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Robot-assisted surgery in gynaecology (Review)

Lawrie TA, Liu H, Lu D, Dowswell T, Song H, Wang L, Shi G

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Robot-assisted surgery in gynaecology (Review)

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TABLE OF CONTENTS

ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
SUMMARY OF FINDINGS	4
BACKGROUND	7
OBJECTIVES	8
METHODS	9
RESULTS	11
Figure 1.	12
Figure 2.	14
Figure 3.	17
DISCUSSION	22
AUTHORS' CONCLUSIONS	24
ACKNOWLEDGEMENTS	24
REFERENCES	25
CHARACTERISTICS OF STUDIES	33
DATA AND ANALYSES	56
Analysis 1.1. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 1 Intraoperative and postoperative complications.	59
Analysis 1.2. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 2 Intraoperative complications.	60
Analysis 1.3. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 3 Complications: intraoperative injury.	60
Analysis 1.4. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 4 Postoperative complications.	61
Analysis 1.5. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 5 Complications: bleeding.	61
Analysis 1.6. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 6 Complications: infection.	62
Analysis 1.7. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 7 Total operating time.	62
Analysis 1.8. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 8 Operating room time [min].	62
Analysis 1.9. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 9 Overall hospital stay.	63
Analysis 1.10. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 10 Conversion to another approach.	63
Analysis 1.11. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 11 Blood transfusions.	64
Analysis 1.12. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 12 Estimated blood loss.	64
Analysis 1.13. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 13 Pain at 1 to 2 weeks.	65
Analysis 1.14. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 14 Quality of life (6 weeks).	65
Analysis 1.15. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 15 Quality of life (6 months).	65
Analysis 1.16. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 16 Re-intervention.	66
Analysis 1.17. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 17 Re-admission.	66
Analysis 1.18. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 18 Overall cost.	66
Analysis 2.1. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 1 Intraoperative and postoperative complications.	68

Analysis 2.2. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 2 Intraoperative complications.	68
Analysis 2.3. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 3 Complications: intraoperative injury.	69
Analysis 2.4. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 4 Postoperative complications.	69
Analysis 2.6. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 6 Complications: infection.	69
Analysis 2.7. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 7 Total operating time.	69
Analysis 2.8. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 8 Operating room time [min].	70
Analysis 2.9. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 9 Overall hospital stay.	70
Analysis 2.10. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 10 Conversion to another approach.	70
Analysis 2.12. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 12 Estimated blood loss.	71
Analysis 2.13. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 13 Pain at 1 to 2 weeks.	71
Analysis 2.14. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 14 Quality of life (6 weeks).	71
Analysis 2.16. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 16 Re-intervention.	72
Analysis 2.18. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 18 Overall cost.	72
Analysis 2.19. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 19 Complications: urinary incontinence.	72
Analysis 2.20. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 20 Complications: sexual dysfunction.	72
Analysis 3.1. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 1 Intraoperative and postoperative complications.	74
Analysis 3.2. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 2 Intraoperative complications.	75
Analysis 3.3. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 3 Postoperative complications.	75
Analysis 3.4. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 4 Death within 30 days.	76
Analysis 3.5. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 5 Complications: bleeding.	76
Analysis 3.6. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 6 Complications: infection.	76
Analysis 3.7. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 7 Blood transfusions.	77
Analysis 3.8. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 8 Quality of life (4 weeks).	77
Analysis 3.9. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 9 Re-admission.	77
Analysis 3.10. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 10 Overall cost.	78
Analysis 3.11. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 11 Lymph node yield.	78
Analysis 4.1. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 1 Intraoperative complications.	79
Analysis 4.2. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 2 Postoperative complications.	80

Analysis 4.3. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 3 Complications: infection.	80
Analysis 4.4. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 4 Total operating time.	80
Analysis 4.5. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 5 Operating room time [min].	80
Analysis 4.6. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 6 Conversion to another approach.	81
Analysis 4.7. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 7 Estimated blood loss.	81
Analysis 4.8. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 8 Quality of life (6 weeks).	81
Analysis 4.9. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 9 Quality of life (6 months).	82
Analysis 4.10. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 10 Re-admission.	82
Analysis 4.11. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 11 Pain at 6 months.	82
APPENDICES	82
WHAT'S NEW	83
HISTORY	84
CONTRIBUTIONS OF AUTHORS	84
DECLARATIONS OF INTEREST	84
SOURCES OF SUPPORT	84
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	84
INDEX TERMS	85

[Intervention Review]

Robot-assisted surgery in gynaecology

Theresa A Lawrie¹, Hongqian Liu², DongHao Lu², Therese Dowswell³, Huan Song⁴, Lei Wang⁵, Gang Shi²

¹E-MBC Ltd, Office 305, 3rd floor, Bath, UK. ²Department of Obstetrics and Gynecology, West China Second University Hospital, Sichuan University, Chengdu, China. ³C/o Cochrane Pregnancy and Childbirth Group, Department of Women's and Children's Health, The University of Liverpool, Liverpool, UK. ⁴Center of Public Health Sciences, Faculty of Medicine, University of Iceland, Reykjavík, Iceland. ⁵Department of Orthopedics, West China Second University Hospital, Sichuan University, Chengdu, China

Contact: Gang Shi, Department of Obstetrics and Gynecology, West China Second University Hospital, Sichuan University, No. 17, Section Three, Ren Min Nan Lu Avenue, Chengdu, Sichuan, 610041, China. dr.gangshi@gmail.com, gang-shi@163.com.

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ABSTRACT

Background

This is an updated merged review of two originally separate Cochrane reviews: one on robot-assisted surgery (RAS) for benign gynaecological disease, the other on RAS for gynaecological cancer. RAS is a relatively new innovation in laparoscopic surgery that enables the surgeon to conduct the operation from a computer console, situated away from the surgical table. RAS is already widely used in the United States for hysterectomy and has been shown to be feasible for other gynaecological procedures. However, the clinical effectiveness and safety of RAS compared with conventional laparoscopic surgery (CLS) have not been clearly established and require independent review.

Objectives

To assess the effectiveness and safety of RAS in the treatment of women with benign and malignant gynaecological disease.

Search methods

For this update, we searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE via Ovid, and EMBASE via Ovid, on 8 January 2018. We searched www.ClinicalTrials.gov on 16 January 2018.

