findings are summarised in [Summary of findings for the main comparison](#), [Summary of findings 2](#); [Summary of findings 3](#); [Summary of findings 4](#); and [Summary of findings 5](#). One year after sterilisation, failure rates were comparable for tubal rings and clips (high-quality evidence), partial salpingectomy and

clips (high-quality evidence), and for partial salpingectomy and electrocoagulation (low-quality evidence). Estimates of failure rates for these methods were less than five pregnancies per 1000 procedures in the first year post-sterilisation, and longer-term pregnancy rates were generally not reported.

No deaths were reported as a results of the procedures in any of the studies. Major morbidity was rare with 22 events reported in three trials ([Aranda 1976](#); [Aranda 1985](#); [WHO 1982](#)), 17 events occurred with partial salpingectomy, four with electrocoagulation, and one with a clip procedure.

Minor morbidity occurred twice as often with tubal rings than with tubal clips (high-quality evidence) and technical failures were also significantly more common with rings than clips (high-quality evidence). There was no significant difference in postoperative pain between these groups (see [Summary of findings for the main comparison](#)).

Major and minor morbidity occurred more frequently with partial salpingectomy than with electrocoagulation for interval sterilisation (low- to moderate-quality evidence; [Summary of findings 2](#)). Postoperative pain (up to 24 hours) was also significantly more common in the partial salpingectomy group than with electrocoagulation (moderate-quality evidence).

There was no significant difference in major or minor morbidity when tubal rings were compared with electrocoagulation for interval sterilisation (low- to moderate-quality evidence; [Summary of findings 3](#)). Evidence relating to technical failures was of a low quality for this comparison. Significantly more women undergoing sterilisation by tubal ring complained of postoperative pain in the first 24 hours compared with those in the electrocoagulation group (low-quality evidence); however, this difference did not persist to the follow-up visit.

For partial salpingectomy versus tubal clips, one large study reported no major morbidity with either method ([Summary of findings 4](#)). We found limited data on minor morbidity (not significantly different between groups; low-quality evidence). Evidence suggested that technical failures were more frequent with clip sterilisation (moderate-quality evidence). There was no significant difference in patients' complaints at follow-up in the one large study that reported this outcome (moderate-quality evidence). Pooled data from two studies indicated that operative time was shorter on average with the clip technique than with partial salpingectomy (high-quality evidence).

Hulka and Filshie clips were comparable in most outcomes for which there were data ([Summary of findings 5](#)), except that technical difficulties occurred more frequently in the Hulka clip group (moderate-quality evidence).

We found little evidence about women's and surgeons' satisfaction for any of the comparisons.

### Overall completeness and applicability of evidence

We found a fairly substantial body of evidence indicating that various established techniques for interrupting tubal patency, including partial salpingectomy, electrocoagulation, and use of tubal clips and rings, are safe and effective methods. As studies utilising electrocoagulation did not always state whether unipolar or bipolar coagulation was used, we were unable to draw

differential conclusions regarding these methods; however, major morbidity attributed to electrocoagulation in the included studies was very low. We found no RCTs that compared sterilisation by tubal inserts (hysteroscopic sterilisation) with other methods, so more evidence on the safety and efficacy of this relatively new method is needed.

The short duration of follow-up in the RCTs included in this review, which was usually one or two years, limits the evidence on failure (pregnancy) rates. In addition, failure rates were possibly underestimated due to high losses to follow-up in those RCTs that reported a two-year follow-up. Thus, data on longer-term failure rates may best be derived from the CREST study (Peterson 1996). Cumulative evidence from this prospective cohort study found that the 10-year probability of pregnancy was highest after clip sterilisation (36.5/1000 procedures) and lowest for postpartum partial salpingectomy (7.5/1000) and unipolar coagulation (7.5/1000). Tubal ring was the most common sterilisation technique in the CREST cohort and was associated with a 10-year probability of pregnancy of 17.7/1000 procedures. The one-year and 10-year probabilities of pregnancy with any procedure was 5.5 /1000 and 18.5/1000 procedures, respectively. Younger women (18 to 27 years) undergoing sterilisation by bipolar coagulation were at greatest risk of sterilisation failure within ten years of the procedure (54.3/1000 procedures).

We did not try to determine the relative effects of different types of anaesthetic methods (local, spinal, general anaesthesia and other) on women's sterilisation experience, including postoperative pain, and this could be the subject of a separate review.

### Quality of the evidence

We graded the quality of the main findings of the review using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach. The quality of the evidence relating to tubal rings versus clips was mainly high. For the evidence related to partial salpingectomy compared with electrocoagulation, we downgraded the evidence quality to low or moderate due to imprecision or indirectness, as the findings may have been due to the access approach rather than the tubal occlusion technique (partial salpingectomy was mainly performed via minilaparotomy, whereas electrocoagulation was performed via laparoscopy). We downgraded the quality of the evidence relating to tubal rings versus electrocoagulation for most outcomes, most frequently due to imprecision of the effect.

We graded the evidence relating to partial salpingectomy versus tubal clips mainly as moderate due to imprecision. Evidence on minor morbidity for this comparison was very sparse and imprecise, hence we downgraded it to low quality evidence. For the comparison of Filshie and Hulka clips, evidence was mainly of a low to moderate quality due to imprecision, with or without other factors.

### Potential biases in the review process

The original review was performed in 2002 using old Cochrane methods for classifying studies and assessing risk of bias. For this update, we revised the methodology to conform with current Cochrane methods for 'Risk of bias' assessment, resulting in the inclusion of three RCTs that had been excluded from previous versions of the review. Two of these studies contributed little

(Geirsson 1985), or no (Goynumer 2009), data. In addition, we identified two RCTs using the related articles feature of PubMed, which should have been included in earlier versions of the review (Dominik 2000; Siegle 2005). Due to resource constraints we did not re-extract the missing risk of bias details from previously included studies for this update.

For the comparison 'partial salpingectomy versus clips', we pooled data from three RCTs that used different methods for partial salpingectomy (modified Pomeroy and Uchida methods) and different clip methods (titanium and silver clips; see [Included studies](#)) and performed subgroup analysis to compare these findings. The test for subgroup differences indicated no difference, however, these subgroup analyses were not pre-specified in the protocol. This subgrouping also served to distinguish between studies according to the timing of the procedure, i.e. postpartum and interval sterilisation, which similarly indicated no significant difference in findings according to the procedure timing.

Although we noted when studies were at moderate or high risk of bias for specific outcomes, we did not perform sensitivity analysis, because few studies contributed to most analyses; however, we downgraded results accordingly in the 'Summary of findings' tables.

We found no RCTs comparing types of tubal inserts or comparing tubal inserts with other methods of interrupting tubal patency; however, we found one RCT comparing two methods of accessing the fallopian tubes (vaginotomy compared with hysteroscopy) to insert Essure inserts (Chapa 2015). Studies comparing methods of accessing the tubes are not included in this review. Abdominal approaches (minilaparotomy versus laparoscopy) for female sterilisation are the subject of a separate Cochrane review (Kulier 2004) and, similarly, studies comparing methods of vaginal approaches to hysteroscopic sterilisation should be considered in a separate Cochrane review.

### Agreements and disagreements with other studies or reviews

Data from newly included studies support the previous findings of this review, that tubal sterilisation by most established methods is an effective and safe procedure. Evidence relating to postoperative pain was limited in our review; however, for the comparison of partial salpingectomy versus electrocoagulation, and tubal rings versus electrocoagulation, moderate-quality evidence indicated that there was less postoperative pain with electrocoagulation. A recent review of RCTs of local anaesthesia to reduce postoperative pain following interval laparoscopic sterilisation found that the intraoperative application of local anaesthetic to the tubes significantly reduced postoperative pain for ring and clip sterilisation (Harrison 2014). In addition, a protocol for a Cochrane Review to evaluate the effectiveness of interventions for pain relief in women undergoing postpartum mini-laparotomy tubal sterilisation has recently been published (Lumbiganon 2015). Once this protocol is published as a full review, the findings should help further towards improving the experience of women requesting this popular form of contraception.

We found no RCTs of hysteroscopic sterilisation compared with other methods of sterilisation. Hysteroscopic sterilisation with tubal inserts has several advantages over older techniques in that the procedure avoids the peritoneal cavity, requires no incisions,



usually requires no anaesthesia, may be well tolerated, and is usually performed as an outpatient procedure (Peterson 2008). In the USA, hysteroscopic sterilisation with Essure<sup>®</sup> is reported to be rapidly replacing laparoscopic sterilisation and is potentially associated with lower cost (Connor 2009; Kraemer 2009). User satisfaction rates are reported to be high (Arjona 2008; Chudnoff 2015; Connor 2009; Sinha 2007), however, placement failure rates vary and long-term efficacy has still to be established. Two systematic reviews of non-randomised studies were unable to calculate the cumulative probability of pregnancy with Essure<sup>®</sup> due to limitations in available data (Cleary 2013; la Chapelle 2015). One found 'fair-quality evidence' that pregnancy was rare in women with documented bilateral tubal occlusion at three months after the procedure (Cleary 2013); the other reported a cumulative three-year probability of pregnancy with Adiana (no longer available) of 16/1000 procedures (la Chapelle 2015). Garipey 2014 used an evidence-based Markov model to estimate the relative probability of pregnancy over 10 years following sterilisation with three methods - Essure<sup>®</sup>, the silicone ring, and bipolar coagulation - and estimated pregnancy probabilities of 96, 24 and 30 per 1000 women, respectively, with the highest risk of pregnancy after Essure<sup>®</sup> sterilisation occurring in the first year post-procedure (57 per 1000 women). This estimate considered the complete clinical pathways of the procedures, taking into account uncertainties regarding placement success, hysterosalpingogram (HSG) follow-up, and successful tubal occlusion, and therefore possibly reflects the 'real-life' situation. Other recent reports of Essure<sup>®</sup> sterilisation include a prospective study that reported no pregnancies in 449 women with successful bilateral placement and confirmed occlusion who completed the five-year follow-up (71% of cohort; Chudnoff 2015), and a retrospective cohort study of 109,277 women who underwent sterilisation by Essure<sup>®</sup> (39,169 women) or laparoscopic tubal ligation procedures (70,108 women) in France between 2006 and 2010 reporting pregnancy rates of 0.36% and 0.45%, respectively (Fernandez 2014).

More data are needed on the short- and long-term side-effects of hysteroscopic sterilisation relative to other methods. In Chudnoff 2015, intermenstrual bleeding occurred among 23.6% of women during the first three months postprocedure, 20% of women (74/386) reported heavier menses at the five-year follow-up visit; 5.3% (25/473) experienced recurrent pelvic pain, and 15 women underwent hysterectomy during the five-year follow-up period (apparently only two were possibly attributable to Essure<sup>®</sup>). Ouzounelli 2015 conducted a review of hysteroscopic sterilisation compared with laparoscopic tubal ligation and found that both had low rates of complications, although complications related to Essure<sup>®</sup> procedures were "more likely to be minor in nature". Another review concluded that "the incidence and severity of complications with hysteroscopic sterilisation has not been adequately studied and remains unclear" (la Chapelle 2015). A review by Cooper 2010 found that the vaginoscopic approach (whereby hysteroscopy is performed without a vaginal speculum or cervical instruments to grasp the cervix) may be associated with less pain than traditional hysteroscopic sterilisation techniques with no difference in the number of failed procedures.

One of the obvious limitations of hysteroscopic sterilisation at present is the delay in achieving its occlusive effect and the need for confirmatory testing at three months. A new iteration of the Essure<sup>®</sup> insert designed to achieve immediate tubal occlusion appears to show promise in this regard, and may reduce pre-HSG pregnancies

(Thiel 2014). A search of clinical trial registries at the time of writing (31 July 2015) found no registered or ongoing RCTs comparing hysteroscopic methods with more widely used methods.

No RCTs investigating the safety and effectiveness of quinacrine sterilisation, which is used unlicensed in some regions, have been conducted or registered. Due to its low cost, easy application, apparent safety, and comparable effectiveness, a call has been made recently for the use of quinacrine in low- and middle-income countries to be reconsidered (Lippes 2015). Concerns about the mutagenicity of quinacrine have not been supported by epidemiological evidence from extensive human studies (Lippes 2015), with at least two large studies finding no association between quinacrine sterilisation (QS) and the risk of gynaecological cancer (Sokal 2010a; Sokal 2010b). Furthermore, studies conducted in China and Iran have reported that QS is more acceptable to women than surgical sterilisation (Lu 2003; Soroodi-Moghaddam 2003). A large, well-conducted RCT of this inexpensive, minimally-invasive method could be important.

## AUTHORS' CONCLUSIONS

### Implications for practice

Failure rates at 12 months post-sterilisation and major morbidity were found to be rare outcomes with sterilisation by partial salpingectomy, electrocoagulation, clips, and tubal rings. Technical failures were more common with tubal rings compared with clips, and more common with clips compared with partial salpingectomy. The choice of the tubal occlusion technique should include consideration of the costs, equipment availability, the setting and the surgeon's experience. We were unable to draw any conclusions about the relative efficacy and safety of hysteroscopic sterilisation and more research is needed.

### Implications for research

RCTs comparing hysteroscopic sterilisation methods, e.g. Essure<sup>®</sup>, with laparoscopic (and other) methods are needed. To assess adverse effects, controlled observational studies of sterilisation by minimally invasive methods would also be of value. Women's satisfaction, side-effects, and cost are important outcomes for future RCTs. Women in their forties without hormonal treatment may experience more dysfunctional uterine bleeding, which is often treated with hormonally-impregnated intrauterine systems (French 2004); studies evaluating differences in long-term effectiveness and adverse effects between hysteroscopic sterilisation methods and IUSs, especially among women over 40 years of age, are therefore of interest. Given that quinacrine sterilisation is cheap, minimally invasive, and in use in some countries (Lippes 2015), a trial of quinacrine compared with hysteroscopic sterilisation would be very informative. Further comparative trials of abdominally accessed sterilisation methods are not considered to be a high priority for research.

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**CHARACTERISTICS OF STUDIES**
**Characteristics of included studies [ordered by study ID]**
**Aranda 1976**

Methods	Randomisation not specified. Concealment of allocation by sealed envelopes containing a card that specified the technique for tubal occlusion
Participants	299 women requesting sterilisation for family planning reasons, at least 6 weeks postpartum

**Techniques for the interruption of tubal patency for female sterilisation (Review)**

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**Aranda 1976** (Continued)

Conducted at the Hospital Mexico, San Jose, Costa Rica

Interventions	Electrocoagulation versus tubal ring, all laparoscopy. All under local anaesthesia and intravenous sedation
Outcomes	Surgical and early postoperative complications and complaints
Notes	Blinding of postoperative evaluation

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomly assigned"
Allocation concealment (selection bias)	Unclear risk	Concealment of allocation by sealed envelopes containing a card which specified the technique of tubal occlusion. Assessed as a 'B' study (unclear allocation concealment) in original review
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessor was blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	-
Selective reporting (reporting bias)	Unclear risk	Unable to determine
Other bias	Low risk	Women had similar socio-demographic characteristics

**Aranda 1985**

Methods	Multicenter study. Randomisation by computer-generated labels. Concealment of allocation by sealed opaque envelopes. Not stated whether sequentially numbered
Participants	663 women requesting sterilisation to limit family size and free of major systemic and pelvic abnormalities. Interval (55%) and postsponaneous abortion (45%). Conducted in San Jose, San Salvador and Cairo
Interventions	Tubal ring versus Rocket clip via minilaparotomy. Under general anaesthesia (55%) or local anaesthesia and intravenous sedation
Outcomes	Major and minor morbidity, technical failures and difficulties, failure rates and complaints
Notes	Blinding of postoperative evaluation. About 90% of women in both groups remained hospitalised for at least 1 night. The operations were performed with general anaesthesia in 55% of cases and with analgesia and/or sedation plus local anaesthesia in 45% of procedures

**Risk of bias**

Bias	Authors' judgement	Support for judgement
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**Aranda 1985** (Continued)

Random sequence generation (selection bias)	Low risk	Randomisation by computer-generated labels
Allocation concealment (selection bias)	Unclear risk	Concealment of allocation by sealed opaque envelopes. Not stated if sequentially numbered. Assessed as a 'B' study (unclear allocation concealment) in original review
Blinding (performance bias and detection bias) All outcomes	Low risk	Blinding of postoperative evaluation
Incomplete outcome data (attrition bias) All outcomes	High risk	30 cases of technical failure (5% of total) were excluded from the analyses
Selective reporting (reporting bias)	Unclear risk	-
Other bias	Unclear risk	-

**Argueta 1980**

Methods	RCT
Participants	299 women requesting sterilisation at the Asociacion Demografica Salvadorena, San Salvador
Interventions	Spring-loaded clip versus tubal ring all laparoscopy. All under local anaesthesia and intravenous sedation
Outcomes	Operative morbidity, technical failures and difficulties, failure rates, complaints
Notes	Participant and postoperative evaluation blinding  1 surgeon performed all surgical procedures on an outpatient basis

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not specified
Allocation concealment (selection bias)	Unclear risk	Assessed as a 'B' study (unclear allocation concealment) in original review
Blinding (performance bias and detection bias) All outcomes	Low risk	Participants and postoperative evaluators were blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	In the clip group 54 women (36%) and 60 (40%) in the ring group were lost to follow-up at 24 months
Selective reporting (reporting bias)	Unclear risk	Unable to determine

**Argueta 1980** (Continued)

Other bias	Low risk	Women had similar socio-demographic characteristics
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**Dominik 2000**

Methods	2 multicentre RCTs conducted by Family Health International in Malaysia, Panama, Dominican Republic, Mexico, Venezuela, Guatemala, Haiti. 1 RCT involved a minilaparotomy approach, the other involved a laparoscopic approach	
Participants	2126 women were included if they were at least 21 years old, had no pregnancy within 42 days, and no chronic medical conditions  878 participants were enrolled in the minilap study and 1248 enrolled in the laparoscopy study	
Interventions	Filshie clip (1066 women) vs Hulka clip (1060 women)	
Outcomes	Failure rates, technical failure and difficulties, morbidity  Assessed at 1, 6, and 12 months after sterilisation. A subset of women were assessed at 24 months	
Notes	Article reports the combined results of 2 RCTs, 1 of sterilisation via minilaparotomy, the other by laparoscopy  Surgeons were experienced. Cumulative failure rates were 11.7 for Filshie and 28.1 per 1000 for Hulka at 24 months	

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer-generated randomisation scheme"
Allocation concealment (selection bias)	Low risk	Sealed sequentially numbered opaque envelope opened at the time of surgery
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessor was blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up at 12 months was high (31% and 34% for the laparoscopy and minilaparotomy studies, respectively) but balanced across the groups. Loss to follow-up at 24 months in a subset of participants was 43%. Protocol deviations were low
Selective reporting (reporting bias)	Unclear risk	Not able to determine. ITT and per protocol analyses performed
Other bias	Low risk	Baseline characteristics were similar. Mean age was 31 years and average parity was 4.2 children

**Geirsson 1985**

Methods	RCT conducted in Scotland	
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**Geirsson 1985** (Continued)

Participants	79 women requesting sterilisation; excluded if postpartum or postabortion
Interventions	Falope rings (36 women) vs Filshie clips (34 women)
Outcomes	Day 1-6 postoperative pain, analgesic requirements, additional medical assistance
Notes	Interval sterilisation via laparoscopy

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"a prospective randomized comparison"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	High risk	9 post-procedure exclusions due to intra-operative difficulties, subsequent UTI, incomplete follow-up and anaesthetic complications. Protocol deviations and ITT analysis not described
Selective reporting (reporting bias)	Unclear risk	Unable to determine
Other bias	High risk	Post-randomisation exclusions of women with complications occurred in this study of morbidity