Selection criteria

Randomised controlled trials (RCTs) comparing RAS versus CLS or open surgery in women requiring surgery for gynaecological disease.

Data collection and analysis

Two review authors independently assessed studies for inclusion and risk of bias, and extracted study data and entered them into an Excel spreadsheet. We examined different procedures in separate comparisons and for hysterectomy subgrouped data according to type of disease (non-malignant versus malignant). When more than one study contributed data, we pooled data using random-effects methods in RevMan 5.3.

Main results

We included 12 RCTs involving 1016 women. Studies were at moderate to high overall risk of bias, and we downgraded evidence mainly due to concerns about risk of bias in the studies contributing data and imprecision of effect estimates. Procedures performed were hysterectomy (eight studies) and sacrocolpopexy (three studies). In addition, one trial examined surgical treatment for endometriosis,

which included resection or hysterectomy. Among studies of women undergoing hysterectomy procedures, two studies involved malignant disease (endometrial cancer); the rest involved non-malignant disease.

• RAS versus CLS (hysterectomy)

Low-certainty evidence suggests there might be little or no difference in any complication rates between RAS and CLS (risk ratio (RR) 0.92, 95% confidence interval (CI) 0.54 to 1.59; participants = 585; studies = 6; $I^2 = 51\%$), intraoperative complication rates (RR 1.05, 95% CI 0.31 to 3.56; participants = 487; studies = 5; $I^2 = 28\%$), postoperative complications (RR 0.82, 95% CI 0.42 to 1.59; participants = 533; studies = 5; $I^2 = 51\%$), and blood transfusions (RR 2.49, 95% CI 0.75 to 8.23; participants = 346; studies = 4; $I^2 = 0\%$). There was no statistical difference between malignant and non-malignant disease subgroups with regard to complication rates. Survival outcomes for women with malignant disease were not reported.

Mean total operating time was longer on average in the RAS arm than in the CLS arm (mean difference (MD) 41.18 minutes, 95% CI -6.17 to 88.53; participants = 148; studies = 2; $I^2 = 80\%$; very low-certainty evidence), and the mean length of hospital stay was slightly shorter with RAS than with CLS (MD -0.30 days, 95% CI -0.53 to -0.07; participants = 192; studies = 2; $I^2 = 0\%$; very low-certainty evidence).

• RAS versus CLS (sacrocolpopexy)

Very low-certainty evidence suggests little or no difference in rates of any complications between women undergoing sacrocolpopexy by RAS or CLS (RR 0.95, 95% CI 0.21 to 4.24; participants = 186; studies = 3; $I^2 = 78\%$), nor in intraoperative complications (RR 0.82, 95% CI 0.09 to 7.59; participants = 108; studies = 2; $I^2 = 47\%$). Low-certainty evidence on postoperative complications suggests these might be higher with RAS (RR 3.54, 95% CI 1.31 to 9.56; studies = 1; participants = 68). Researchers did not report blood transfusions and deaths up to 30 days.

Low-certainty evidence suggests that RAS might be associated with increased operating time (MD 40.53 min, 95% CI 12.06 to 68.99; participants = 186; studies = 3; $I^2 = 73\%$). Very low-certainty evidence suggests little or no difference between the two techniques in terms of duration of stay (MD 0.26 days, 95% CI -0.15 to 0.67; participants = 108; studies = 2; $I^2 = 0\%$).

• RAS versus open abdominal surgery (hysterectomy)

Two studies of 20 and 96 participants with non-malignant disease and malignant disease, respectively, compared RAS with open surgery. For most outcomes only one study contributed data, with most evidence assessed as very low-certainty. Low-certainty evidence from the study among women with endometrial cancer suggests that lymph node yields may be lower with RAS (MD -8.00, 95% CI -14.97 to -1.03), operating time may be longer (233 minutes (range 166 to 320 minutes) compared with 187 minutes (range 109 to 300)), hospital stays may be shorter (mean of 2 days [1 to 5] versus 5 days [4 to 9]; $P < 0.001$), and overall costs may be less (MD -1568.00 US dollars, 95% CI -3100.75 to -35.25) than open surgery. Survival outcomes were not reported.

• RAS versus CLS for endometriosis

A single study with data for 73 women was included in this comparison; women with endometriosis underwent procedures ranging from relatively minor endometrial resection through hysterectomy; many of the women included in this study had undergone previous surgery for their condition. For most outcomes, event rates were low, and the sample size was insufficient to detect potential differences between groups.

Authors' conclusions

Evidence on the effectiveness and safety of RAS compared with CLS for non-malignant disease (hysterectomy and sacrocolpopexy) is of low certainty but suggests that surgical complication rates might be comparable. Evidence on the effectiveness and safety of RAS compared with CLS or open surgery for malignant disease is more uncertain, particularly because survival data are lacking. RAS is an operator-dependent expensive technology; therefore evaluating the safety of this technology independently will present challenges.

PLAIN LANGUAGE SUMMARY

Use of computer or robotic technology to assist surgeons in performing gynaecological surgery

This updated review was originally covered by two separate Cochrane reviews on robot-assisted surgery for benign and malignant gynaecological disease.

The question

Laparoscopic (keyhole) surgery is widely used in gynaecology. Robot-assisted surgery (RAS) is a relatively new type of laparoscopic surgery that allows the surgeon to conduct the operation from a computer console situated away from the patient via remote-controlled mechanical arms attached to the surgical table. RAS is already in use in several countries for gynaecological surgery, particularly for hysterectomy (removal of the uterus/womb), and it has been reported to be useful for myomectomy (removal of uterine fibroids), tubal re-anastomosis (joining two ends of one fallopian tube to restore fertility), sacrocolpopexy (designed to repair vaginal vault prolapse, when the uppermost part of the vagina slips downwards), and other procedures for benign (non-cancerous) disease. It has also been used for

treatment of women with gynaecological cancers, especially endometrial (lining of the womb) and cervical cancers. However, the benefits and risks of RAS versus standard surgical approaches have not been clearly established.

How we conducted the review

We identified studies by searching databases and writing to researchers of registered trials. Two review authors independently assessed studies and collected the data from each study. We included only randomised controlled trials. We pooled data from similar individual studies in the analyses, and we examined different types of operations separately (hysterectomy, sacrocolpopexy, or surgery for endometriosis).

Findings

We included 12 studies involving 1016 women requiring surgery for gynaecological disease. Studies were at moderate to high overall risk of bias. Operations performed were hysterectomy (eight studies) and sacrocolpopexy (three studies). In addition, one trial examined surgical treatment for endometriosis, which included resection or hysterectomy. We are uncertain as to whether RAS or conventional laparoscopic surgery (CLS) has lower overall complication rates because the evidence gathered was of low certainty. The time taken to carry out the operation varied considerably among studies reporting this outcome, so results are difficult to interpret, and although the evidence suggested slightly shorter hospital stays with RAS (one-third of a day), we considered the evidence to be very uncertain and studies to be at high risk of bias.

For sacrocolpopexy procedures, overall evidence shows no clear differences in rates of any complications with RAS compared with CLS, but the evidence was of low certainty. Only one study reported postoperative complications, which were higher in the RAS group (low-certainty evidence). RAS was associated with an average increase in operating time of 40.53 minutes in the RAS group (low-certainty evidence), but these results probably are not reliable, as there was a lot of variation between studies. We found very low-certainty evidence suggesting there was little or no difference between RAS and CLS in terms of duration of hospital stay for this procedure.

Two small studies looked at hysterectomy using RAS versus open abdominal surgery; however, most findings were assessed as being too uncertain to draw any conclusions. Similarly, a study with data for 73 women looked at RAS versus CLS for surgery for endometriosis; women with endometriosis underwent procedures ranging from relatively minor endometrial resection through hysterectomy; many of the women included in this study had undergone previous surgery for their condition, and the sample size was insufficient to show potential differences between surgical techniques.

Conclusions

Complication rates (during and after surgery) for RAS might be similar to those for CLS; however, the evidence is generally of low quality/certainty. Evidence on its use for gynaecological cancer surgery is more uncertain because we found no comparative evidence on cancer recurrence or survival after cancer surgery. As RAS depends on the skill and experience of the surgeon and is an expensive technology, evaluating its effectiveness and safety independently will present challenges.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Robot-assisted surgery compared with conventional laparoscopic surgery for hysterectomy

Robot-assisted surgery compared with conventional laparoscopic surgery for hysterectomy

Patient or population: women undergoing hysterectomy

Setting: hospital settings

Intervention: robot-assisted surgery

Comparison: conventional laparoscopic surgery

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with conventional laparoscopic surgery (hysterectomy)	Risk with robot-assisted surgery				
Intraoperative and postoperative complications	164 per 1000	151 per 1000 (89 to 261)	RR 0.92 (0.54 to 1.59)	585 (6 RCTs)	⊕⊕⊕⊕ LOW ^{a,b}	No significant differences between subgroups (women treated for malignant vs non-malignant disease)
Intraoperative complications	52 per 1000	56 per 1000 (16 to 185)	RR 1.05 (0.31 to 3.56)	487 (5 RCTs)	⊕⊕⊕⊕ LOW ^{a,b}	Number of participants reported to experience these complications was relatively small. Difference between non-malignant and malignant disease subgroups was not statistically significant (P = 0.08)
Postoperative complications	140 per 1000	115 per 1000 (59 to 223)	RR 0.82 (0.42 to 1.59)	533 (5 RCTs)	⊕⊕⊕⊕ LOW ^{a,b}	No significant differences between subgroups (women treated for malignant vs non-malignant disease)
Total operating time	Mean total operating time across included studies ranged from 75 to 102.7 minutes	MD 41.18 higher (6.17 lower to 88.53 higher)	-	148 (2 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,c,d}	Studies involved women with non-malignant disease only
Overall hospital stay	Mean stay across included studies ranged from 1.4 to 3.6 days	MD 0.3 lower (0.53 lower to 0.07 lower)	-	192 (2 RCTs)	⊕⊕⊕⊕ VERY LOW ^{e,f}	Studies involved women with non-malignant disease only

Blood transfusions	20 per 1000	50 per 1000 (15 to 165)	RR 2.49 (0.75 to 8.23)	346 (4 RCTs)	⊕⊕○○ LOW ^a	No significant differences between subgroups (women treated for malignant vs non-malignant disease)
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***The risk in the intervention group** (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; MD: mean difference; RCT: randomised controlled trial; RR: risk ratio.

GRADE Working Group grades of evidence.

High-certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate-certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low-certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low-certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aStudies contributing data had serious design limitations.

^bWide 95% CI crossing the line of no effect.

^cTwo studies with inconsistent findings (I^2 of 80%).

^dWide 95% CI crossing the line of no effect and small sample size.

^eStudies contributing data had very serious risk of bias for this outcome.

^fStudies with small sample sizes.

Summary of findings 2. Robot-assisted surgery compared with conventional laparoscopic surgery for sacrocolpopexy

Robot-assisted surgery compared with conventional laparoscopic surgery for sacrocolpopexy

Patient or population: gynaecology

Setting: hospital settings

Intervention: robot-assisted surgery

Comparison: conventional laparoscopic surgery (sacrocolpopexy))

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with conventional laparoscopic surgery (sacrocolpopexy)	Risk with robot-assisted surgery				
Intraoperative and postoperative complications	200 per 1000	190 per 1000 (42 to 848)	RR 0.95 (0.21 to 4.24)	186 (3 RCTs)	⊕○○○ VERY LOW ^{a,b,c}	
Intraoperative complications	77 per 1000	63 per 1000 (7 to 584)	RR 0.82 (0.09 to 7.59)	108 (2 RCTs)	⊕○○○	

					VERY LOW ^{a,c}
Postoperative complications	121 per 1000	429 per 1000 (159 to 1000)	RR 3.54 (1.31 to 9.56)	68 (1 RCT)	⊕⊕⊕⊕ LOW ^{d,e}
Total operating time	Mean total operating time across studies ranged from 178.4 to 199 minutes	MD 40.53 higher (12.06 higher to 68.99 higher)	-	186 (3 RCTs)	⊕⊕⊕⊕ LOW ^{a,f}
Overall hospital stay	Mean overall hospital stay across included studies ranged from 1.4 to 3.8 days	MD 0.26 higher (0.15 lower to 0.67 higher)	-	108 (2 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,c}
Blood transfusions		Not estimable			

***The risk in the intervention group** (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; MD: mean difference; RCT: randomised controlled trial; RR: risk ratio.

GRADE Working Group grades of evidence.

High-certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate-certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low-certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low-certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aStudies contributing data had design limitations.

^bSerious inconsistencies in study findings (I^2 of 78%).