**Gentile 2006**

Methods	RCT
Participants	118 women requesting sterilisation
Interventions	62 Hulka clips and 56 electrocautery
Outcomes	Urinary and serum oestradiol and progesterone levels; participants' satisfaction and regret
Notes	<p>Secondary outcomes relating to women's satisfaction/regret have never been published. The authors were contacted and provided some additional information regarding method of randomisation/allocation concealment but were unable to find the unpublished data regarding women's satisfaction. Included but no pertinent outcome data available</p> <p>Anaesthesia not specified</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table

**Gentile 2006** (Continued)

Allocation concealment (selection bias)	Low risk	Consecutively numbered sealed opaque envelopes (unpublished information)
Blinding (performance bias and detection bias) All outcomes	Low risk	Participants blinded throughout the 2-year follow-up (unpublished information)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not able to determine
Selective reporting (reporting bias)	Unclear risk	Secondary outcomes were never reported
Other bias	Unclear risk	Not able to determine

**Goynumer 2009**

Methods	RCT
Participants	88 women  Inclusion criteria: regular menses, no risk of ovarian failure in personal or family history, ovarian reserve on transvaginal ultrasound (TVU) in normal range  Exclusion criteria: perimenopausal symptoms, abnormal BMI, ovarian cysts > 25 mm on TVU, pelvic surgery in previous year
Interventions	Laparoscopic interval sterilisation via electrocoagulation or mechanical clips
Outcomes	Post-operative 10 <sup>th</sup> month mean values of ovarian reserve i.e. serum FSH, LH, estradiol, inhibin-B, antimullerian hormone. Total ovarian volume and antral follicle count on TVU
Notes	General anaesthesia used  No review outcomes reported, therefore this study contributed no data to the review

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information on loss to follow-up or postrandomisation exclusions

**Goynumer 2009** (Continued)

Selective reporting (reporting bias)	Unclear risk	Not able to determine
Other bias	Unclear risk	Not able to determine

**Koetsawang 1978**

Methods	Did not specify method of randomisation
Participants	300 women requesting sterilisation for family planning purposes at the Siriraj Hospital in Bangkok
Interventions	Unipolar electrocoagulation versus tubal ring via laparoscopy. All performed under local anaesthesia and intravenous sedation
Outcomes	Operative morbidity, technical failures and difficulties, failure rates, operative time, complaints
Notes	Postoperative evaluation blinding, prophylactic antibiotics for 5 days Up to 54% loss to follow-up at 12 months

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	Assessed as a 'B' study (unclear allocation concealment) in original review
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessor was blinded
Other bias	Low risk	The 2 groups had similar socio-economic characteristics

**Kohaut 2004**

Methods	RCT pilot study of postpartum sterilisation techniques. Computer-generated randomisation; sealed opaque envelope opened immediately before sterilisation
Participants	32 pregnant patients requesting sterilisation after vaginal delivery (25) or Caesarean section (4). Inclusion criteria: $\geq 21$ years
Interventions	14 Filshie clip vs 15 Pomeroy method
Outcomes	Time from skin incision to closure, technical difficulties, surgeon's satisfaction, surgeon's preference (7/10 preferred Filshie to Pomeroy)
Notes	Baseline characteristics similar in the 2 groups. 2/32 study questionnaires lost = missing data (1 in each group). 1 post-randomisation exclusion from the Filshie group as the woman had had a previous failed Filshie sterilisation and so Pomeroy was performed when surgeon saw old clips - no other details provided

**Kohaut 2004** (Continued)

General or spinal anaesthesia used

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation
Allocation concealment (selection bias)	Low risk	Sealed opaque envelope opened immediately before sterilisation
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	-
Selective reporting (reporting bias)	Unclear risk	-
Other bias	Unclear risk	Baseline characteristics similar in the 2 groups

**Pymar 2004**

Methods	RCT. Women received a Filshie clip on 1 fallopian tube and a ring on the opposite side; site allocation was randomized. Randomisation (via random number table) was performed following laparoscopic abdominal examination after excluding adhesions, endometriosis and pelvic masses. Allocation concealment by sequentially numbered sealed opaque envelopes. Group assignment determined the device that would be applied first and the side to which the first occlusion method would be placed. The subject was blind to her group, as were the monitoring and research staff
Participants	40 women in Pittsburg, USA, requesting sterilisation  Inclusion criteria: > 21years, literate and with telephone access  Exclusion criteria: allergy to local anaesthetic, morbid obesity > 100 kg, > 2 previous laparotomies, history of moderate to severe endometriosis, pelvic mass, current chronic pelvic pain, use of pain medications for any indication regularly during the past 2 weeks, history of depression or anxiety or other psychiatric disorder, allergy/intolerance to analgesics, plan for open laparoscopic procedure, previous tubal surgery, in-operative discovery of dense adhesions, endometriosis or pelvic mass that required concurrent surgery
Interventions	Sterilisation with Filshie clip and fallopian ring on opposite fallopian tubes following topical bupivacaine application to the tubes (abdominal entry via laparoscopy)
Outcomes	Postoperative pain in first 24 h by visual analogue scale at 1 h, 2 h and 24 h
Notes	Rationale behind design was that women are apparently able to discriminate pain on each side of their abdomen after tubal occlusion (Kaplan 1990). ITT analysis; no significant difference in results when reported major (8) and minor (9); deviations from protocol were excluded

**Risk of bias**

**Pymar 2004** (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Low risk	Allocation concealment was by sequentially numbered sealed opaque envelopes
Blinding (performance bias and detection bias) All outcomes	Low risk	Participants were blinded to group allocation, as were the monitoring and research staff
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Minimal loss to follow-up. 8 women had major deviations from protocol and 17 women had minor deviations from protocol. Results were reported according to ITT
Selective reporting (reporting bias)	Unclear risk	Unable to determine
Other bias	Unclear risk	None noted

**Qui 2011**

Methods	Multicentre RCT conducted in 20 clinics in China between June 2007 and August 2008
Participants	2198 women requiring sterilisation  Inclusion criteria: 20-40 years old, at least 2 children, married  Exclusion criteria: history of major abdominal surgery, epilepsy, neurosis, chronic pelvic inflammatory disease, acute infectious disease, body temperature > 37.5 °C, noted to have severe adhesions in previous operations
Interventions	1116 women sterilised via Uchida technique  1082 via silver clips
Outcomes	Pregnancy rates, morbidity, operative time, satisfaction  Follow-up at 1 week, 3, 6, 12 months following sterilisation
Notes	Mostly interval sterilisation but < 2% were performed postabortion. Approximately 63% were performed in lactating women in whom menses had not resumed  Operations were performed under local anaesthetic and women were monitored for 2-4 h after the operation  Surgical duration was significantly longer and amount of bleeding (classified as small, moderate or large amount) was greater in the Uchida arm

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"participants were randomly assigned"

**Qui 2011** (Continued)

Allocation concealment (selection bias)	Unclear risk	"this information was placed in an envelope and delivered to the surgeon"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding of assessors was not described  Possibly high risk of performance bias for personnel
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	61 lost to follow-up altogether with 20 lost in Uchida group and 41 lost in the clip group
Selective reporting (reporting bias)	Unclear risk	Did not report morbidity or postoperative/persistent pain. However, reported 'chief complaints' which were not significantly different between the study arms. Also, investigators only included data from women who attended all 3 follow-up visits
Other bias	Unclear risk	Unable to determine. Baseline characteristics were similar

**Rodriguez 2013**

Methods	Multicentre RCT conducted by Family Health International in Thailand, Taiwan, Panama and the Phillipines with recruitment from April 1984 to June 1989	
Participants	1400 postpartum women  Inclusion criteria: able to consent, within 42 days postpartum, $\geq 21$ years old, normal physical and pelvic examination  Exclusion criteria: incapable of consenting, severe pre-existing systemic disease, profound anaemia, anticipated concurrent surgery, limited accessibility for follow-up, caesarean section	
Interventions	Sterilisation within 72 h of delivery by:  Titanium clip (Filshie; 698 women) or  partial salpingectomy (Pomeroy; 702 women)  All procedures were by infra-umbilical mini-laparotomy incision of 1 cm-2 cm in length	
Outcomes	Failure rate. Follow-up at 1, 6, 12, and 24 months following sterilisation	
Notes	Loss to follow-up was 51% at end of study. Method of anaesthesia was "local, epidural or spinal at the surgeon's discretion" Cumulative failure rates at one year were reported as 11 per 1000 for Filshie versus 2 per 1000 for partial salpingectomy; at two years, cumulative failure rates in this study were reported as 17 per 1000 versus 4 per 1000, respectively	

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer-generated code"
Allocation concealment (selection bias)	Low risk	"assignment was performed immediately before surgery after consent using an off-site computer-generated code that was unavailable to study staff"

**Rodriguez 2013** (Continued)

Blinding (performance bias and detection bias) All outcomes	Low risk	"the investigator in charge of follow-up was" blinded to the procedure
Incomplete outcome data (attrition bias) All outcomes	High risk	High attrition at 6 months with approximately 30% lost to follow-up; at 1 year approximately 42% were lost to follow-up, and at 2 years 51% were lost to follow-up. 348 women were present in each group at the end of the study. 13 technical failures and random allocation errors occurred (but these did not result in pregnancy) - it is not clear in which study groups these occurred
Selective reporting (reporting bias)	High risk	Only the primary outcome was reported
Other bias	Unclear risk	Unable to determine but "demographic variables were comparable between groups at baseline"

**Siegle 2005**

Methods	RCT conducted in the USA with recruitment between July 1999 and June 2001	
Participants	109 women requesting sterilisation. Inclusion/exclusion criteria not stated	
Interventions	Salpingectomy after bipolar coagulation (55 women) versus Pomeroy partial salpingectomy (54 women)	
Outcomes	Pain at 6 h and 14 days postoperatively	
Notes	Sterilisation via micro-laparoscopy. Timing not clear, but probably interval sterilisation Third-year residents performed the procedure	

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer-generated randomisation code"
Allocation concealment (selection bias)	Low risk	"Technique assignment was written on a card placed in the sealed opaque envelope"; the "next consecutively numbered envelope" was allocated
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Numbers analyzed/loss to follow-up not described
Selective reporting (reporting bias)	Unclear risk	Not able to determine
Other bias	Unclear risk	Coagulation group was heavier than ligation group (180 vs 160 pounds) and had had more previous abdominal operations (12 vs 8)

### Sitompul 1984

Methods	Not specified method of randomisation
Participants	300 women requesting sterilisation at the University Hospital in Medan, Indonesia Exclusion criteria: heart, pulmonary, endocrine or other systemic illness, PID or vulvovaginal infections
Interventions	Modified Pomeroy technique (via minilaparotomy or culdoscopy) versus electrocoagulation (via laparoscopy). All under local anaesthesia and 10 mg intravenous valium
Outcomes	Operative time, hospitalisation, postoperative complications, failure rates
Notes	Interval sterilisation

#### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	5 women were excluded after randomisation (3 Pomeroy, 2 electrocoagulation)
Selective reporting (reporting bias)	Unclear risk	Unable to determine
Other bias	Unclear risk	Unable to determine

### Sokal 2000

Methods	Multicentre RCT conducted by FHI from 1984 to 1990 in centres in Panama, Peru, Kenya, Brazil, Mexico, Indonesia, Thailand and the Dominican Republic
Participants	2746 women requiring interval sterilisation  Inclusion criteria: at least 21 years old, legally able to consent, normal physical and pelvic examination  Exclusion criteria: pregnant within last 42 days, pre-existing chronic disease, no concomitant surgical procedures needed except curettage
Interventions	Titanium clip (Filshie; 1381 women) or  tubal ring (1365 women)  Randomisation was in 2 groups: 1) access via minilaparotomy (5 centres) 482 Filshie, 453 ring; 2) access via laparoscopy (7 centres) 919 Filshie, 912 ring
Outcomes	Pregnancy, adverse events, hospital admissions, further surgery



**Sokal 2000** (Continued)

Follow-up conducted at 1, 6, and 12 months following sterilisation. A 24-month follow-up "was planned for a subset" of women

Notes

Report combined data from 2 studies, one utilising a minilapraotomy approach, the other utilising laparoscopy. 'Experienced surgeons' performed the procedures

There were more tubal injuries in the ring group (e.g. tubal transections, haematomas) and also more surgical difficulties and failures Filshie clip expulsions occurred at 10, 30 and 34 months after sterilisation in 3 women

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer-generated randomisation scheme"
Allocation concealment (selection bias)	Low risk	"sealed, sequentially numbered opaque envelope" provided by FHI
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessors were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up was relatively low, approximately 7% (low) for the early follow-up visit and 18% at 12 months. 30 and 41 protocol violations of inclusion/exclusion criteria in Filshi and tubal ring groups respectively. Characteristics of women lost to follow-up were similar in both groups
Selective reporting (reporting bias)	Unclear risk	Reported treated population data mainly (i.e. not ITT data)
Other bias	Unclear risk	One centre used its own randomisation schedule and randomized 68 women (34 to each group), therefore assignment was not according to FHI randomisation schedule

**Stovall 1991**

Methods	Randomisation by computer-generated schedule
Participants	365 women at the University of Tennessee, Memphis
Interventions	Spring-loaded clip (Hulka-Clemens) versus tubal ring (Falope ring). All procedures via laparoscopy
Outcomes	Failure rates
Notes	All procedures performed by third-year residents. Urine hCG within 72 h before procedure. Methylene-blue test with no spillage recorded

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated schedule

**Stovall 1991** (Continued)

Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No post-randomisation exclusion or losses to follow-up were reported
Selective reporting (reporting bias)	Unclear risk	Unable to determine
Other bias	Unclear risk	Both groups had similar socio-demographic characteristics

**Toplis 1988**

Methods	Randomisation not specified. Concealment of allocation by envelope opened immediately before operation	
Participants	200 non pregnant women at the Churchill Hospital, Oxford	
Interventions	Spring-loaded clip (Hulka-Clemens) versus Filshie clip (titanium clip) via laparoscopy	
Outcomes	Operative morbidity, operative time, complaints	
Notes	Interval sterilisation Authors as the only surgeons	

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Concealment of allocation by envelope opened immediately before operation
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Two women from the Hulka clip group were excluded from the study because of technical failure
Selective reporting (reporting bias)	Unclear risk	Unable to determine
Other bias	Unclear risk	Unable to determine. Women in the Filshie group were slightly heavier than those in the Hulka clip group

**WHO 1982**

Methods	Multicenter, multinational randomized study. Randomisation centrally generated by WHO. Concealment of allocation by sealed, sequentially numbered opaque envelopes
Participants	1827 healthy women with at least one child and eligible for both interventions. Exclusion criteria: pelvic pathologies, history of previous PID or peritonitis, scar below the umbilicus or any condition which would increase the risk of any surgical procedure Conducted in Bangkok, Havana, London, Los Angeles, Santiago, Seoul, Singapore, Sydney
Interventions	Modified Pomeroy method via minilaparotomy versus electrocoagulation via laparoscopy
Outcomes	Major and minor morbidity, technical failures, postoperative complaints
Notes	Interval sterilisation  Anaesthesia standardised within individual centres according to routine practice in the institution. In the 3 high-income country centres (London, Los Angeles, Sydney) all operations were performed under general anaesthesia, whereas in 2 middle- or low-income country centres (Bangkok, Seoul) local anaesthesia was used for both procedures. In Havana and Singapore all women in the electrocoagulation group received general anaesthesia and most Pomeroy procedures were done under spinal/epidural anaesthesia. In Santiago all Pomeroy procedures were performed under spinal anaesthesia, and all electrocoagulation procedures under local anaesthesia. All centres used sedatives for pre-medication were used All procedures performed by experienced surgeons

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation generated centrally by WHO
Allocation concealment (selection bias)	Low risk	Concealment of allocation by sealed, sequentially numbered opaque envelopes. Assessed as an 'A' study) in original review
Blinding (performance bias and detection bias) All outcomes	Unclear risk	-
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The post-randomisation exclusion rate was about 12% (121 women) in the Pomeroy group and about 10% (96 women) in the electrocoagulation group due to protocol violations
Selective reporting (reporting bias)	Unclear risk	Unable to determine
Other bias	High risk	There were important differences in baseline characteristics mainly due to 1 centre (Bangkok) where women in the electrocoagulation group were older, had more living children and had been married longer. Also, women in the Pomeroy group were lighter and had a lower ponderal index, mainly due to the contribution of 2 centres (Bangkok and Havana). These differences were statistically significant for the Bangkok centre

**Yan 1990**

Methods	Randomisation not specified. Concealment of allocation by sealed preprinted labels
Participants	200 women postpartum at the Tri-Service General Hospital, Taipei, Taiwan
Interventions	Pomeroy method versus Filshie clip, all via subumbilical minilaparotomy. 88% under epidural anaesthesia and the remainder under local anaesthesia
Outcomes	Complications, menstrual irregularities, failure rates
Notes	Postpartum sterilisation with 24 month follow-up  Blinding of postoperative evaluation. All procedures were performed by one of the authors

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Concealment of allocation by sealed preprinted labels
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessor blinded.
Selective reporting (reporting bias)	Unclear risk	Unable to determine
Other bias	Low risk	Selected socio-demographic characteristics (age, total live births and previous contraceptive use) were found to be similar between groups

**Abbreviations**

BMI: body mass index  
 FSH: follicle-stimulating hormone  
 h: hour(s)  
 hCG: human chorionic gonadotropin  
 ITT: intention-to-treat analysis  
 LH: lutenising hormone  
 PID: pelvic inflammatory disease  
 RCT: randomized controlled trial  
 TVU: transvaginal ultrasound  
 UTI: urinary tract infection  
 WHO: World Health Organization

**Characteristics of excluded studies [ordered by study ID]**

Study	Reason for exclusion
<a href="#">Alvarez 1989</a>	RCT (uncertain whether quasi-randomised) of post-tubal sterilisation hormone levels following Pomeroy or Uchida techniques 17/38 completed the protocol and only 17 were included in analyses
<a href="#">Bordahl 1984</a>	Quasi-RCT with about 40% postrandomisation exclusions

Study	Reason for exclusion
Chapa 2015	RCT of methods of access (vaginostomy vs hysteroscopy) for hysteroscopic sterilisation (Essure), not of techniques for interrupting tubal patency
Dueholm 1986	Not an RCT
Lee 1991	Women were 'randomized' (no details provided) before surgery to Hulka clips or modified Pomeroy technique, but at the time of surgery, those found to have tubal disease underwent sterilisation with standard modified Pomeroy technique and were then analyzed in that group
Lipscomb 1994	An RCT of chromotubation vs no chromotubation to confirm poststerilisation tubal occlusion. Although women were apparently also randomized to the sterilisation method (tubal ring, electrocautery, or Hulka clips), comparisons of these methods were not the objective of the study and outcomes and losses to follow-up were not described separately for each method
Madrigal 1977	ITT analysis was not performed. 1 participant from the clip group was changed to the electrocoagulation group due to a technical problem and was included in the latter for the further analysis
Murray 1992	Quasi-RCT
Rivera 1989	Quasi-RCT. The groups were divided into equal numbers of women. In addition, a fourth group was taken as a control group
Sahwi 1989	Quasi-RCT. The groups were divided into equal numbers of women

### Abbreviations

ITT: intention-to-treat analysis

RCT: randomized controlled trial

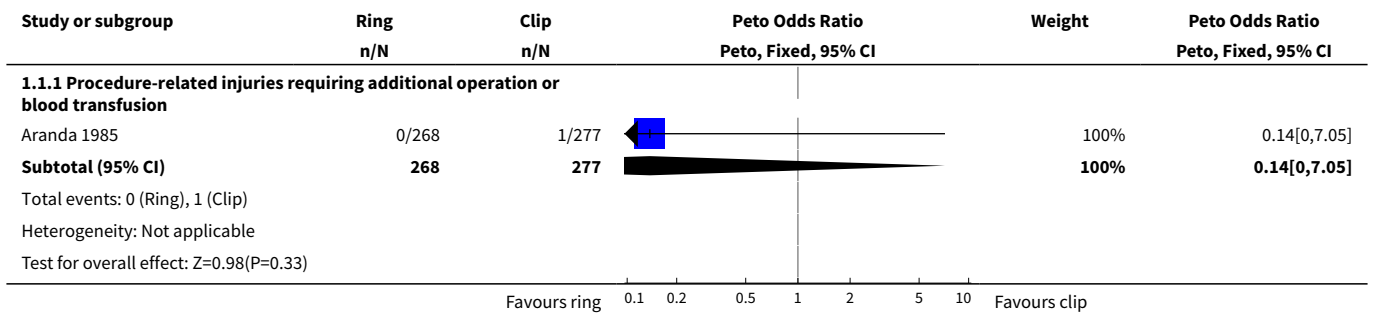
## DATA AND ANALYSES

### Comparison 1. Tubal ring versus clip

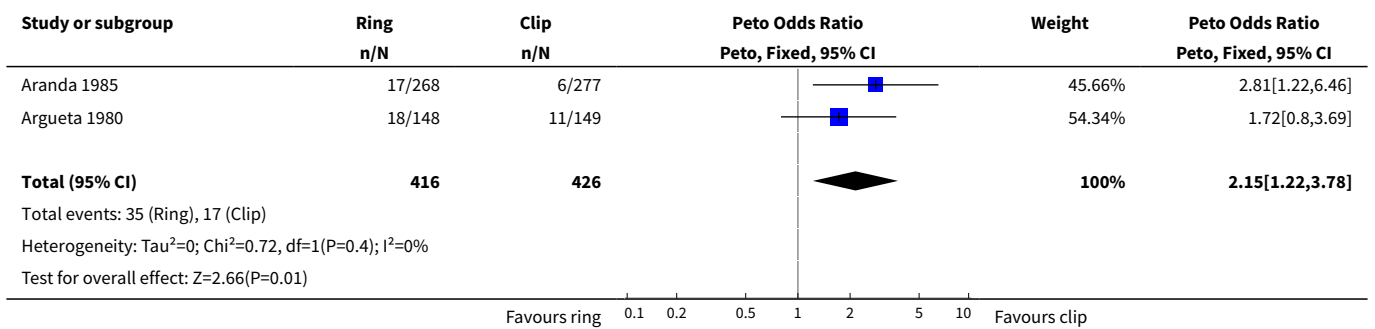
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Major morbidity: total	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
1.1 Procedure-related injuries requiring additional operation or blood transfusion	1	545	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.00, 7.05]
2 Minor morbidity: total	2	842	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.15 [1.22, 3.78]
3 Minor morbidity: details	3		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
3.1 Procedure related injuries with no additional operation	3	3575	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.95 [1.36, 2.78]
3.2 Urogenital infections	3	3145	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.88 [0.83, 4.28]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.3 Wound infection	3	3144	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.17 [0.73, 1.87]
3.4 Postoperative temperature > 38 °C without hospitalisation	1	296	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.49 [0.15, 377.52]
4 Technical failures	3	3476	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.93 [2.43, 6.35]
5 Technical difficulties	3	3590	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.13 [0.87, 1.46]
6 Failure rate: total	4	3822	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.72 [0.33, 1.57]
7 Failure rate: details	2		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
7.1 Failure rate ≤ 1 year, total	2	2629	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.85 [0.23, 3.14]
7.2 Failure rate ≤ 1 year, extrauterine pregnancy	1	2202	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.3 Failure rate > 1 year, extrauterine pregnancy	1	427	Peto Odds Ratio (Peto, Fixed, 95% CI)	8.11 [0.16, 410.33]
8 Operative time	1	297	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Hospital stay > 24 h	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
10 Complaints	4		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
10.1 Postoperative pain < 24 h	3	922	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.14 [0.88, 1.48]
10.2 Postoperative analgesic use	1	70	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.70 [0.28, 1.79]
10.3 Cramping pain during first week after surgery	1	70	Peto Odds Ratio (Peto, Fixed, 95% CI)	5.24 [1.52, 18.00]
11 Menstrual irregularities	2	612	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.61 [0.75, 3.49]

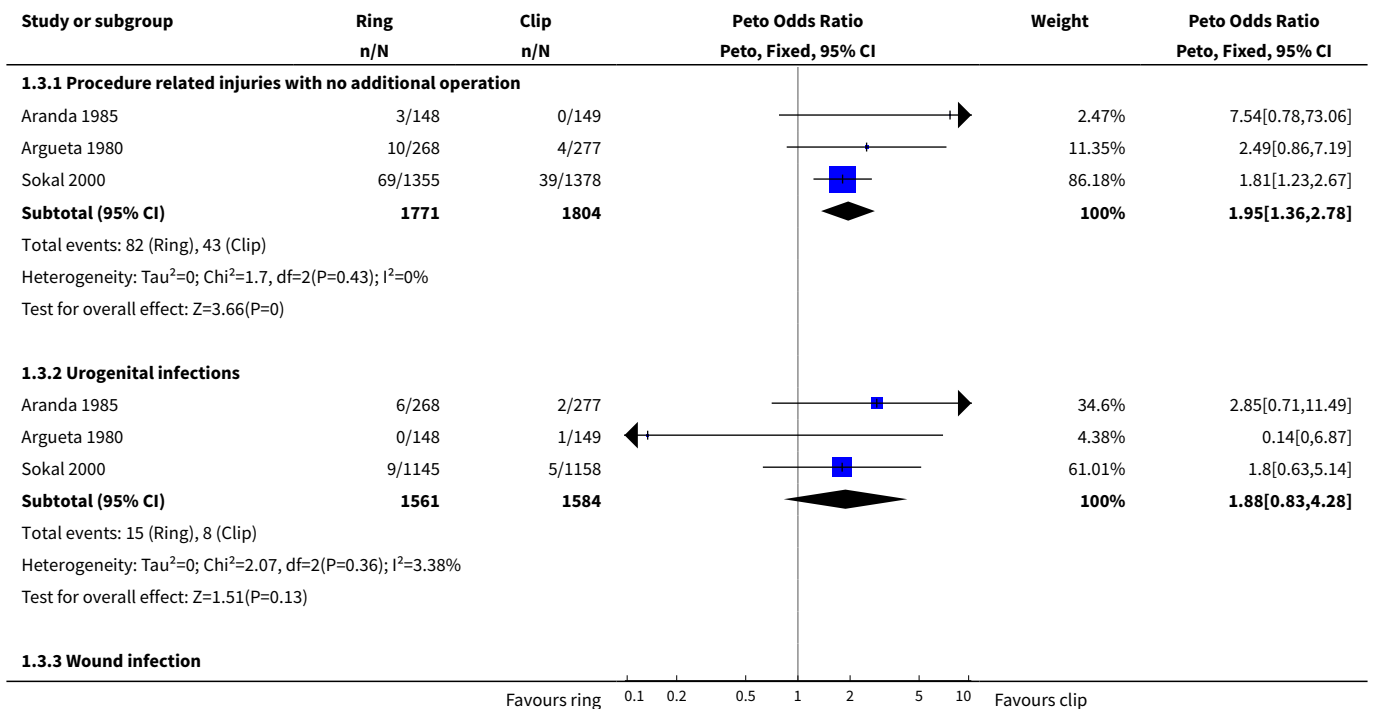
**Analysis 1.1. Comparison 1 Tubal ring versus clip, Outcome 1 Major morbidity: total.**

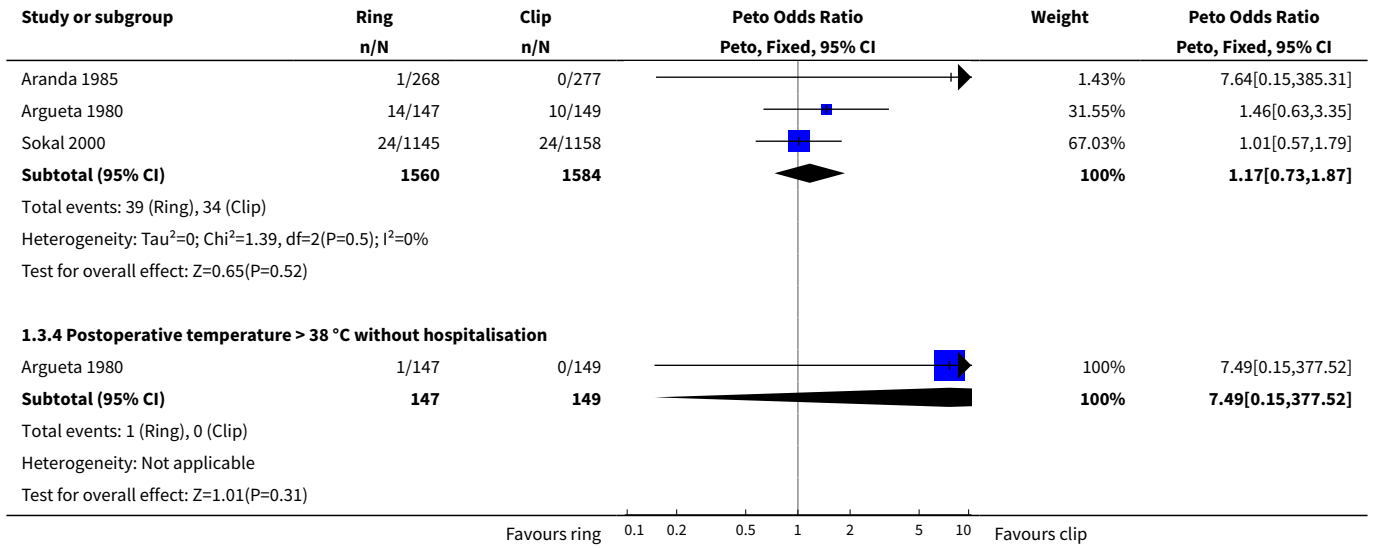


**Analysis 1.2. Comparison 1 Tubal ring versus clip, Outcome 2 Minor morbidity: total.**

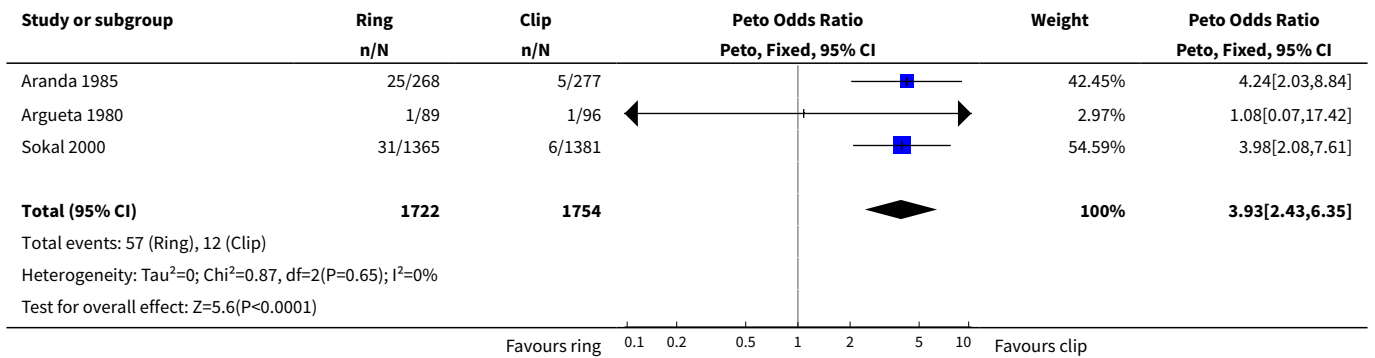


**Analysis 1.3. Comparison 1 Tubal ring versus clip, Outcome 3 Minor morbidity: details.**

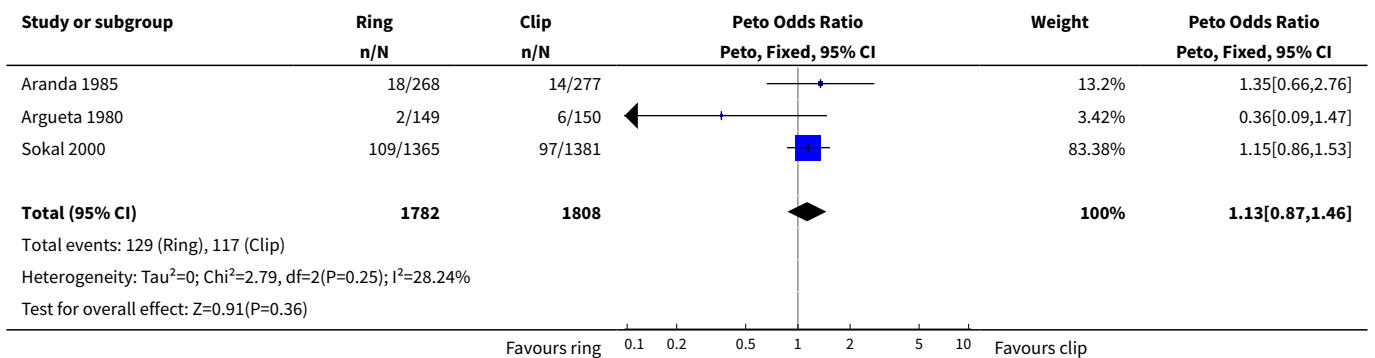




**Analysis 1.4. Comparison 1 Tubal ring versus clip, Outcome 4 Technical failures.**

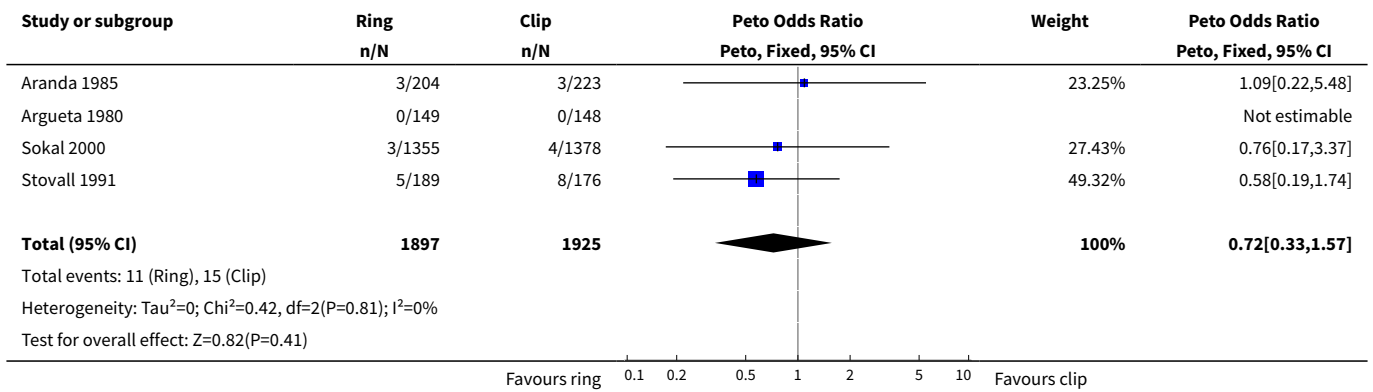


**Analysis 1.5. Comparison 1 Tubal ring versus clip, Outcome 5 Technical difficulties.**

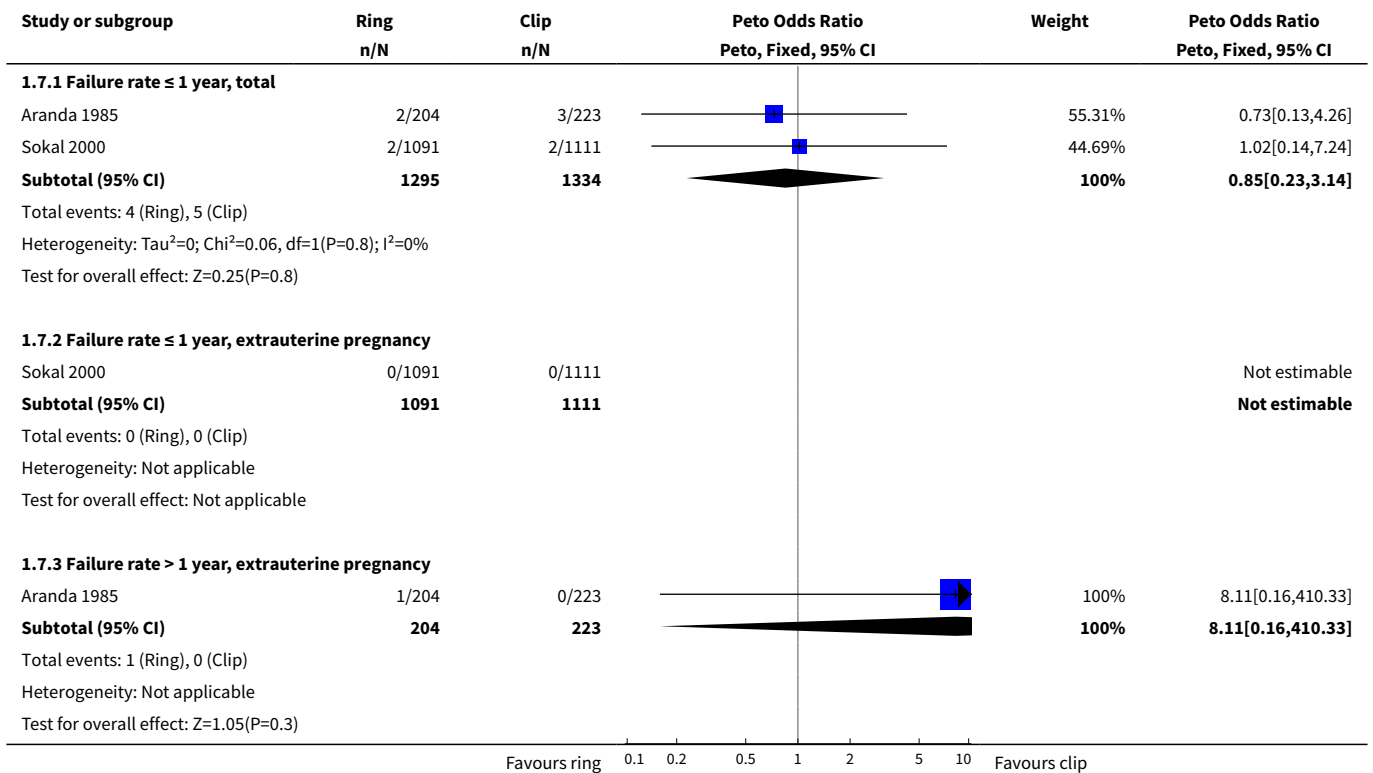




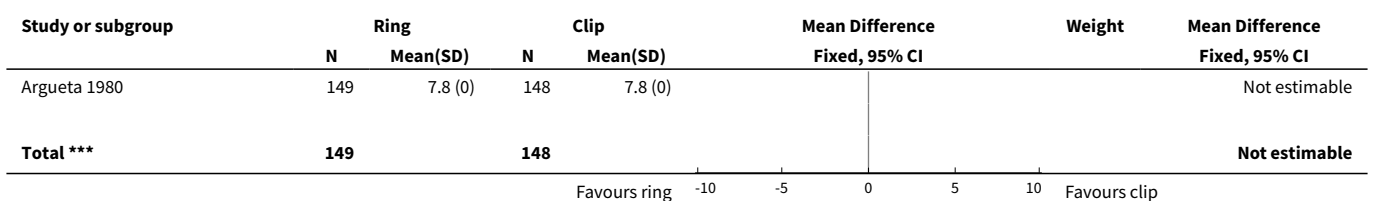
**Analysis 1.6. Comparison 1 Tubal ring versus clip, Outcome 6 Failure rate: total.**