^cWide 95% CI crossing the line of no effect and effect estimate based on small sample size.

^dStudy contributing data had design limitations.

^eEstimate based on findings from a single study with a small sample size.

^fSize of difference in effect varied across trials (I^2 of 73%).

BACKGROUND

This is an updated review of two originally separate Cochrane reviews concerning the use of robot-assisted surgery for benign gynaecological disease - in [Liu 2012](#) - and for gynaecological cancer - in [Lu 2012](#).

Description of the condition

Common benign gynaecological conditions include uterine fibroids, endometriosis (endometrial tissue found outside the uterus), benign ovarian tumours, pelvic organ prolapse, and vesicovaginal fistula (a passage between the bladder and the vagina), among others. Surgery for such conditions may involve removal of the affected part or structure (e.g. hysterectomy (removal of the uterus), myomectomy (removal of fibroids), ovarian cystectomy (removal of ovarian cysts)), endometriosis surgery or surgical repair (e.g. sacrocolpopexy (designed to repair vaginal prolapse, where the uppermost part of the vagina slips downwards), fistula repair, or tubal re-anastomosis (joining two ends of one fallopian tube to restore fertility)). Hysterectomy is the most commonly performed major gynaecological operation; one in five women in the United Kingdom and one in three women in the USA are likely to undergo the procedure during their lifetime ([Hyst 2013](#)). Hysterectomy and most other surgical procedures for benign gynaecological conditions can be performed effectively via a laparoscopic approach.

Malignant gynaecological conditions may affect the uterus, ovaries, fallopian tubes, cervix, vagina, and vulva and may account for 10% to 15% of cancers among women, with differing incidence and prognosis depending on geographical location ([Jemal 2011](#)). Worldwide, cervical, endometrial, and ovarian cancers are the fourth, fifth, and eighth most common cancers, respectively, among women up to the age of 65 years ([Jemal 2011](#)). However, in developed countries, endometrial cancer is the most common gynaecological cancer, followed by ovarian cancer, whereas cervical cancer is the most common gynaecological cancer in developing countries ([Jemal 2011](#)). A high proportion of endometrial and cervical cancers are detected at an early stage in developed countries, where the primary approach to management of these conditions is surgical. For early endometrial cancer, surgery involves hysterectomy and bilateral salpingo-oophorectomy (BSO) with or without lymphadenectomy; surgery for early cervical cancer involves a radical hysterectomy (removal of the uterus, cervix, upper vagina, and parametria). Ovarian cancer frequently is detected only at an advanced stage and typically requires more extensive surgery, including hysterectomy, BSO, pelvic and para-aortic lymphadenectomy, omentectomy, appendectomy, and abdominal exploration. Staging procedures are usually conducted via laparotomy; however, minimally invasive approaches are being used increasingly, particularly for early-stage endometrial and cervical cancers. A 2012 Cochrane review of laparoscopy for endometrial cancer found that laparoscopy was associated with reduced operative morbidity and hospital stay, and with survival similar to that of laparotomy ([Galaal 2018](#)). However, the role of laparoscopy in early cervical and ovarian cancer surgery has not been established ([Kucukmetin 2013](#); [Lawrie 2013](#)).

Description of the intervention

Robot-assisted surgery (RAS), also known as robotic surgery, robot-assisted laparoscopic surgery, or computer-assisted surgery, is

a recent innovation in the field of minimally invasive surgery. Although not yet widely available in most countries, in the past decade the use of robotic surgical systems for all kinds of gynaecological and non-gynaecological surgery has increased. One of the first applications of RAS was AESOP (Automated Endoscopic System for Optical Positioning; Computer Motion, Goleta, CA, USA) - a voice-activated endoscope ([Mettler 1998](#)). Another predecessor of the current system was the ZEUS Robotic Surgical System (ZRSS) (Computer Motion). ZEUS consisted of three remote-controlled robotic arms attached to the surgical table, along with a robotic console, which housed the instrument controls. This differed from earlier models in that it allowed the surgeon to step away from the operating table. Early studies reported successful application of ZEUS for tubal re-anastomosis ([Falcone 2000](#)). In 2003, Computer Motion merged with its rival company Intuitive Surgical, and these earlier systems were discontinued. The merged company instead developed the da Vinci® Surgical System, which became commercially available for gynaecological surgery in 2005.

The da Vinci® Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) consists of three components: a surgeon-operated console with stereoscopic viewer and hand and foot controls, three-dimensional (3D) stereoscopic imaging through an endoscope, and a patient side cart with three or four robotic arms with swivelling instruments, which are reported to be more dexterous than the human hand ([Holloway 2009a](#)). This system is currently the only commercially available robotic surgical platform that has received US Food and Drug Administration (FDA) approval for performing gynaecological procedures. According to the manufacturer's website (www.intuitivesurgical.com), more than 1.5 million operations have been performed and more than 2000 da Vinci® units have been sold worldwide ([da Vinci 2014](#)). In addition, the company's US market share for hysterectomies performed for benign conditions was apparently 27% in 2011 ([da Vinci 2014](#)).

How the intervention might work

Minimally invasive surgery is a surgical approach that minimises surgical incisions to reduce trauma to the body. Laparoscopic surgery is a type of minimally invasive surgery whereby the surgeon makes small incisions in the abdominal wall, through which fine instruments are then inserted. Such instruments include a laparoscope (a camera with magnification), which allows structures within the abdomen and the pelvis to be visualised. In conventional laparoscopic surgery (CLS), the laparoscope and other instruments are held and physically directed by the surgeon or a surgical assistant; this requires a high degree of dexterous skill and training ([Ramsey 2012](#)). The main disadvantage of any laparoscopic system compared with laparotomy is the lack of tactile perception (haptic feedback), although the importance of tactile perception in most gynaecological procedures is currently unknown ([Moy 2010](#)). Laparoscopic surgery is increasingly preferred to laparotomy (open abdominal surgery) for several gynaecological procedures. For benign ovarian tumours, laparoscopic surgery is associated with fewer perioperative complications, less postoperative pain, and a shorter hospital stay compared with laparotomy ([Medeiros 2009](#)). A review of laparoscopic surgery for early endometrial cancer reported similar advantages, with no differences in survival ([Galaal 2018](#)).

Robot-assisted surgery (RAS) represents a technological advance in CLS in that the laparoscope and the surgical instruments are part of a mechanical system that the surgeon operates from a separate console. Advocates of RAS claim that the system is more comfortable for the surgeon and offers additional technical advantages compared with CLS, including 3D vision, minimisation of the effects of hand tremors, greater freedom of motion, greater precision in dissection, easier suturing and knot tying, and a shorter learning process (Cho 2009). Compared with CLS, these advantages have the potential to translate into reduced perioperative complications, as well as less blood loss and postoperative pain, shorter hospital stay, and increased survival in malignant disease. However, several disadvantages are known, including the high cost of equipment and disposable instruments, complete lack of haptic feedback, and the need to train both surgeons and nurses. Furthermore, some aspects of RAS, for example, the number of port incisions required, might increase risks associated with the procedure compared with the conventional approach.

Role of RAS in benign gynaecological disease

Since the late 1990s, RAS has been used in gynaecological surgery, and a proliferation of reports have described its applications. For benign disease, the most commonly performed robot-assisted gynaecological operation is hysterectomy. Various aspects of robot-assisted laparoscopic hysterectomy are reported to be performed more easily than CLS, such as securing the uterine vessels and cardinal ligaments, performing an accurate colpotomy, and oversewing the vaginal cuff (Dimitri 2010; Lenihan 2008; Nezhat 2006; Reynolds 2006). Other reports of robot-assisted procedures include myomectomy (Advincula 2004; Advincula 2007; Cela 2013; Gocmen 2013; Nezhat 2009), tubal re-anastomosis to restore fertility (Deguelldre 2000; Dharia 2008; Rodgers 2007), sacrocolpopexy and repair of vesicovaginal fistulas (Hemal 2008; Melamud 2005; Schimpf 2007; Sundaram 2006), and complex endometriosis surgery (Cadiere 2001; Nezhat 2006; Sener 2006). Preliminary studies of RAS for these procedures have indicated that they can feasibly be performed with RAS.

Role of RAS in gynaecological cancers

Surgical staging operations for gynaecological malignancies are lengthy procedures, which can lead to surgeon fatigue and muscular complaints that may limit the surgeon's performance (Verheijen 2012). For endometrial cancer, an increasing number of non-randomised studies describe excellent results with RAS, including good lymph node yield, low blood loss, comparable operative time, low complication and conversion rates, and short hospital stays (Bell 2008; Cardenas-Goicoechea 2010; Coronado 2012; DeNardis 2008; Field 2007; Gehrig 2008; Holloway 2009b; Lambaudie 2008; Reynisson 2013; Reynolds 2005; Seamon 2009a; Shafer 2008; Veljovich 2008). Few studies have evaluated survival following RAS staging; however, a retrospective review of 499 women who underwent RAS endometrial cancer staging suggests that recurrence-free and overall survival rates are not adversely affected (Kilgore 2013).

For cervical cancer, various studies of robot-assisted laparoscopic radical hysterectomy have reported reduced blood loss, shorter hospital stay, and lesser analgesia requirements compared with CLS (Boggess 2008a; Fanning 2008; Kim 2008; Lowe 2009; Maggioni 2009; Magrina 2008; Nezhat 2008; Persson 2009; Soliman

2013). Furthermore, case reports suggest that robot-assisted trachelectomy may offer a good option for women seeking to preserve fertility, because it allows excellent visualisation of the vasculature and parametrial tissues (connective tissue and fat adjacent to the uterus), which must be isolated during the procedure (Diaz 2008; Geisler 2008; Persson 2008; Plante 2008).

Reports of RAS for ovarian cancer are uncommon because of the difficulty involved in extensive exploration of the abdomen with RAS (and CLS). However, limited evidence suggests that selected early cases may be suitable (Finger 2014; Madhuri 2012; Verheijen 2012). Vergote 2008 reported on a series of five patients undergoing retroperitoneal node assessment using RAS with excellent results, including brief hospital stays and minimal blood loss. All procedures were completed within less than one hour console time, and the study authors concluded that robotic retroperitoneal para-aortic sampling is a feasible procedure that warrants further evaluation.

Why it is important to do this review

Robot-assisted surgery (RAS) is a newer technology that may confer advantages (or disadvantages) compared with the conventional surgical approaches used in gynaecology. As with any new healthcare technology, RAS requires rigorous evaluation. RAS is controversial because of the significant commercial interests involved, and because the technology is expensive, reports tend to be generated by proponents of the approach. In the USA, according to Schiavone 2012, marketing of RAS by hospitals for gynaecology is widespread, with potential limitations and costs rarely presented to women, and with most websites claiming reduced pain, shorter recovery time, and less blood loss with RAS. Yet individual studies and reviews to date have provided insufficient evidence on the clinical effectiveness of RAS compared with CLS. In addition, considerable risk of bias has been noted in a review of mainly non-randomised studies of RAS versus other approaches for hysterectomy (O'Neill 2013).

The high cost of robotic systems may be mitigated if significant clinical benefits over CLS can be independently proven. It has been suggested that costs may also be mitigated by indirect benefits for the surgeon (ergonomics, healthcare costs) (Nieboer 2014).

Our original reviews of RAS in benign and malignant gynaecological disease yielded few high-quality studies and little evidence to support claims of equivalence and/or superiority over conventional, less expensive approaches (Liu 2012; Lu 2012). Only two small RCTs (both for benign disease) contributed data, and no robust conclusions could be drawn. Over the past few years, the results of several RCTs have been published, potentially providing evidence of the clinical effectiveness of RAS compared with CLS. We have updated this review to aid decision-making by women, clinicians, and other stakeholders.

OBJECTIVES

To assess the effectiveness and safety of RAS in the treatment of women with benign and malignant gynaecological disease.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) only.

Types of participants

Women requiring surgery for benign or malignant gynaecological disease at any age.

Types of interventions

- Robot-assisted surgery (RAS) versus conventional laparoscopic surgery (CLS).
- RAS versus open surgery.
- Comparison of different types of robot assistants.