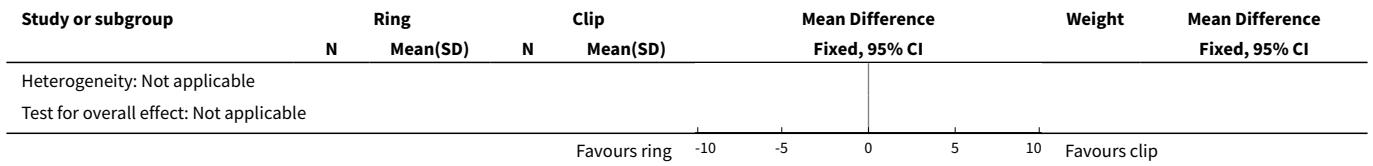


**Analysis 1.7. Comparison 1 Tubal ring versus clip, Outcome 7 Failure rate: details.**

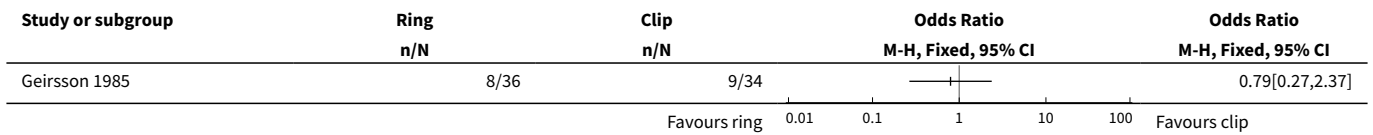


**Analysis 1.8. Comparison 1 Tubal ring versus clip, Outcome 8 Operative time.**

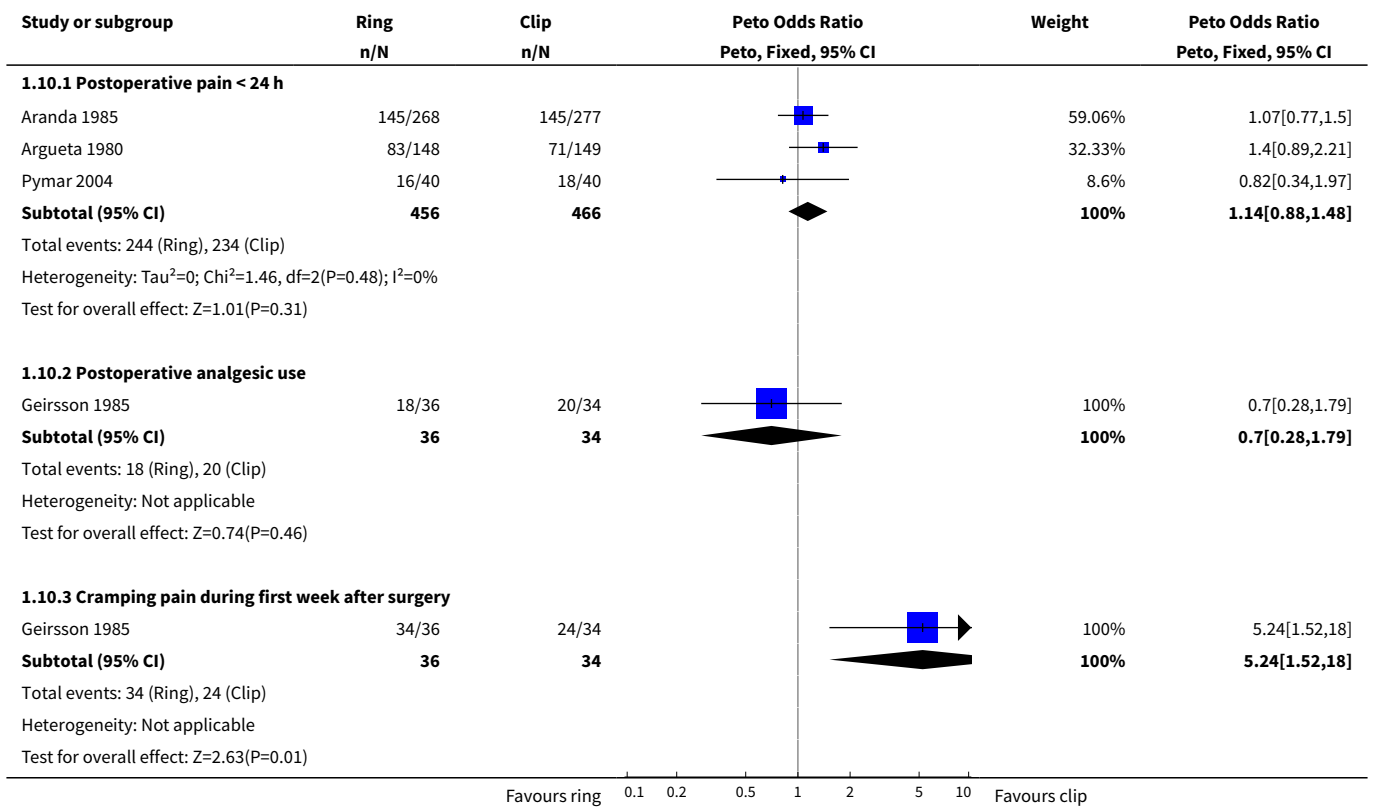




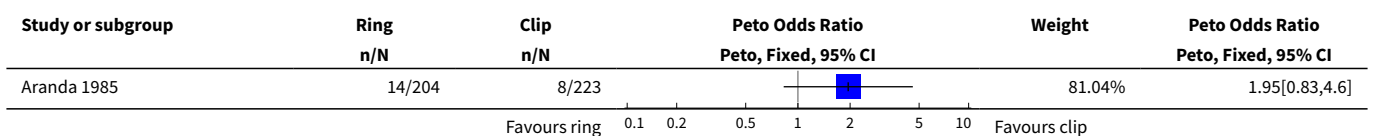
**Analysis 1.9. Comparison 1 Tubal ring versus clip, Outcome 9 Hospital stay > 24 h.**

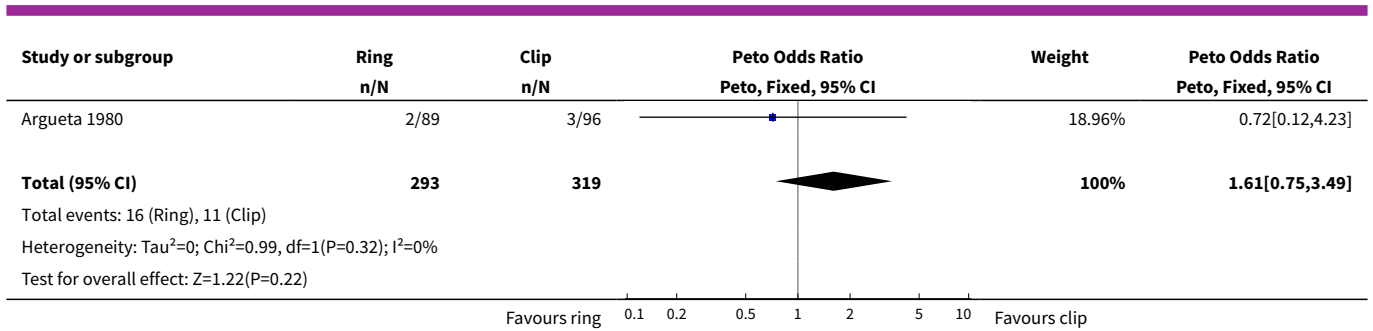


**Analysis 1.10. Comparison 1 Tubal ring versus clip, Outcome 10 Complaints.**



**Analysis 1.11. Comparison 1 Tubal ring versus clip, Outcome 11 Menstrual irregularities.**



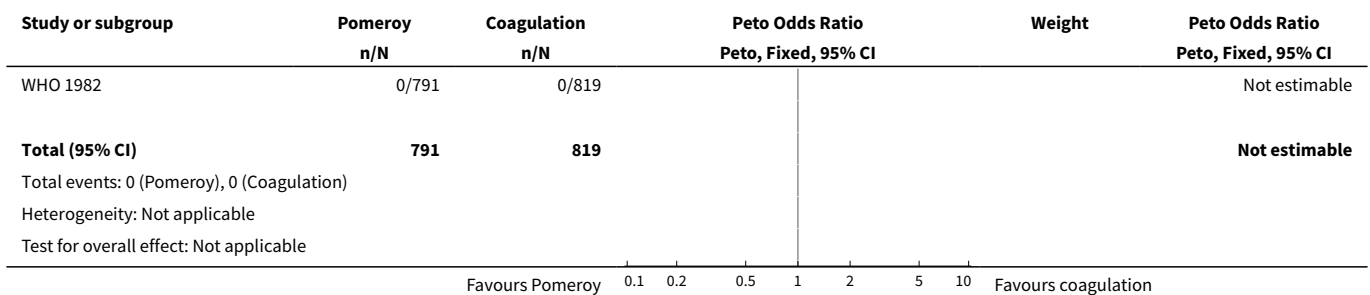


**Comparison 2. Partial salpingectomy (modified Pomeroy) versus electrocoagulation**

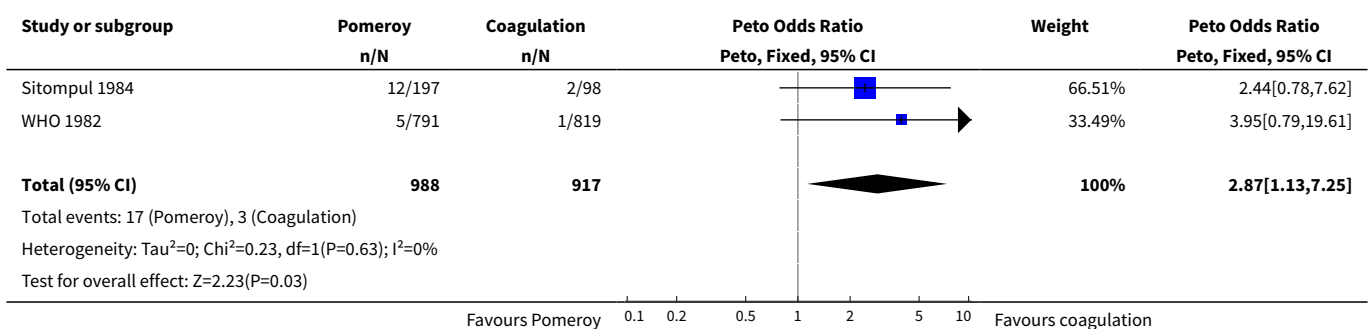
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Operative mortality	1	1610	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Major morbidity: total	2	1905	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.87 [1.13, 7.25]
3 Major morbidity: details	2		Odds Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 Procedure-related injuries requiring additional operation or blood transfusion	2	1905	Odds Ratio (M-H, Random, 95% CI)	1.90 [0.19, 18.96]
3.2 Rehospitalisation as a consequence of operation	1	295	Odds Ratio (M-H, Random, 95% CI)	5.74 [0.73, 45.09]
4 Minor morbidity: total	2	1905	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.60 [1.10, 2.33]
5 Minor morbidity: details	2		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
5.1 Procedure-related injuries with no additional operation	1	1610	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.53 [0.06, 5.11]
5.2 Urogenital infections	1	1610	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.81 [0.43, 1.50]
5.3 Wound infection	1	1610	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.49 [1.54, 4.04]
5.4 Postoperative temperature > 38 °C without hospitalisation	1	295	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.45 [0.18, 11.77]
6 Failure rate: total	1	295	Peto Odds Ratio (Peto, Fixed, 95% CI)	4.47 [0.07, 286.78]
6.1 Failure rate, total	1	295	Peto Odds Ratio (Peto, Fixed, 95% CI)	4.47 [0.07, 286.78]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
<a href="#">7 Failure rate: details</a>	1	295	Peto Odds Ratio (Peto, Fixed, 95% CI)	4.47 [0.07, 286.78]
7.1 Failure rate > 1 year, total	1	295	Peto Odds Ratio (Peto, Fixed, 95% CI)	4.47 [0.07, 286.78]
<a href="#">8 Hospital stay more 24 h</a>	1	108	Odds Ratio (M-H, Fixed, 95% CI)	0.48 [0.08, 2.74]
<a href="#">9 Complaints</a>	3		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
9.1 Postoperative pain < 24 h	2	1905	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.85 [2.91, 5.10]
9.2 Postoperative analgesic use	1	109	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.05 [0.40, 10.56]
9.3 Persistent pain at follow-up visit	1	1610	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.09 [0.81, 1.47]

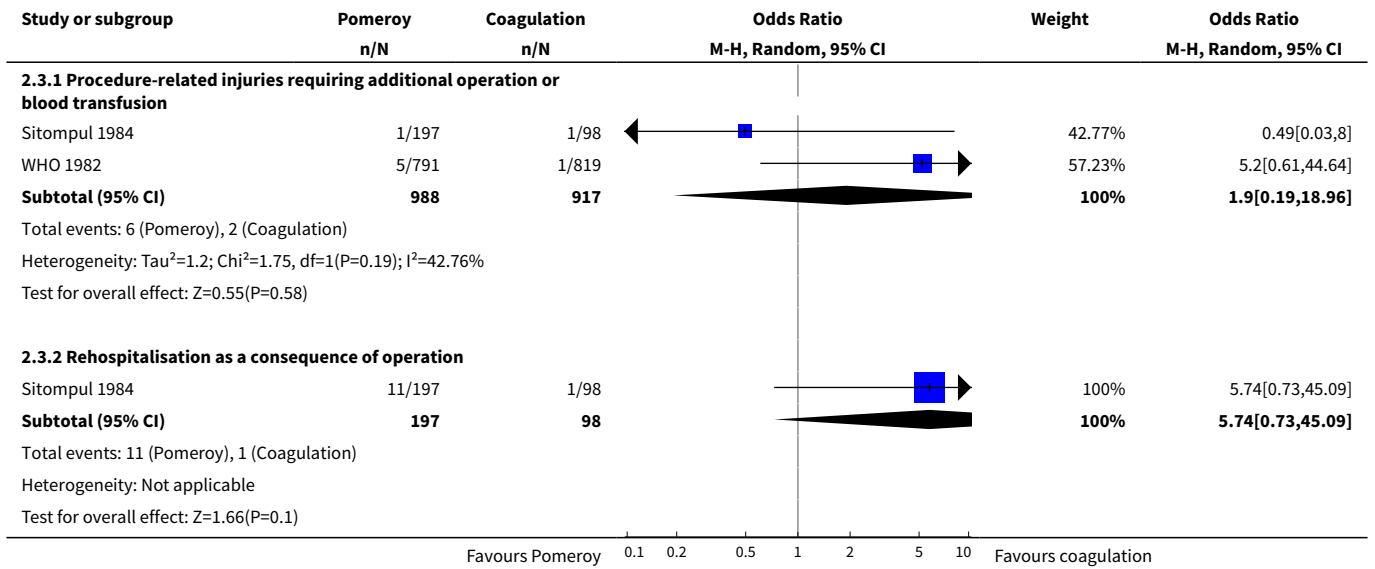
**Analysis 2.1. Comparison 2 Partial salpingectomy (modified Pomeroy) versus electrocoagulation, Outcome 1 Operative mortality.**



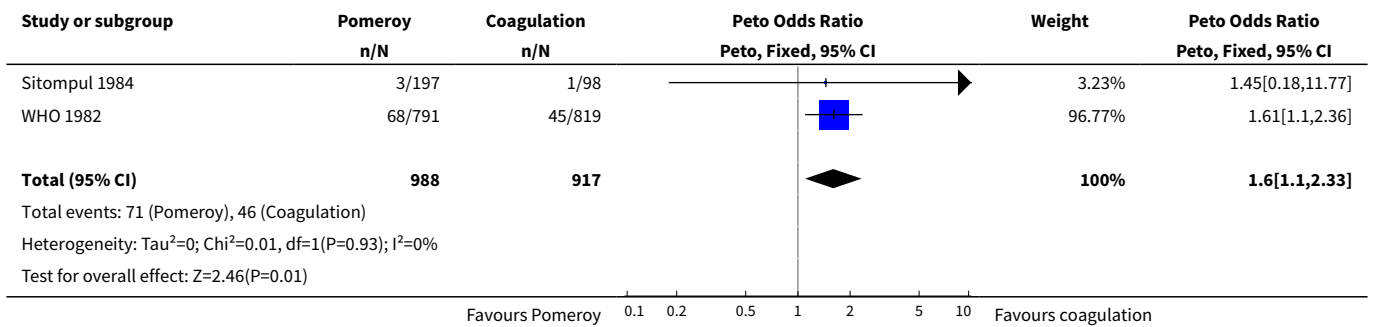
**Analysis 2.2. Comparison 2 Partial salpingectomy (modified Pomeroy) versus electrocoagulation, Outcome 2 Major morbidity: total.**



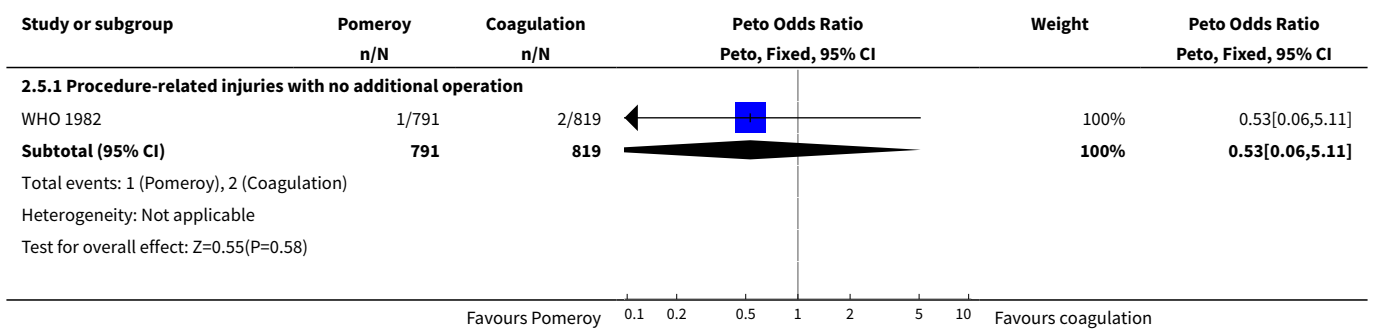
**Analysis 2.3. Comparison 2 Partial salpingectomy (modified Pomeroy) versus electrocoagulation, Outcome 3 Major morbidity: details.**