Types of outcome measures

Primary outcomes

- Intraoperative complications including injury to the bladder, ureters, bowel, blood vessels, and nerves
- Postoperative complications including vascular (e.g. haemorrhage, deep vein thrombosis), wound (e.g. infection, dehiscence (wound breakdown)), gastrointestinal (e.g. bowel obstruction due to fibrous adhesions, paralytic ileus due to paralysis of intestinal muscles), incisional hernia (swelling caused by tissue poking through a surgical scar of a previous operation), neurological, respiratory (e.g. pneumonia, embolism (blood clot in a lung blood vessel)), and urinary complications (e.g. acute urinary retention)

Secondary outcomes

For all procedures

- Early and late mortality (early mortality defined as death within 30 days; late mortality defined as death within three months)
- Total operating time (from skin incision to closure)
- Instrument setup time
- Overall and postoperative duration of hospital stay
- Estimated blood loss
- Blood transfusion
- Rate of conversion to open surgery (for RAS vs CLS)
- Quality of life (QoL) as assessed using validated scales (e.g. Quality of Life Questionnaire-Core 30 (QLQ-C30) - developed to assess the quality of life of people with cancer; Functional Assessment of Cancer Therapy - Ovarian (FACT-O))
- Postoperative pain as assessed using visual analogue or other validated scales
- Total cost (including equipment costs, theatre costs, and cost of hospital stay)
- Surgeon's performance and workload as assessed by investigators (e.g. using NASA Task Load Index (NASA-TLX))

Additionally, for cancer surgery

- Disease-free survival
- Overall survival

- Numbers of lymph nodes harvested: total, pelvic, and para-aortic lymph nodes

Search methods for identification of studies

Electronic searches

For this review update, we searched the following databases (8 January 2018).

- Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 12).
- MEDLINE via Ovid (June 2014 to December week 4 2018).
- Embase via Ovid (June 2014 to 2018 week 2).

Search strategies can be found in [Appendix 1](#), [Appendix 2](#), and [Appendix 3](#). We identified all potentially eligible articles on PubMed, and we performed searches for related articles using the 'Related articles' feature.

Original searches

We conducted the original searches (14 July 2010) for the review of 'Robotics and malignant disease' as follows ([Lu 2012](#)).

- Cochrane Gynaecological Cancer Review Group Trials Register.
- CENTRAL (2010, Issue 3).
- MEDLINE (from 1950 to June week 5 2010).
- Embase (from 1974 to week 27 2010).

Similarly, we performed the original searches from inception to 21 November 2011, for the review of 'Robotics and benign disease.' In addition, we searched the Cochrane Menstrual Disorders and Subfertility Group (MDSG) Trials Register, the Chinese Biomedical Literature Database (CBM), and Chinese Medical Current Contents (CMCC). Search strategies for the original reviews can be found as appendices to the respective original reviews ([Liu 2012](#); [Lu 2012](#)).

Searching other resources

Grey literature

We searched *metaRegister*, Physicians Data Query, www.controlled-trials.com/rct, www.clinicaltrials.gov, and www.cancer.gov/clinicaltrials for ongoing trials. We contacted the main investigators of identified ongoing trials for further information.

Handsearching

We handsearched the reference lists of all relevant trials obtained by the search to look for further trials.

Correspondence

We contacted the authors of relevant trials to ask if they knew of further published and unpublished data.

Language restrictions

We sought papers in all languages and carried out translations if necessary.

Data collection and analysis

Selection of studies

For the update, we downloaded all titles and abstracts retrieved by electronic searching to the reference management database Endnote. After de-duplication, two review authors (DongHao Lu (DL) and Theresa Lawrie (TL)) independently examined the remaining references. We excluded studies that clearly did not meet the inclusion criteria and obtained copies of the full text of potentially relevant references. Two review authors (DL, TL), who resolved disagreements by discussion and if necessary involved a third review author (Hongqian Liu (HL)), assessed studies independently for eligibility. We documented reasons for exclusion.

Data extraction and management

We designed a data extraction form for the combined review and piloted it using two of the eligible studies (Paraiso 2013; Sarlos 2010). Thereafter, two review authors (DL, TL) independently extracted data from eligible studies. When studies had multiple publications, we used the main trial report as the reference and supplemented these data by referring to the secondary papers. When previously included data had been included from unpublished studies (e.g. conference abstracts) that had been subsequently published, we extracted data from the published full texts for this updated review. When necessary, we sought additional information on methodology and data from trial investigators. We resolved differences of opinion by reaching consensus or by obtaining the assistance of a third review author (HL).

When possible, we extracted the following data from each study.

- *Study details:* design; setting; country; accrual dates; sample size; inclusion and exclusion criteria; funding source.
- *Participants:* diagnosis/indication for procedure (e.g. benign conditions, including fibroids, abnormal bleeding, endometriosis, fertility surgery, vaginal prolapse; malignant disease, including endometrial, cervical, and ovarian cancers); mean age; mean body mass index (BMI); previous abdominal surgery; performance status. Additionally, for cancer studies: disease stage/grade.
- *Interventions:* types of interventions compared; numbers randomly assigned and numbers analysed in each group; surgeon experience.
- *Outcomes:* for all studies: deaths within 30 days and within three months; postoperative complications; intraoperative complications; types of complications (including bleeding, infection, intraoperative injury, bowel obstruction, other); late complications (including urinary and faecal incontinence, dyspareunia, hernia, other); re-intervention; re-admission; total operating time (skin-to-skin); operating room time; length of hospital stay; estimated blood loss; blood transfusions; quality of life (QoL) score at four to six weeks and six months postoperatively; activity score at six weeks postoperatively; pain scores (at two weeks or as defined by investigators); total estimated cost (including equipment costs, theatre costs, and costs of hospital stay). For cancer studies: overall survival; disease-free survival; lymph node yield; duration of response.

Assessment of risk of bias in included studies

We assessed risk of bias in included RCTs using the 'Risk of bias' tool of the Cochrane Collaboration and the criteria specified in Chapter

8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We assessed the following.

- Sequence generation (low risk if true random sequence generation was described).
- Allocation concealment (low risk if sealed, opaque, numbered envelopes or central allocation after registration).
- Blinding (restricted to blinding of outcome assessors).
- Incomplete outcome data (considered low risk if > 80% of those randomly assigned were assessed).
- Selective reporting of outcomes (low risk if prespecified outcomes were reported).
- Trial funding (low risk if funding was obtained from non-profit organisations (e.g. government body)).
- Other possible sources of bias (e.g. a potential source of bias related to the specific study design used, trial stopped early because of some data-dependent process, extreme baseline imbalance).

Two review authors (DL, TL) applied the 'Risk of bias' tool independently and resolved differences by discussion. We presented the results in 'Risk of bias' tables along with the characteristics of each study, and in a 'Risk of bias' summary graph. We interpreted results of meta-analyses in the light of findings with respect to risk of bias.