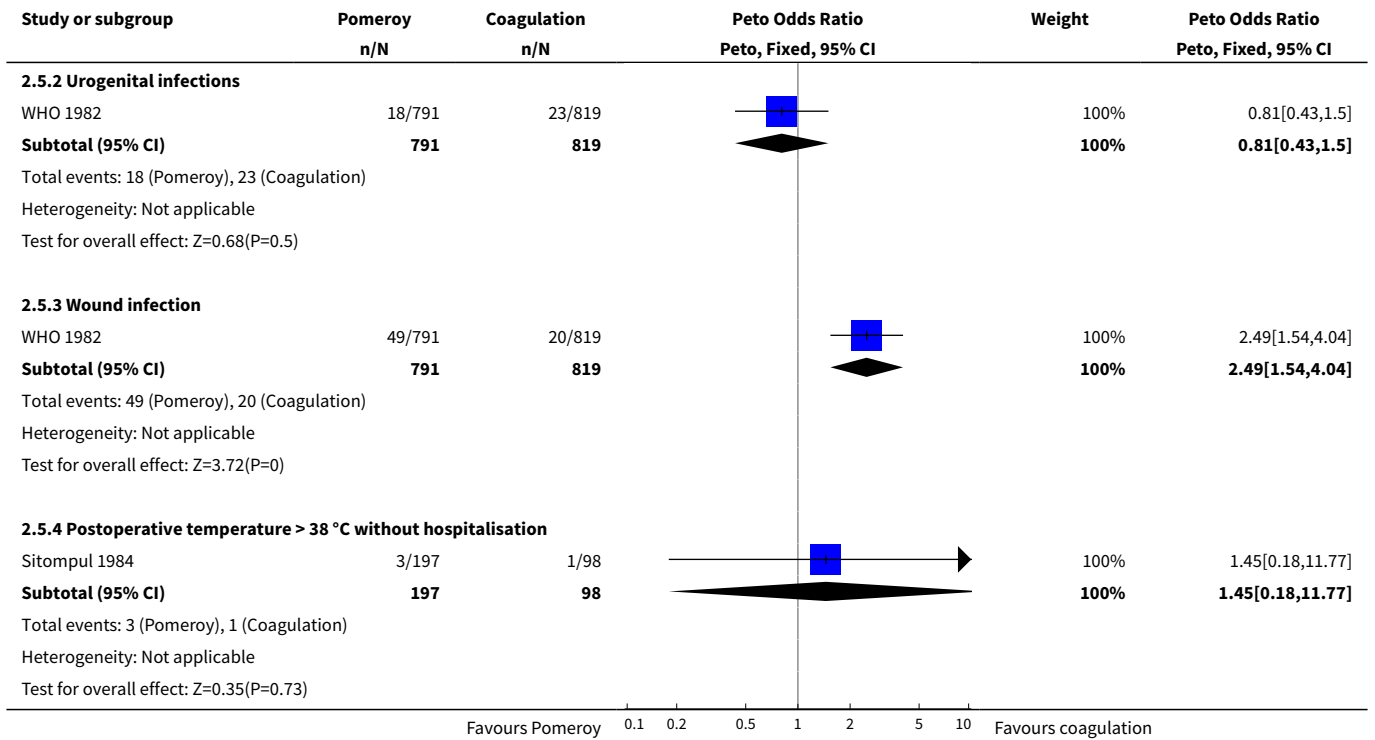


**Analysis 2.4. Comparison 2 Partial salpingectomy (modified Pomeroy) versus electrocoagulation, Outcome 4 Minor morbidity: total.**

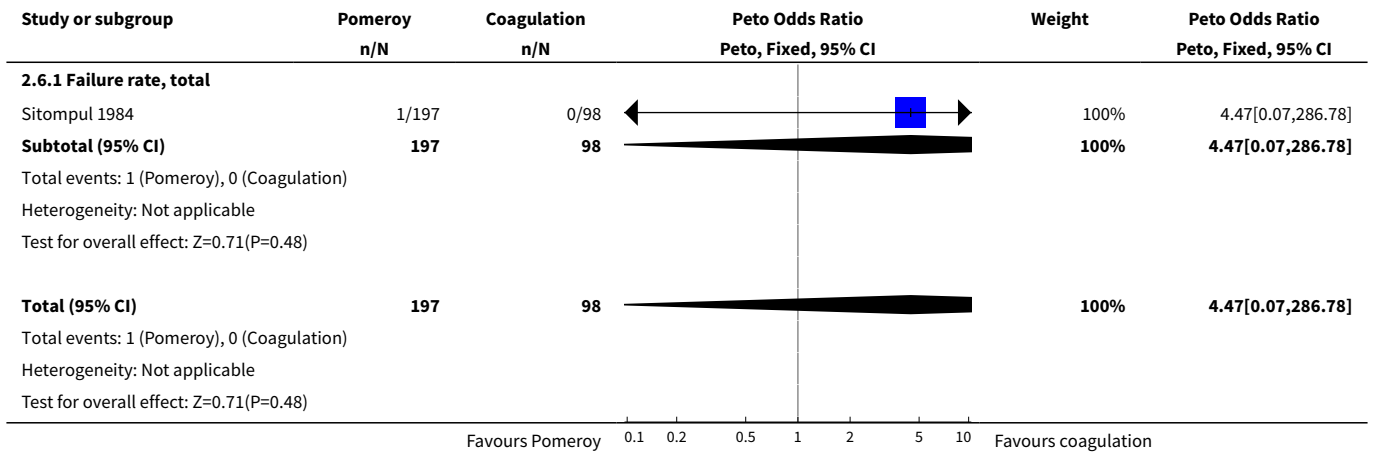


**Analysis 2.5. Comparison 2 Partial salpingectomy (modified Pomeroy) versus electrocoagulation, Outcome 5 Minor morbidity: details.**

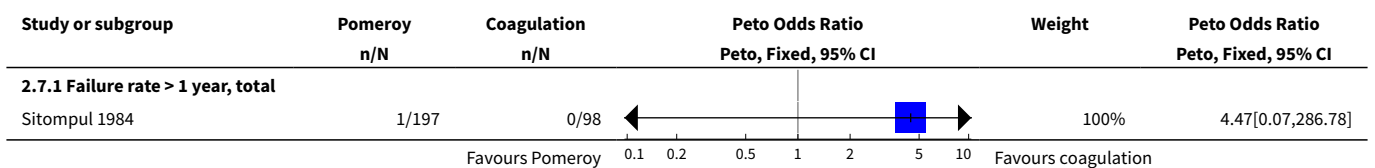


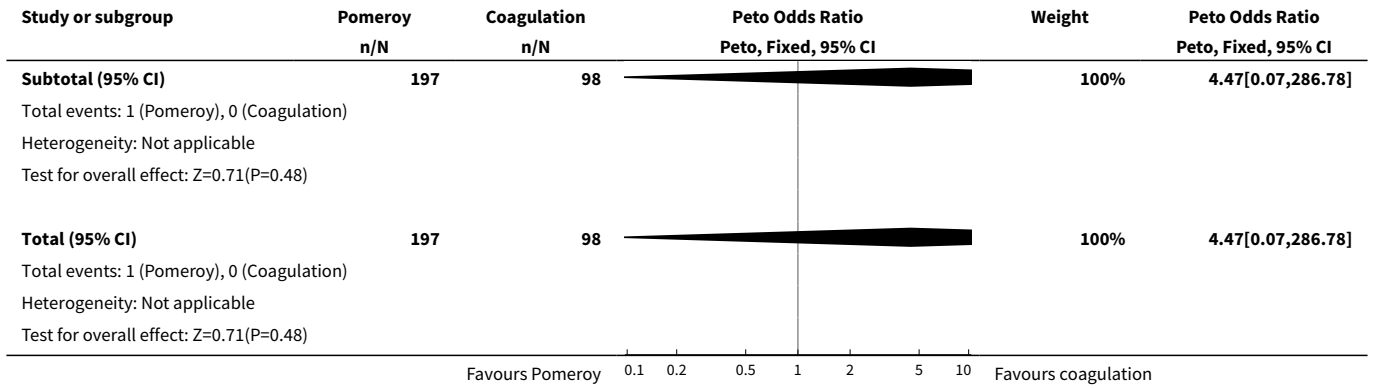


**Analysis 2.6. Comparison 2 Partial salpingectomy (modified Pomeroy) versus electrocoagulation, Outcome 6 Failure rate: total.**

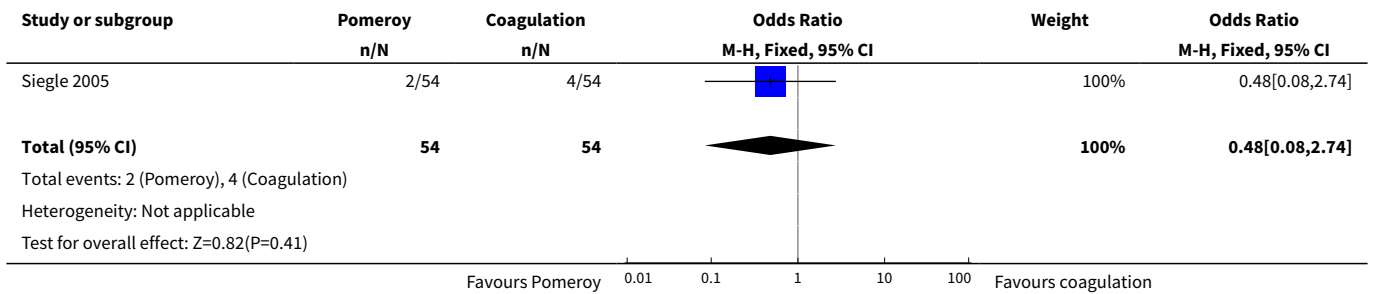


**Analysis 2.7. Comparison 2 Partial salpingectomy (modified Pomeroy) versus electrocoagulation, Outcome 7 Failure rate: details.**

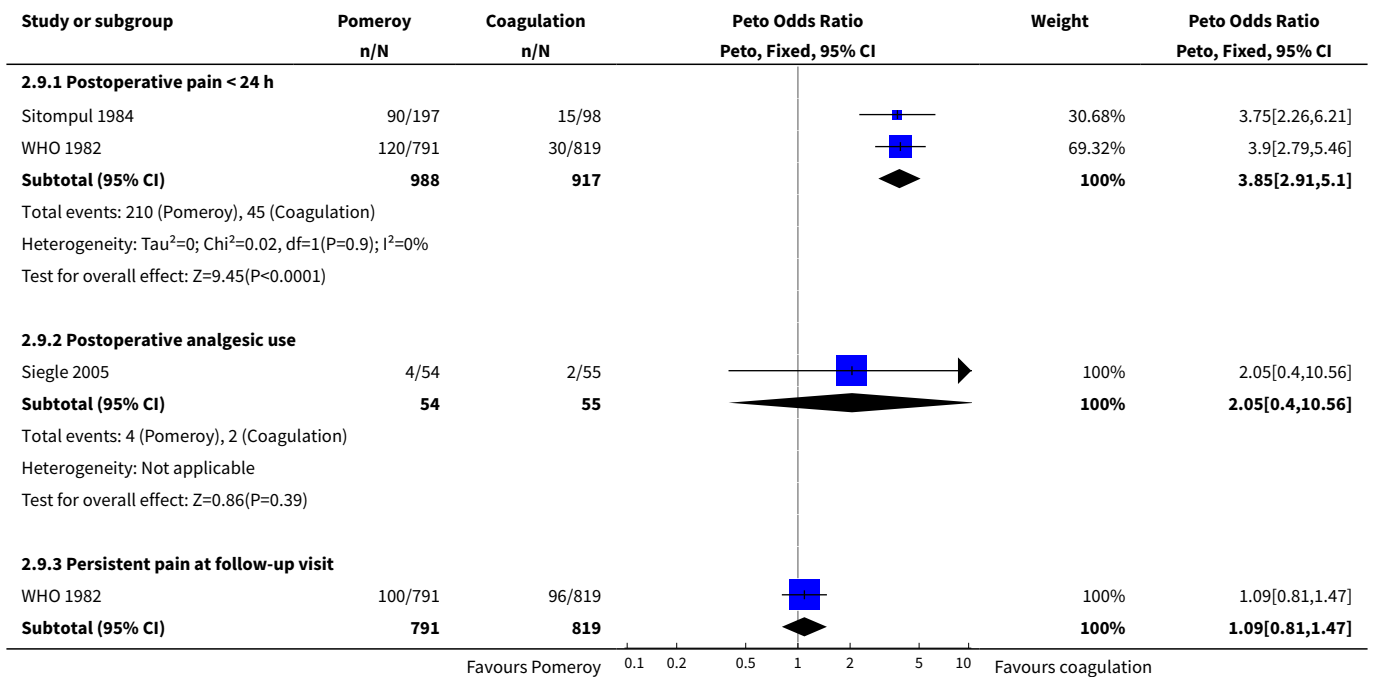


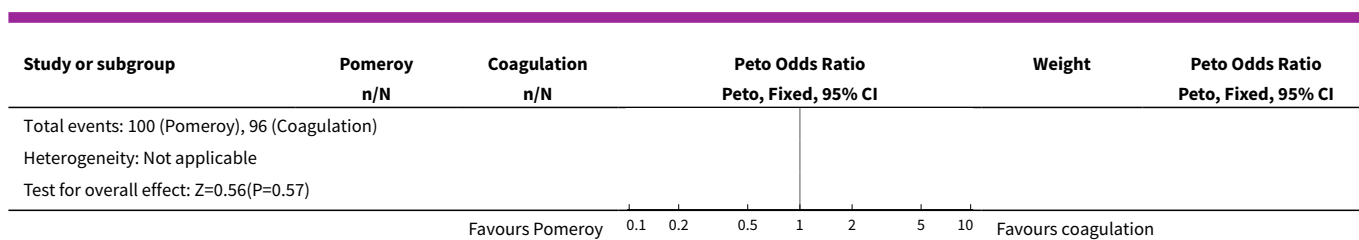


**Analysis 2.8. Comparison 2 Partial salpingectomy (modified Pomeroy) versus electrocoagulation, Outcome 8 Hospital stay more 24 h.**



**Analysis 2.9. Comparison 2 Partial salpingectomy (modified Pomeroy) versus electrocoagulation, Outcome 9 Complaints.**





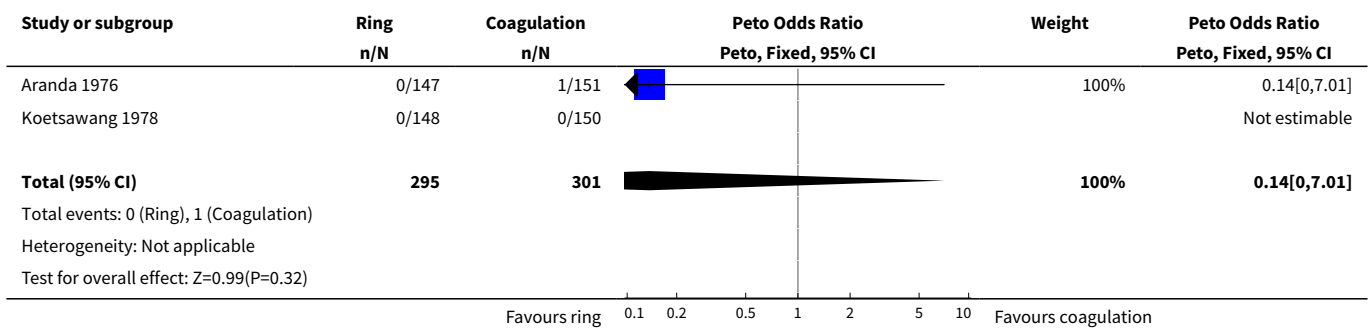
### Comparison 3. Tubal ring versus electrocoagulation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Major morbidity: total	2	596	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.00, 7.01]
2 Major morbidity: details	1	298	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.00, 7.01]
2.1 Procedure-related injuries requiring additional operation or blood transfusion	1	298	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.00, 7.01]
3 Minor morbidity: total	2	596	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.97 [0.50, 1.87]
4 Minor morbidity: details	2		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
4.1 Procedure-related injuries with no additional operation	2	596	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.76 [0.17, 3.38]
4.2 Urogenital infections	1	296	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.03 [0.14, 7.37]
4.3 Wound infection	1	296	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.93 [0.38, 2.25]
4.4 Postoperative temperature > 38 °C without hospitalisation	2	594	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.37 [0.31, 6.06]
5 Technical failures: total	2	596	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.42 [0.59, 19.81]
6 Technical difficulties	1	298	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.01, 1.33]
7 Failure rate: total	1	160	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.1 Failure rate, total	1	160	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Operative time	1	298	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Complaints	2		Odds Ratio (M-H, Random, 95% CI)	Subtotals only

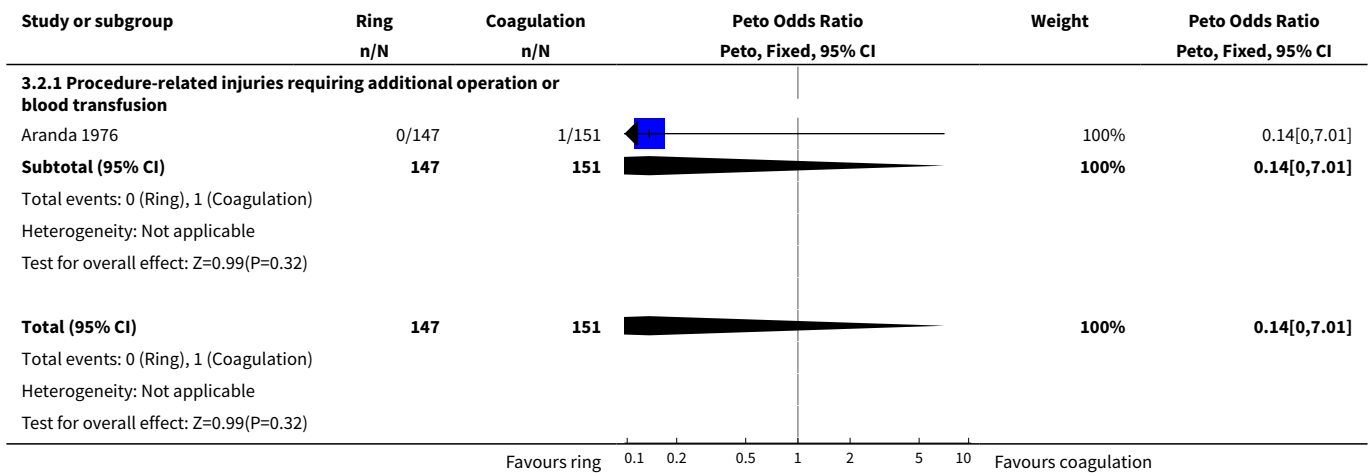


Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.1 Postoperative pain < 24 h	2	596	Odds Ratio (M-H, Random, 95% CI)	3.40 [1.17, 9.84]
9.2 Postoperative analgesic use	1	298	Odds Ratio (M-H, Random, 95% CI)	2.51 [1.00, 6.30]
9.3 Persistent pain at follow-up visit	2	594	Odds Ratio (M-H, Random, 95% CI)	1.22 [0.75, 1.97]
<b>10 Menstrual irregularities</b>	<b>1</b>	<b>296</b>	<b>Peto Odds Ratio (Peto, Fixed, 95% CI)</b>	<b>0.90 [0.56, 1.45]</b>

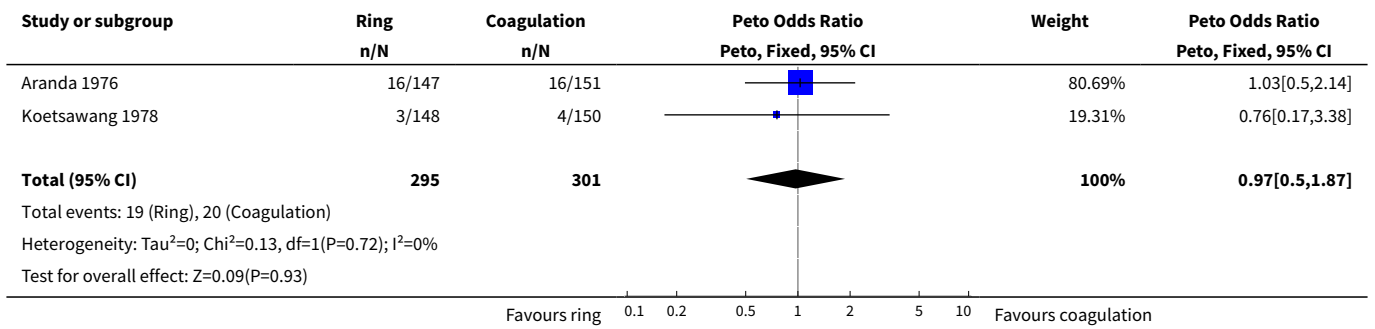
**Analysis 3.1. Comparison 3 Tubal ring versus electrocoagulation, Outcome 1 Major morbidity: total.**