Measures of treatment effect

For dichotomous outcomes (e.g. complications), we extracted the number of women in each group who experienced the outcome of interest (e.g. women who developed the complication) and the number of women assessed at endpoint, to estimate a risk ratio (RR) with 95% confidence interval (CI).

For continuous outcomes (e.g. QoL measures), we extracted the final value and the standard deviation of the outcome of interest and the number of women assessed at endpoint in each treatment arm, at the end of follow-up, to estimate the mean difference (MD) with 95% CI. In the case of outcomes with continuous data from different scales, we used the standardised mean difference (SMD) with 95% CI.

Time-to-event data were not available for this review. For time-to-event outcomes (e.g. disease-free survival), we would have extracted hazard ratios (HRs) and 95% CIs. If these were not presented, we would have attempted to extract the data required to estimate them using Parmar's methods (Parmar 1998) (e.g. number of events in each arm with log-rank P value comparing relevant outcomes in each arm, relevant data from Kaplan-Meier survival curves). If it was not possible to estimate the HR, we would have extracted the number of participants in each treatment arm who experienced the outcome of interest and the number of participants assessed to estimate an RR (i.e. dichotomous data). When possible, we extracted data according to intention-to-treat analysis, by which we analysed participants in the groups to which they were assigned.

Unit of analysis issues

The unit of analysis was per woman randomly assigned. We included no cross-over trials and no cluster-randomised trials.

Dealing with missing data

For included studies, we noted levels of attrition. We did not impute data for any outcomes. If necessary, we contacted the investigators of the primary studies to request missing data, including missing participants due to dropouts and missing statistics. The denominator for each outcome in each trial was the number randomly assigned minus the number of participants whose outcomes were known to be missing. If the numbers randomly assigned and the numbers analysed were inconsistent, we calculated the percentage lost to follow-up and reported this under [Characteristics of included studies](#).

Assessment of heterogeneity

We checked included studies to determine whether participants, interventions, and outcomes were similar enough to be pooled in a meta-analysis. We carried out tests for heterogeneity using the χ^2 test, with significance set at P value less than 0.1. We explored statistical heterogeneity by visually inspecting forest plots. We used the I^2 statistic to estimate the total variation across studies that was due to heterogeneity: less than 25% was considered as mild, 25% to 50% as moderate, and greater than 50% as substantial heterogeneity ([Higgins 2011](#)). If the primary outcome measures had substantial heterogeneity ($I^2 > 50\%$), we explored possible sources of heterogeneity by performing sensitivity and subgroup analyses as described below.

Assessment of reporting biases

We assessed within-study reporting bias by seeking published protocols and comparing outcomes between the protocol and the final published study. This was not possible for all studies. We planned to prepare funnel plots corresponding to meta-analysis of the primary outcomes to assess the potential for small-study effects and publication bias if we included 10 or more studies in an analysis. We also planned to assess funnel plot asymmetry visually, and if asymmetry was suggested by visual assessment, we would perform exploratory analyses to investigate this. However, studies were insufficient for evaluation of this type of bias.

Data synthesis

We combined data from included studies using random-effects (RE) methods with inverse variance weighting for all meta-analyses ([DerSimonian 1986](#)). We chose RE methods because of the clinical heterogeneity of the participants and the different procedures performed (sacrocolpopexy and hysterectomy). We used the Mantel Haenszel method to pool dichotomous data and the inverse variance method for continuous outcomes. For trials with multiple treatment groups, we planned to divide the 'shared' comparison group by the number of treatment groups and the number of comparisons between treatment groups, and to treat the split comparison groups as independent comparisons.

We created 'Summary of findings' tables in RevMan 5.3 ([RevMan 2014](#)), using the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) approach ([GRADE 2008](#)). For assessments of the overall quality of evidence for each outcome that included pooled data from RCTs only, we downgraded the evidence from 'high quality' by one level for serious (or by two for very serious) study limitations (risk of bias), indirectness of evidence, serious inconsistency, imprecision of effect estimates, or

potential publication bias. We included the following outcomes in the 'Summary of findings' table.

- Intraoperative and postoperative complications (combined and separate).
- Total operating time.
- Length of hospital stay.
- Blood transfusion.

Subgroup analysis and investigation of heterogeneity

We performed subgroup analyses according to type of surgical procedure (e.g. hysterectomy, sacrocolpopexy) for all outcomes. In addition, we explored potential sources of heterogeneity according to surgeons' experience (30 or fewer robotic procedures or more than 30 robotic procedures performed). We assessed subgroup differences by performing interaction tests available within RevMan ([RevMan 2014](#)). We reported the results of subgroup analyses by quoting the χ^2 statistic and the P value, as well as the interaction test I^2 value.

Sensitivity analysis

We conducted sensitivity analyses for the primary outcomes to determine whether the conclusions were robust to arbitrary decisions made regarding eligibility of trials and analysis. These analyses included consideration of whether conclusions would have differed if:

- eligibility was restricted to studies without high risk of bias for the outcome concerned; or
- a fixed-effect model had been adopted.

RESULTS

Description of studies

Results of the search

Searches conducted for the two original reviews contributed the following studies to a combined review.

- [Liu 2012](#) (benign gynaecological disease) included [Sarlos 2010](#) (conference abstract only) and [Paraíso 2011](#), and excluded three studies (not RCTs). These previously included studies comprised six citations (five conference abstracts and one full published report).
- [Lu 2012](#) (malignant gynaecological disease) included no studies and excluded 27 studies (not RCTs).

For further details of these searches, please consult the original reviews ([Liu 2012](#); [Lu 2012](#)).

2014 update

For the 2014 update of this review, we included four additional studies associated with nine records ([Anger 2014](#); [Green 2013](#); [Lonnerfors 2014](#); [Paraíso 2013](#)), and we excluded six records ([Campos 2013](#); [Desille-Gbaguidi 2013](#); [Gocmen 2013](#); [Martinez-Maestro 2014](#); [McNanley 2012](#); [Palmer 2013](#)) ([Figure 1](#)). An additional record that was identified was a later publication (full report) of a previously included study, which had been included based on a conference abstract alone ([Sarlos 2010](#)).

Figure 1. Study flow diagram for updated searches (30 June 2014).