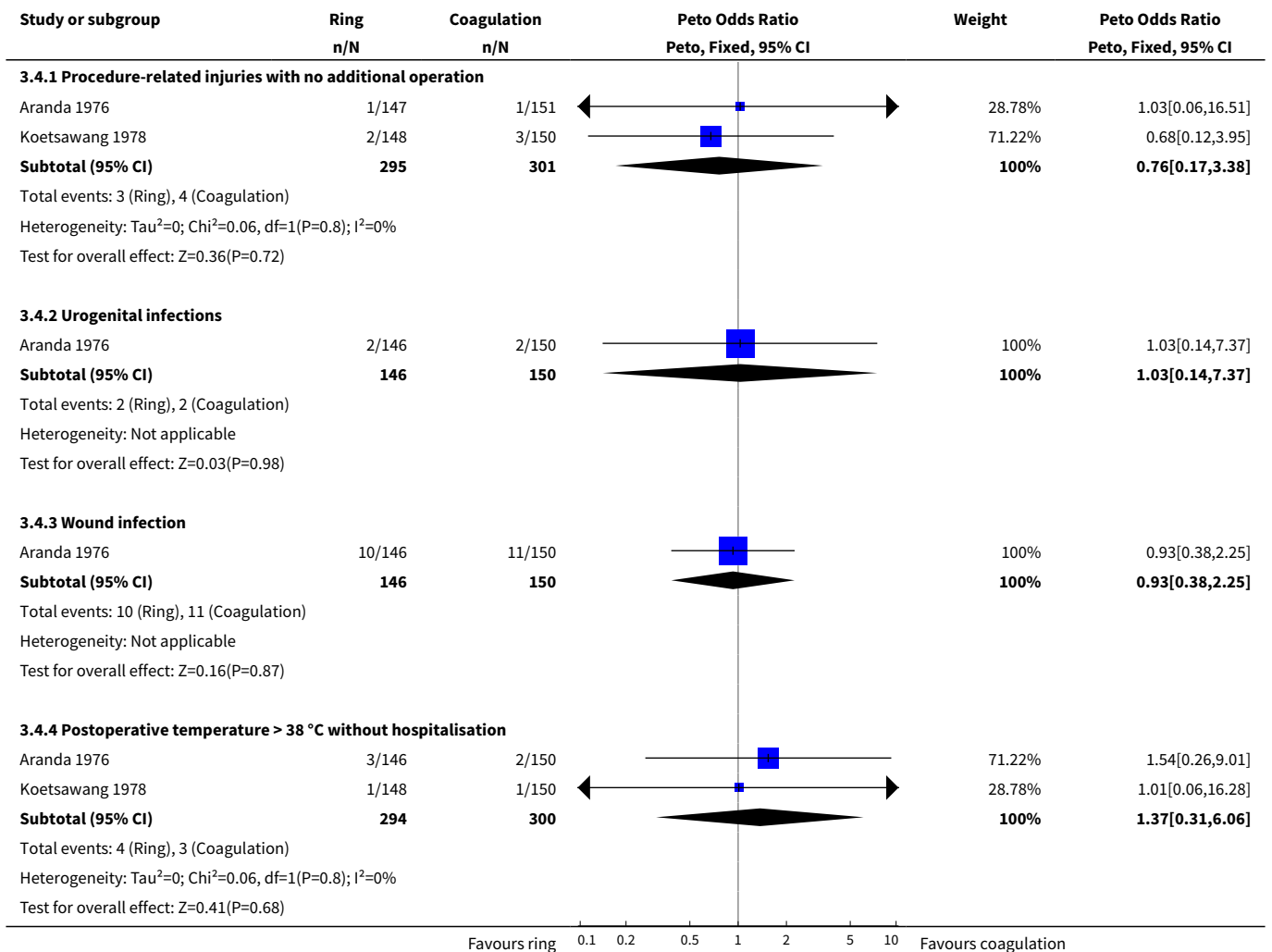
**Analysis 3.2. Comparison 3 Tubal ring versus electrocoagulation, Outcome 2 Major morbidity: details.**



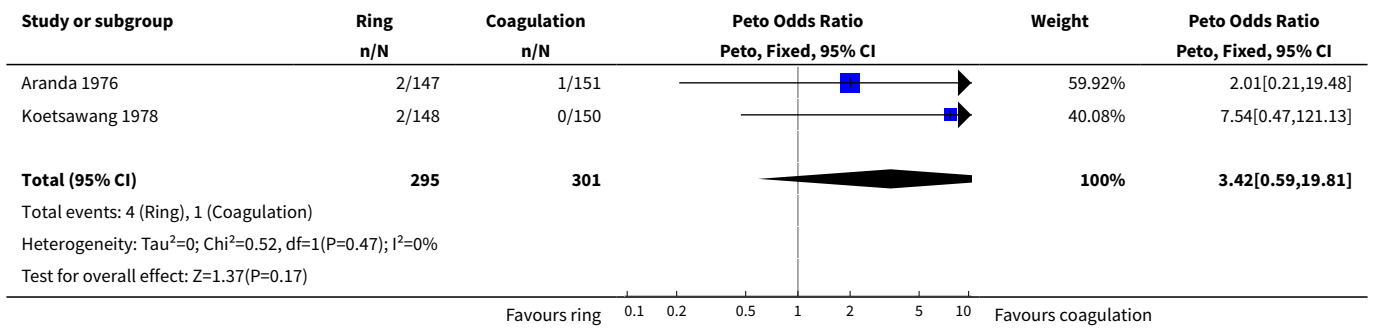
**Analysis 3.3. Comparison 3 Tubal ring versus electrocoagulation, Outcome 3 Minor morbidity: total.**



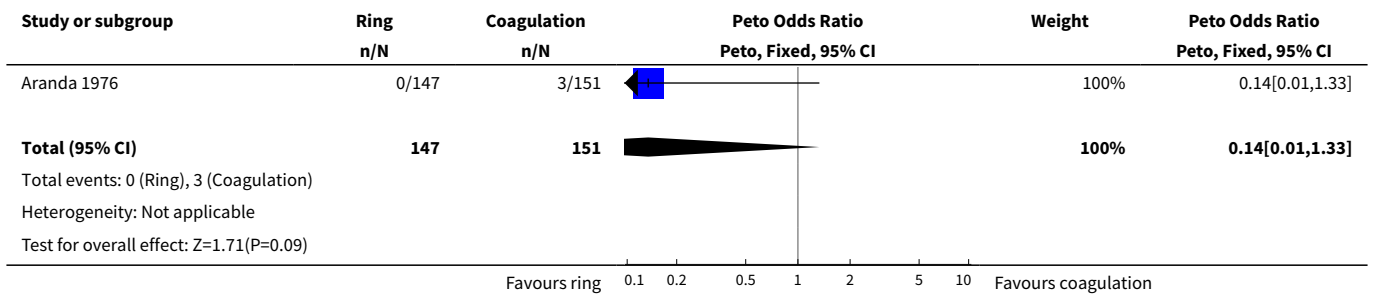
**Analysis 3.4. Comparison 3 Tubal ring versus electrocoagulation, Outcome 4 Minor morbidity: details.**



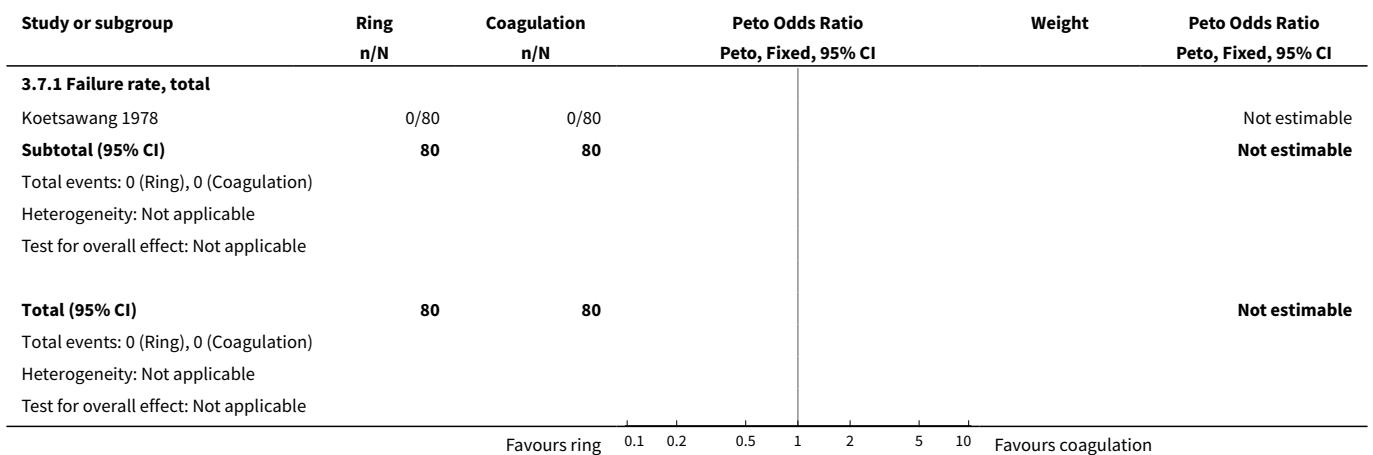
**Analysis 3.5. Comparison 3 Tubal ring versus electrocoagulation, Outcome 5 Technical failures: total.**



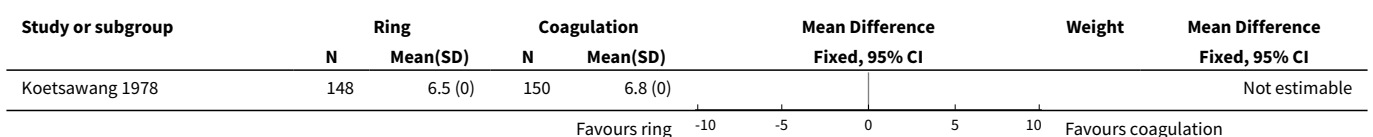
**Analysis 3.6. Comparison 3 Tubal ring versus electrocoagulation, Outcome 6 Technical difficulties.**



**Analysis 3.7. Comparison 3 Tubal ring versus electrocoagulation, Outcome 7 Failure rate: total.**



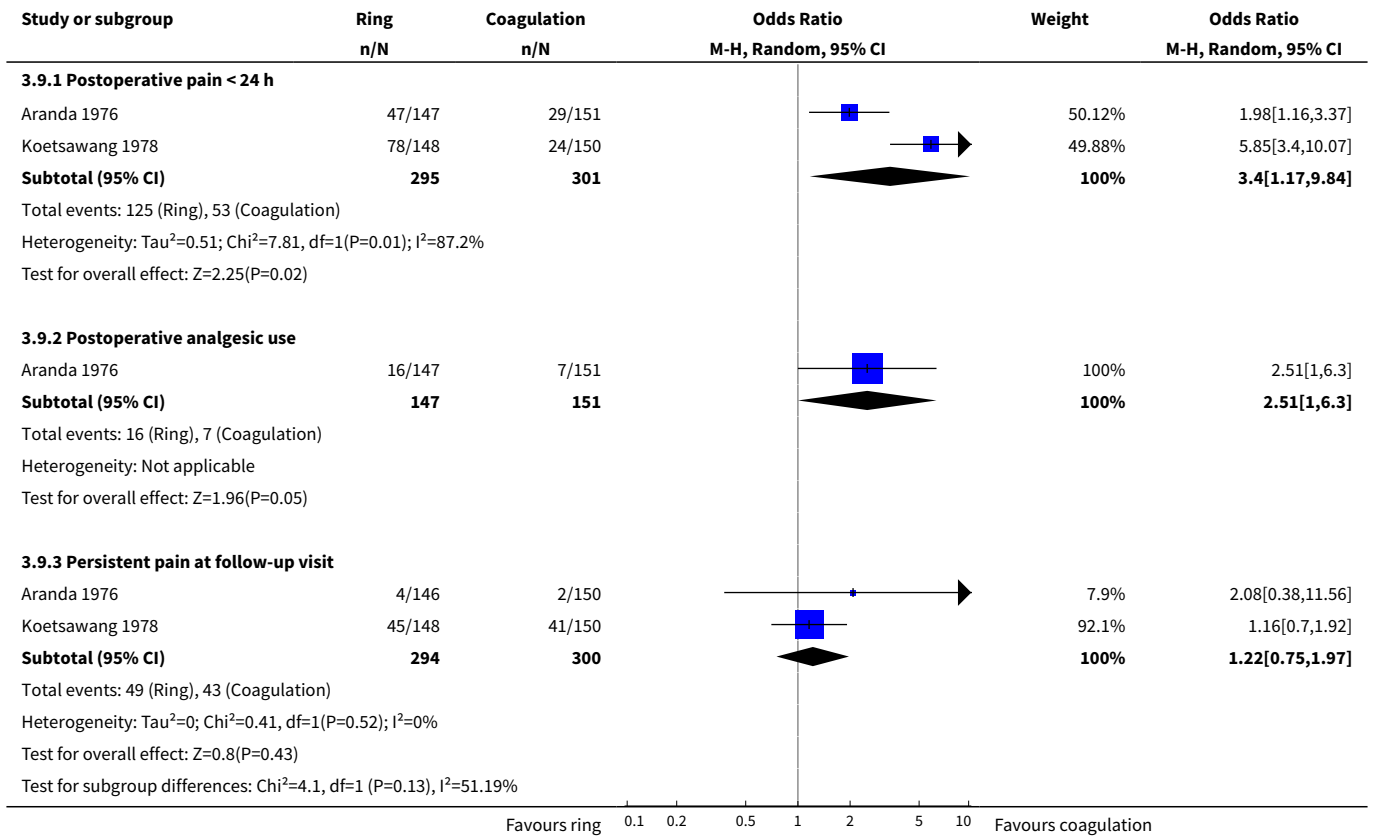
**Analysis 3.8. Comparison 3 Tubal ring versus electrocoagulation, Outcome 8 Operative time.**



Study or subgroup	Ring		Coagulation		Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)			
<b>Total ***</b>	<b>148</b>		<b>150</b>				<b>Not estimable</b>
Heterogeneity: Not applicable Test for overall effect: Not applicable							

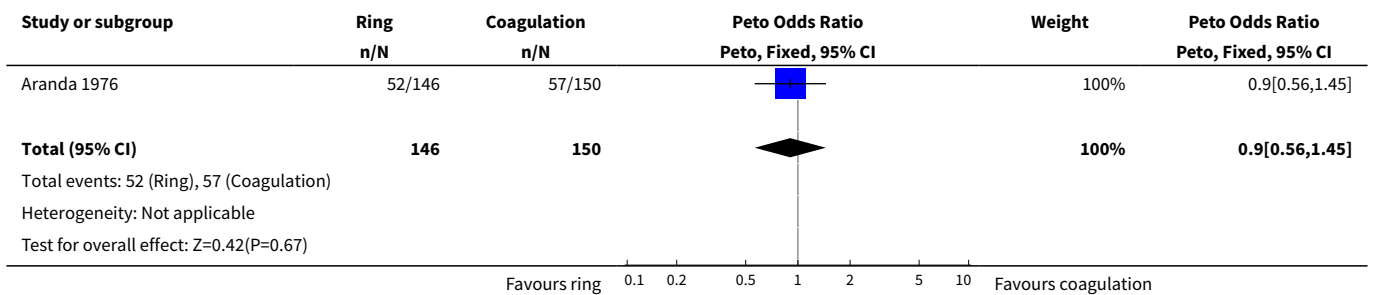
Favours ring -10 -5 0 5 10 Favours coagulation

**Analysis 3.9. Comparison 3 Tubal ring versus electrocoagulation, Outcome 9 Complaints.**



Favours ring 0.1 0.2 0.5 1 2 5 10 Favours coagulation

**Analysis 3.10. Comparison 3 Tubal ring versus electrocoagulation, Outcome 10 Menstrual irregularities.**

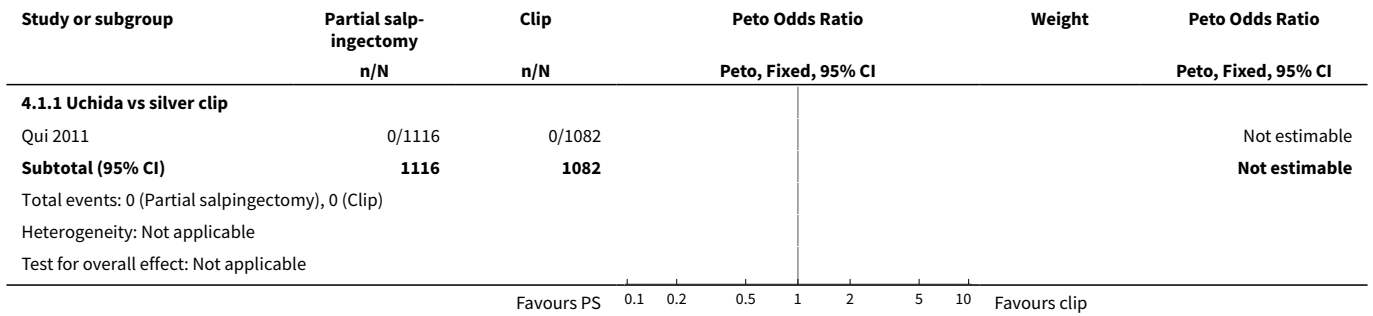


Favours ring 0.1 0.2 0.5 1 2 5 10 Favours coagulation

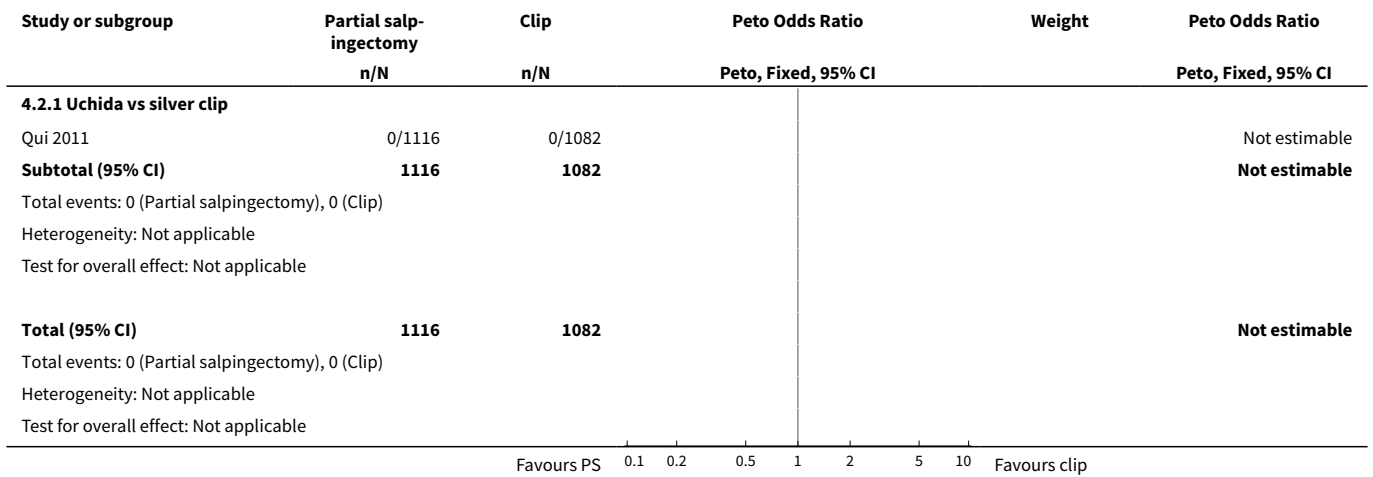
**Comparison 4. Partial salpingectomy (PS) versus clip**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
<b>1 Operative mortality</b>	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
1.1 Uchida vs silver clip	1	2198	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
<b>2 Major morbidity: total</b>	1	2198	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.1 Uchida vs silver clip	1	2198	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
<b>3 Minor morbidity: total</b>	1	193	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.39 [0.46, 119.01]
<b>4 Minor morbidity: details</b>	1	193	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.39 [0.46, 119.01]
4.1 Procedure related injuries with no additional operation	1	193	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.39 [0.46, 119.01]
<b>5 Technical failures</b>	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
5.1 Uchida vs silver clip	1	2198	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.18 [0.08, 0.40]
<b>6 Technical difficulties</b>	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
6.1 Uchida vs silver clip	1	2198	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.97 [0.42, 2.24]
<b>7 Failure rate: total</b>	3	3685	Odds Ratio (M-H, Random, 95% CI)	0.36 [0.08, 1.59]
7.1 Pomeroy vs Filshie	2	1548	Odds Ratio (M-H, Random, 95% CI)	0.59 [0.04, 7.79]
7.2 Uchida vs silver clip	1	2137	Odds Ratio (M-H, Random, 95% CI)	0.19 [0.01, 3.95]
<b>8 Operative time</b>	2	2223	Mean Difference (IV, Fixed, 95% CI)	4.26 [3.65, 4.86]
8.1 Pomeroy vs Filshie	1	25	Mean Difference (IV, Fixed, 95% CI)	6.70 [0.77, 12.63]
8.2 Uchida vs silver clip	1	2198	Mean Difference (IV, Fixed, 95% CI)	4.23 [3.62, 4.84]
<b>9 All complaints</b>	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
9.1 Uchida vs silver clip	1	2137	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.30 [0.92, 1.82]
<b>10 Menstrual irregularities</b>	2	2283	Odds Ratio (M-H, Random, 95% CI)	1.43 [0.73, 2.79]
10.1 Pomeroy vs Filshie	1	146	Odds Ratio (M-H, Random, 95% CI)	2.49 [0.88, 7.05]
10.2 Uchida vs silver clip	1	2137	Odds Ratio (M-H, Random, 95% CI)	1.16 [0.90, 1.49]
<b>11 Women's satisfaction</b>	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
11.1 Uchida vs silver clip	1	2110	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.27 [0.99, 1.64]
<b>12 Surgeon's satisfaction</b>			Other data	No numeric data

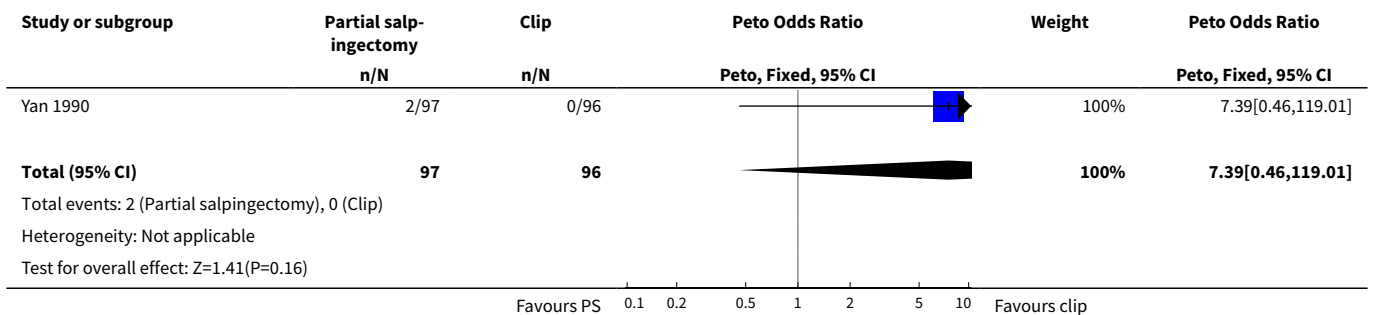
**Analysis 4.1. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 1 Operative mortality.**



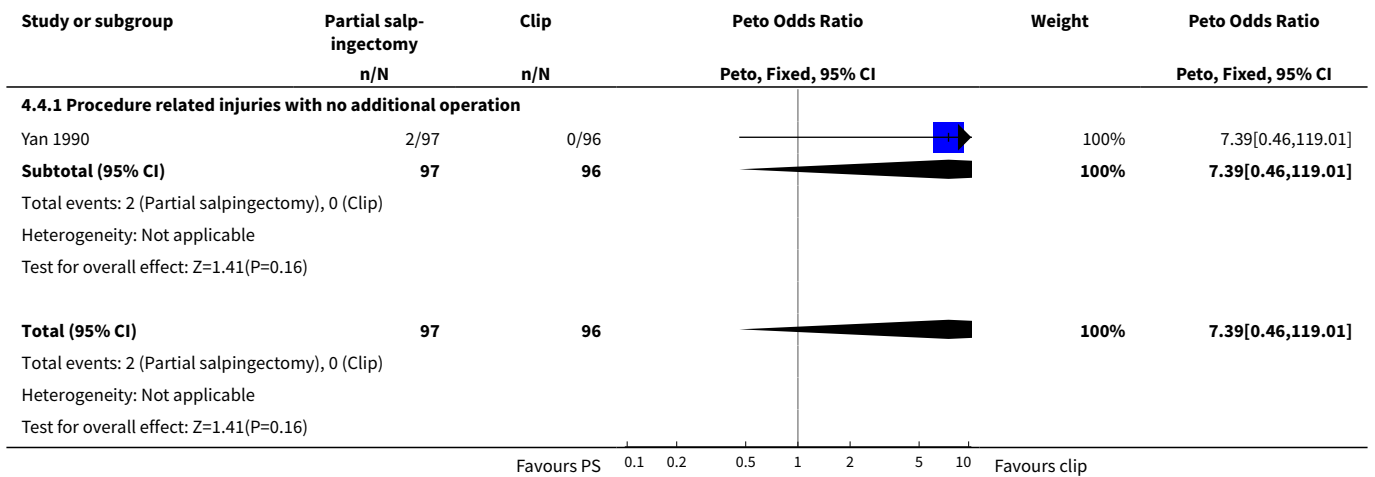
**Analysis 4.2. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 2 Major morbidity: total.**



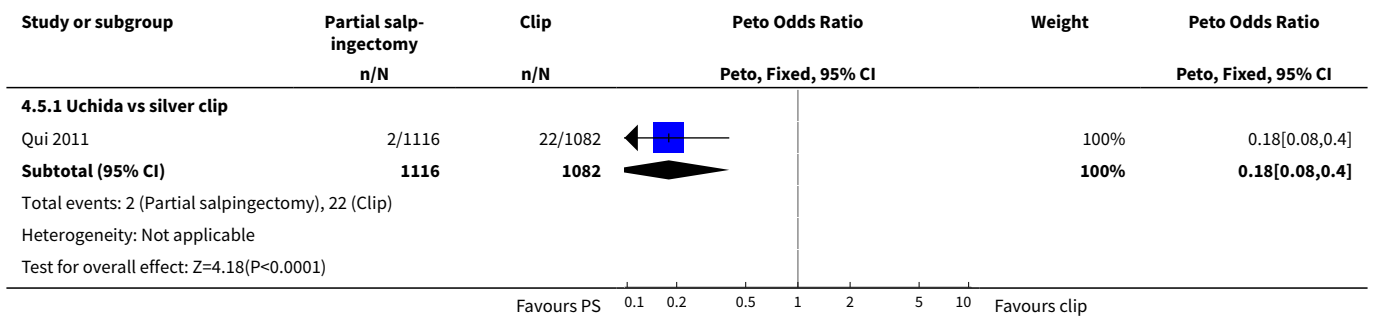
**Analysis 4.3. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 3 Minor morbidity: total.**



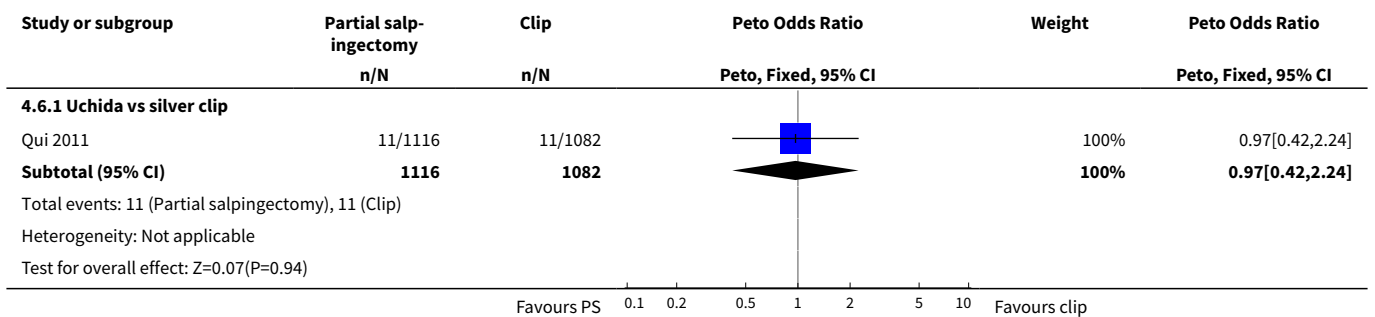
**Analysis 4.4. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 4 Minor morbidity: details.**



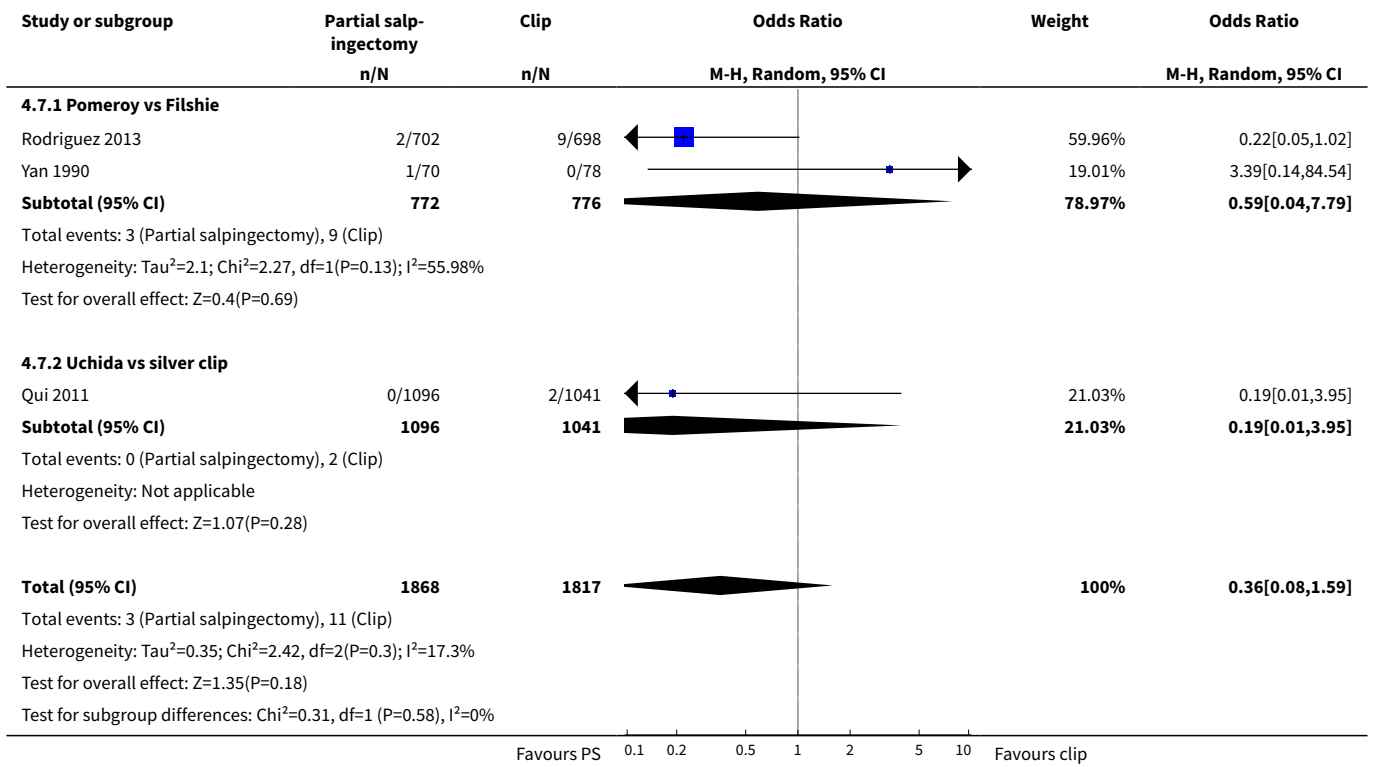
**Analysis 4.5. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 5 Technical failures.**



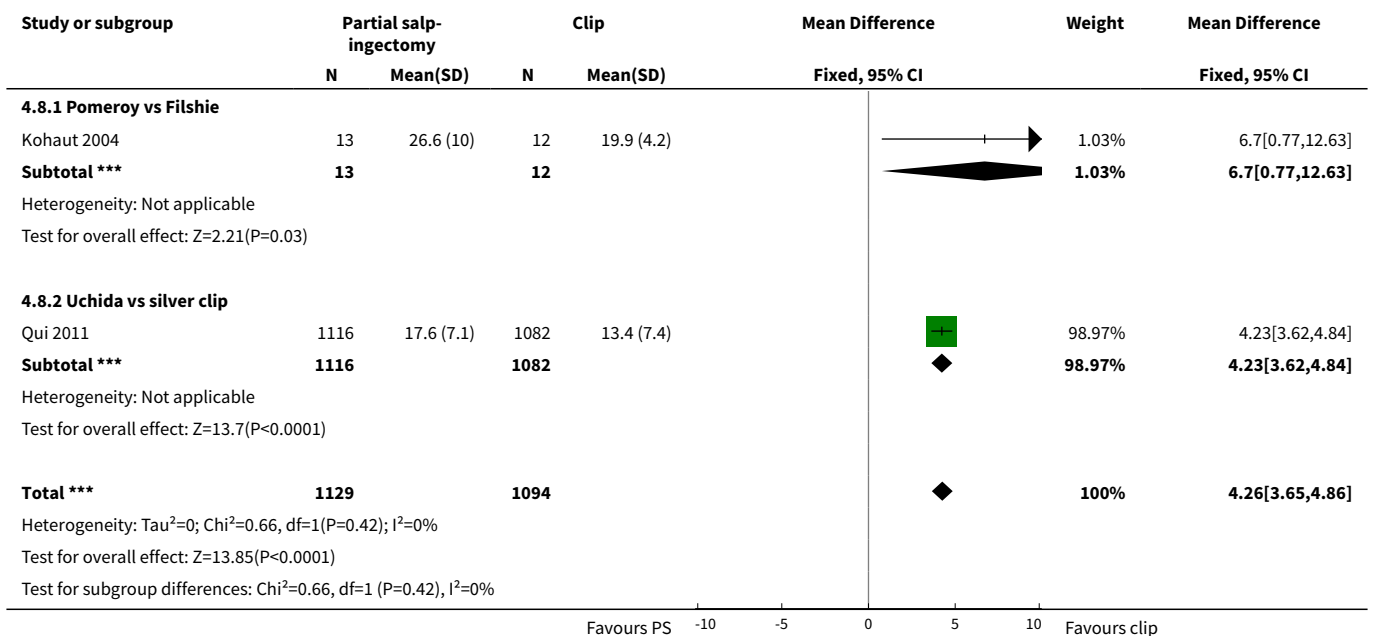
**Analysis 4.6. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 6 Technical difficulties.**



**Analysis 4.7. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 7 Failure rate: total.**

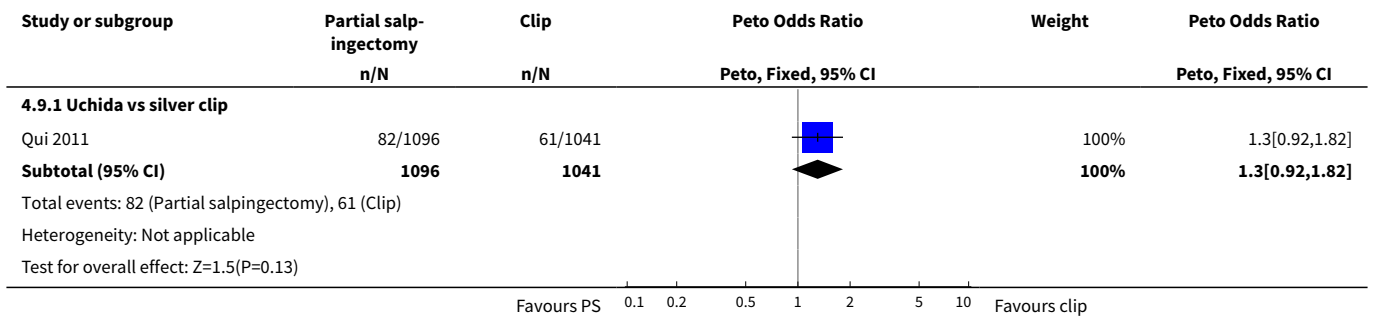


**Analysis 4.8. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 8 Operative time.**

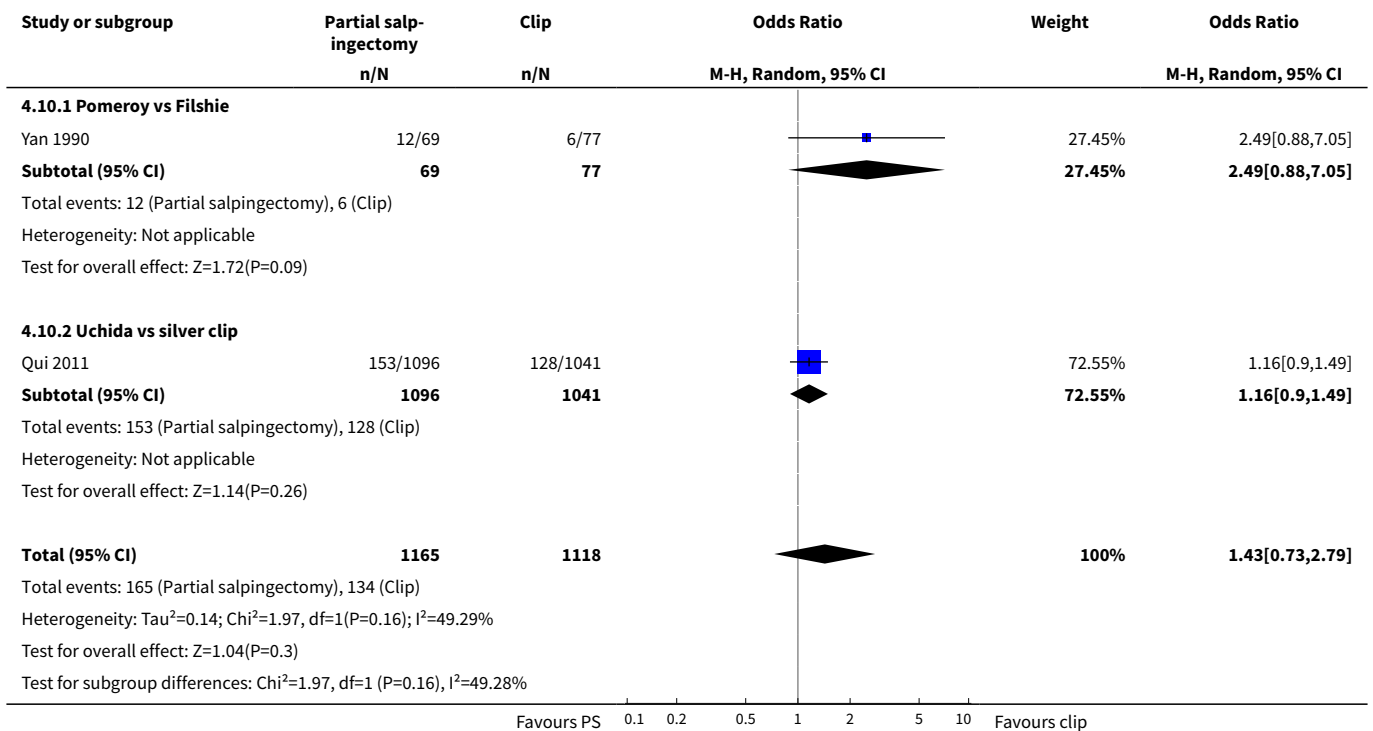




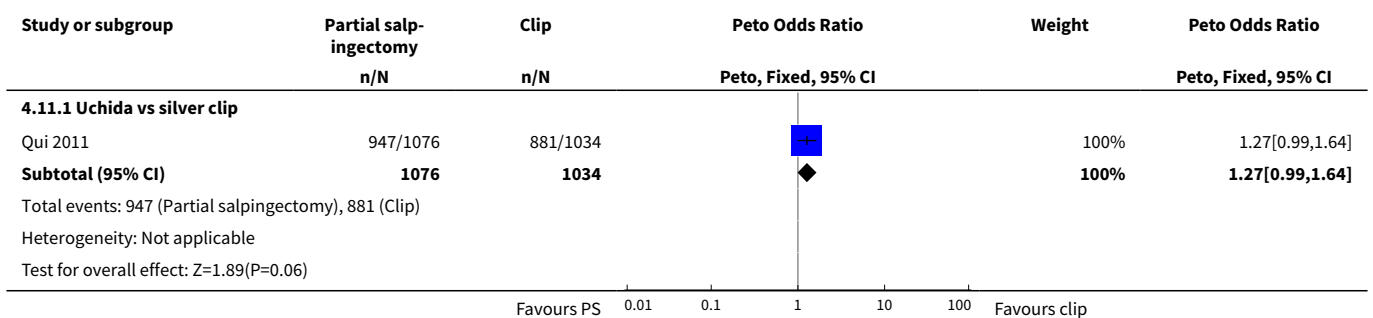
**Analysis 4.9. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 9 All complaints.**



**Analysis 4.10. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 10 Menstrual irregularities.**



**Analysis 4.11. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 11 Women's satisfaction.**



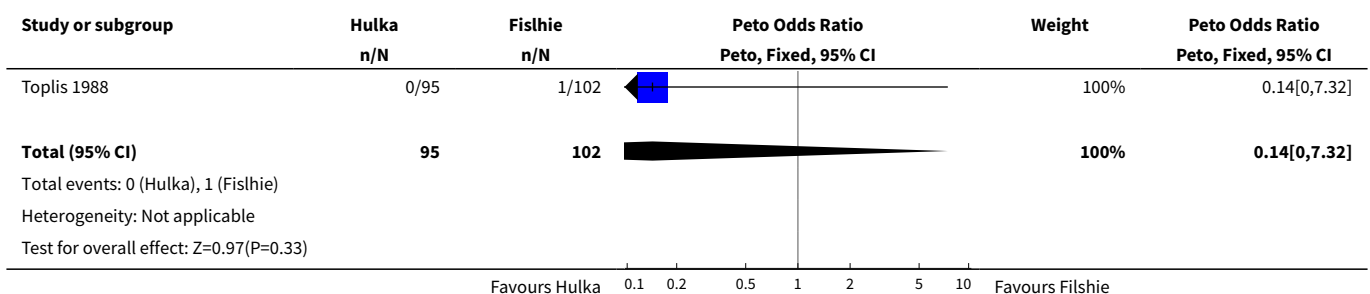
**Analysis 4.12. Comparison 4 Partial salpingectomy (PS) versus clip, Outcome 12 Surgeon's satisfaction.**

Study	Surgeon's satisfaction
Kohaut 2004	Seven out of 10 surgeons performing a total of 29 sterilisations preferred the Filshie clip method to the Pomeroy method.

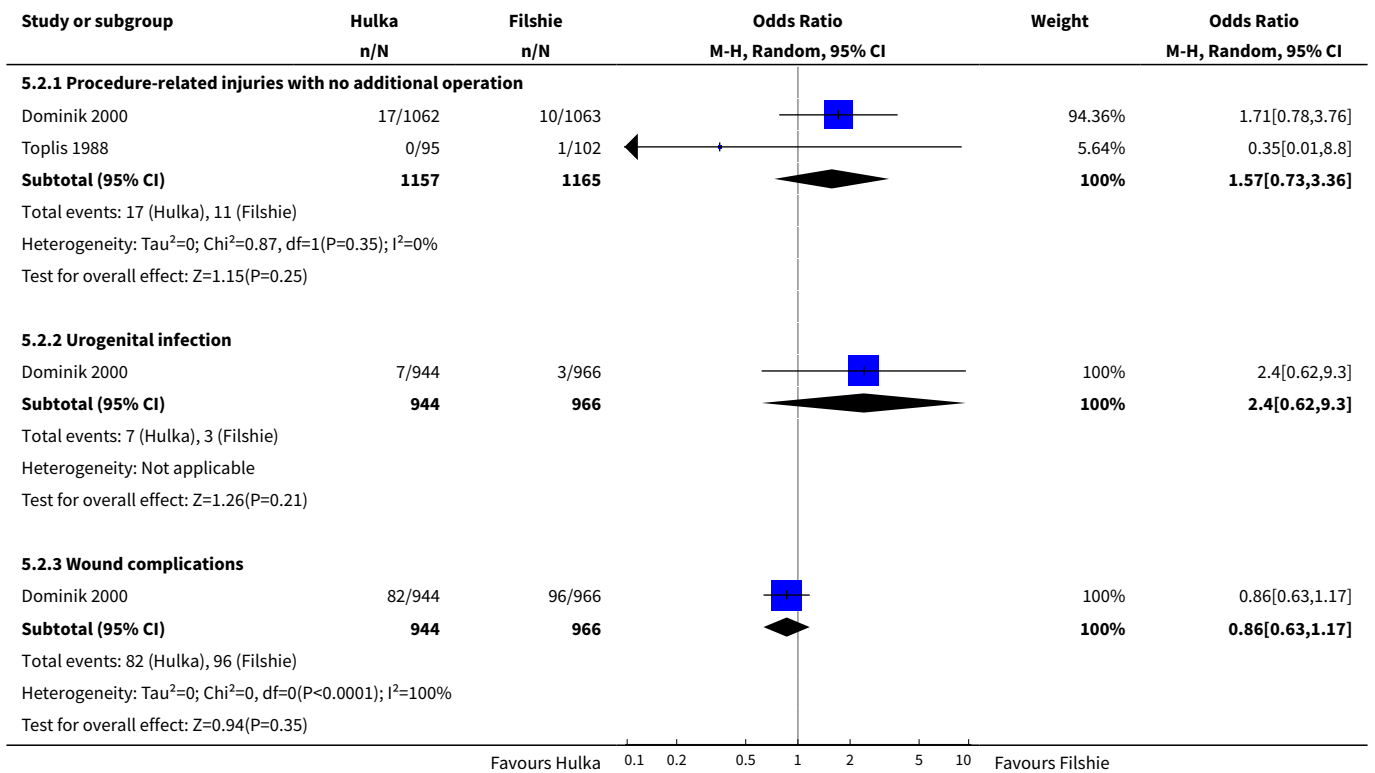
**Comparison 5. Hulka versus Filshie clip**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Minor morbidity: total	1	197	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.00, 7.32]
2 Minor morbidity: details	2		Odds Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 Procedure-related injuries with no additional operation	2	2322	Odds Ratio (M-H, Random, 95% CI)	1.57 [0.73, 3.36]
2.2 Urogenital infection	1	1910	Odds Ratio (M-H, Random, 95% CI)	2.40 [0.62, 9.30]
2.3 Wound complications	1	1910	Odds Ratio (M-H, Random, 95% CI)	0.86 [0.63, 1.17]
3 Technical failures	2	2325	Odds Ratio (M-H, Random, 95% CI)	1.04 [0.10, 11.33]
4 Technical difficulties	2	2323	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.51 [1.09, 2.10]
5 Failure rate: total	1	1441	Odds Ratio (M-H, Fixed, 95% CI)	6.20 [0.75, 51.66]
6 Operative time	1	197	Mean Difference (IV, Fixed, 95% CI)	0.70 [-0.04, 1.44]
7 Complaints	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
7.1 Postoperative pain < 24 h	1	197	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.74 [0.99, 3.03]

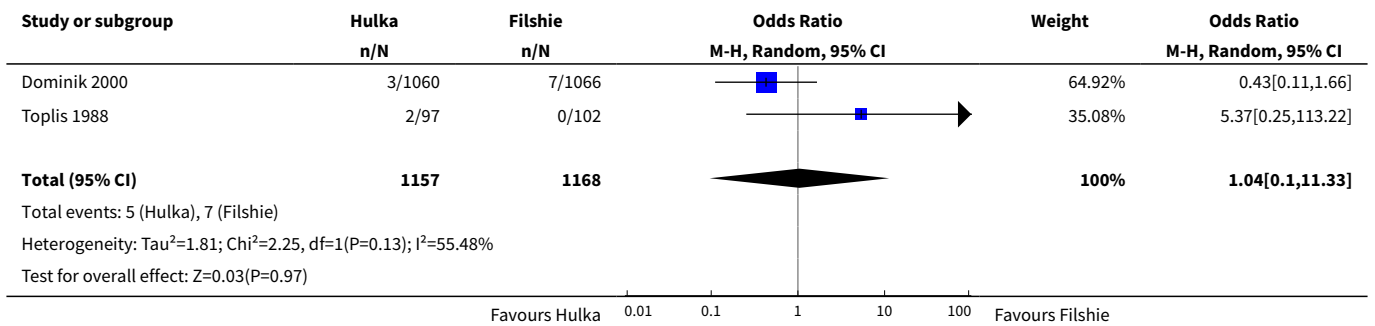
**Analysis 5.1. Comparison 5 Hulka versus Filshie clip, Outcome 1 Minor morbidity: total.**



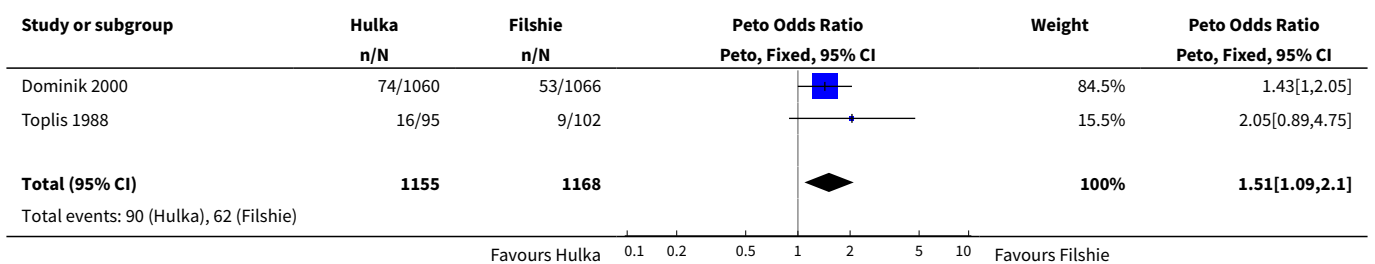
**Analysis 5.2. Comparison 5 Hulka versus Filshie clip, Outcome 2 Minor morbidity: details.**

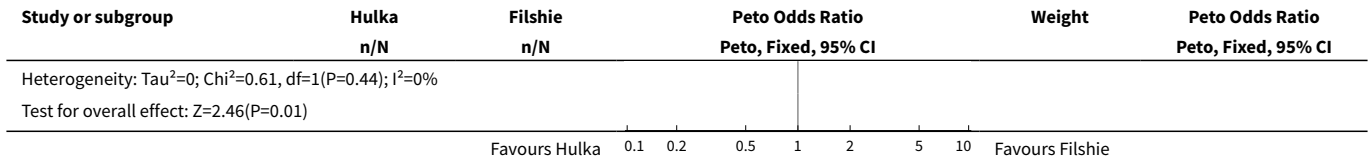


**Analysis 5.3. Comparison 5 Hulka versus Filshie clip, Outcome 3 Technical failures.**

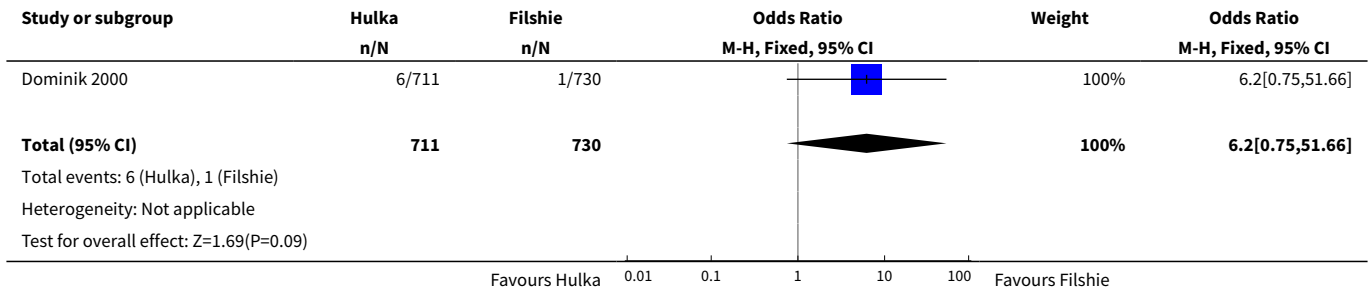


**Analysis 5.4. Comparison 5 Hulka versus Filshie clip, Outcome 4 Technical difficulties.**

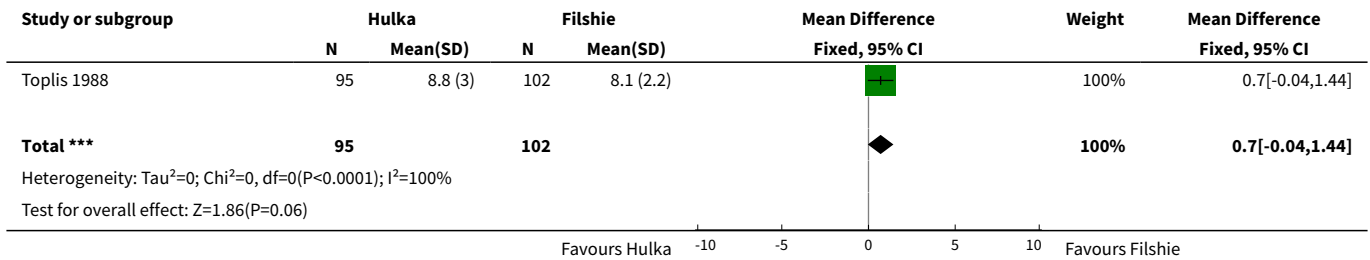




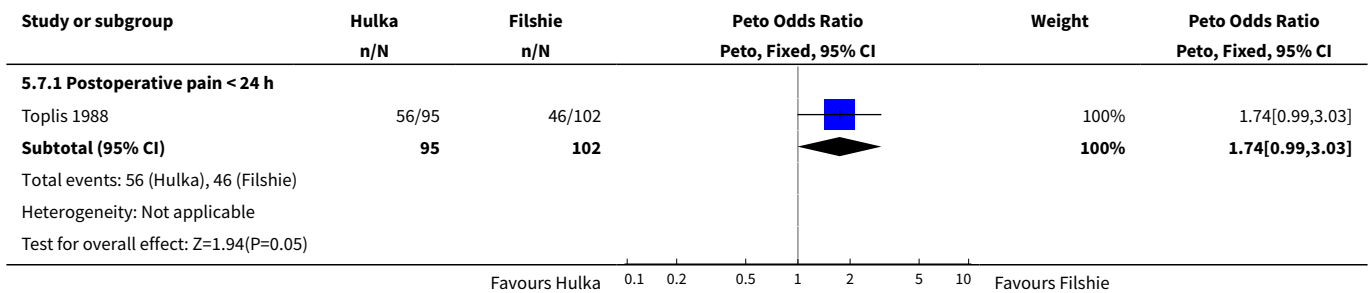
**Analysis 5.5. Comparison 5 Hulka versus Filshie clip, Outcome 5 Failure rate: total.**



**Analysis 5.6. Comparison 5 Hulka versus Filshie clip, Outcome 6 Operative time.**



**Analysis 5.7. Comparison 5 Hulka versus Filshie clip, Outcome 7 Complaints.**



## APPENDICES

### Appendix 1. Risk of bias assessment used in earlier versions of this review

A quality score for concealment of allocation was assigned to each trial, using the following criteria:

A = adequate concealment of allocation

B = unclear whether concealment of allocation is adequate

C = inadequate concealment of allocation, quasi-randomisation

Only studies scoring A or B were included in the review originally.

For withdrawals, studies were classified as follows:

a = less than 3% of participants withdrawn;

b = between 3% to 9.9% of participants withdrawn;

c = between 10% to 19.9% of participants withdrawn.

Trials were excluded if it was not possible to enter data on an intention-to-treat basis and/or 20% or more participants were excluded.

### WHAT'S NEW

Date	Event	Description
10 August 2015	New citation required but conclusions have not changed	Review updated.
31 July 2015	New search has been performed	Seven additional studies included. Risk of bias assessment methods updated.

### HISTORY

Protocol first published: Issue 2, 2001

Review first published: Issue 4, 2002

Date	Event	Description
27 August 2010	New citation required but conclusions have not changed	Update submitted.
15 May 2010	New search has been performed	Three additional studies included (Kohaut 2004, Gentile 2006 and Pymar 2004).
3 March 2010	New search has been performed	Search updated.
15 April 2008	Amended	Converted to new review format.
20 July 2002	New citation required and conclusions have changed	Substantive amendment

### CONTRIBUTIONS OF AUTHORS

JM Nardin and R Kulier wrote the original version of the review, performed the methodological assessment of studies, and performed the data extraction. TL and RK updated the review in 2010 and 2015. All listed authors reviewed the draft manuscript and approved the final version.

### DECLARATIONS OF INTEREST

TL: none known

**Techniques for the interruption of tubal patency for female sterilisation (Review)**

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RK: none known  
JMN: none known

## SOURCES OF SUPPORT

### Internal sources

- Department of Obstetrics and Gynaecology, University Hospital of Geneva (HUG), Switzerland.
- Centro Rosarino de Estudios Perinatales (CREP), Rosario, Argentina.

### External sources

- Department of Reproductive Health and Research. World Health Organization (WHO), Geneva, Switzerland.
- National Institute for Health Research, UK.

**“This project was supported by the National Institute for Health Research, via Cochrane Incentive Award funding to the Fertility Regulation Group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.”**

- New Source of support, Other.

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The protocol and previous versions of this review used an older Cochrane method for assessment of the risk of bias of studies (see [Appendix 1](#)). We updated the methodology for the 2015 review to reflect current Cochrane 'Risk of bias' assessment methods.

## INDEX TERMS

### Medical Subject Headings (MeSH)

\*Surgical Instruments [adverse effects]; Electrocoagulation [\*methods]; Randomized Controlled Trials as Topic; Salpingectomy [\*methods]; Sterilization, Tubal [adverse effects] [instrumentation] [\*methods]

### MeSH check words

Female; Humans