Figure 1. (Continued)

One included study was a conference abstract of a study initially identified as an 'ongoing study' (see study and protocol citation linked to [Green 2013](#)). We requested unpublished data from these investigators and received limited data in the form of a Microsoft PowerPoint presentation. We were informed by the investigators that they had difficulty getting the paper published because of 'too many cross-overs in the stats'; however, we understand that they plan to make further attempts to get the study published. (See [Green 2013](#) in [Characteristics of included studies](#) for additional details.)

2018 update

For this latest update, we searched the Cochrane Gynaecological Cancer Review Group Trials Register, the Cochrane Central Register

of Controlled Trials (CENTRAL), MEDLINE, and Embase databases on 8 January 2018, and we searched [www.ClinicalTrials.gov](#) on 16 January 2018. The combined updated searches yielded 1343 records; we identified one additional record through an online clinical trial registry ([Lauszus 2017](#)), and we identified another by following up on an ongoing study ([Ramirez 2018](#)). After full text screening of the 41 potentially eligible records identified, we included 12 records associated with six new studies ([Costantini 2017](#); [Deimling 2017](#); [LAROSE 2017](#); [Maenpaa 2016](#); [RASHEC 2013](#); [Wijk 2016](#)), and we excluded 25 with reasons ([Figure 2](#)). We identified one new ongoing study ([Lauszus 2017](#)), and we found six records that were associated with previously included studies.

Figure 2. Study flow diagram for updated search (8 January 2018).

Since the last update, three ongoing studies have been completed (LAROSE 2017; Ramirez 2018; RASHEC 2013), and although the other two should have been completed by now, it does not appear that they have been reported yet (Kjohde 2012; Narducci 2010).

Therefore, in total, this review now reports on 12 included studies (associated with 34 individual records); 61 excluded studies, with reasons; and three ongoing studies.

Included studies

This 2018 update includes 12 studies (six new and six previously included studies) (Anger 2014; Costantini 2017; Deimling 2017; Green 2013; LAROSE 2017; Lonnerfors 2014; Maenpaa 2016; Paraiso 2011; Paraiso 2013; RASHEC 2013; Sarlos 2010; Wijk 2016). All included studies were conducted from 2007 onwards and evaluated RAS versus conventional laparoscopic or open surgery for benign or malignant gynaecological disease. Two of the new included studies were ongoing at the time of the last update (LAROSE 2017; RASHEC 2013).

Study design

All included studies were RCTs. Nine were single-centre studies (Costantini 2017; Deimling 2017; Green 2013; Lonnerfors 2014; Maenpaa 2016; Paraiso 2011; RASHEC 2013; Sarlos 2010; Wijk 2016); two were conducted at two centres each (Anger 2014; Paraiso 2013), and the LAROSE 2017 study recruited women at three centres. Studies were conducted in the USA (Anger 2014; Deimling 2017; Green 2013; LAROSE 2017; Paraiso 2011; Paraiso 2013), Switzerland (Sarlos 2010), Sweden (Lonnerfors 2014; RASHEC 2013; Wijk 2016), Finland (Maenpaa 2016), and Italy (Costantini 2017).

Participants

Included studies contributed a total of 1016 participants as follows: Anger 2014 (66 women); Costantini 2017 (40 women); Deimling 2017 (144 women); Green 2013 (98 women); LAROSE 2017 (74 women); Lonnerfors 2014 (122 women); Maenpaa 2016 (101 women); Paraiso 2011 (78 women); Paraiso 2013 (53 women); RASHEC 2013 (120 women); Sarlos 2010 (100 women); and Wijk 2016 (20 women). Women participating in studies of RAS for hysterectomy were on average in their mid-40s (Deimling 2017; Green 2013; Lonnerfors 2014; Paraiso 2013; Sarlos 2010), although women undergoing hysterectomy for malignant disease in the RASHEC 2013 and Maenpaa 2016 trials were on average more than 60 years of age. In the studies of RAS for sacrocolpopexy (Anger 2014; Costantini 2017; Paraiso 2011), women were on average about 60 years old. Women undergoing endometrial resection for endometriosis were on average 34 years of age, but the study also included many older women (standard deviation (SD) 34.5 years) (Lonnerfors 2014). Wijk 2016 compared robot-assisted laparoscopic hysterectomy versus traditional open abdominal hysterectomy (women were on average 52 years of age). Participant body mass indexes (BMIs) were not significantly different between study arms for any of these studies, and reported means and medians ranged between 24 and 32 kg/m².

Indications for hysterectomy were stated as benign gynaecological conditions (mainly uterine fibroids or abnormal bleeding) requiring hysterectomy in most studies; however, Maenpaa 2016 included women with low-grade endometrial cancer, and the RASHEC 2013 trial recruited women with high-risk endometrial cancer. Wijk 2016 included women with both benign and malignant gynaecological

disease. Two studies stated that they excluded women for whom a vaginal hysterectomy was indicated (Green 2013; Sarlos 2010). In the studies of RAS for sacrocolpopexy, the indication for surgery was symptomatic pelvic organ prolapse. LAROSE 2017 recruited women with endometriosis for endometrial resection (some women had extensive surgery including hysterectomy). Ninety per cent of women in Paraiso 2011 and 42% of women in Anger 2014 had previously undergone a hysterectomy. No significant baseline differences between study arms were described in any of the studies reporting previous abdominal surgery (Lonnerfors 2014; Paraiso 2013; Sarlos 2010), or caesarean section (Green 2013; Lonnerfors 2014). Many of the women in both arms of the LAROSE 2017 study had previous surgery to treat endometriosis.

Interventions

Two included studies compared RAS versus open surgery (RASHEC 2013; Wijk 2016). Other included trials compared RAS versus CLS. Lonnerfors 2014 compared RAS versus other minimally invasive surgery to include CLS or vaginal hysterectomy. Procedures performed were hysterectomy (Deimling 2017; Green 2013; Lonnerfors 2014; Maenpaa 2016; Paraiso 2013; RASHEC 2013; Sarlos 2010; Wijk 2016), as well as sacrocolpopexy (Anger 2014; Costantini 2017; Paraiso 2011). In addition, one trial examined surgical treatment for endometriosis, which included resection or hysterectomy (LAROSE 2017). In Anger 2014, 58% of women underwent a concomitant hysterectomy, and we noted no statistically significant differences between study arms in the numbers of women undergoing these additional procedures. In Paraiso 2013, concomitant procedures, including culdoplasty, adhesiolysis, and excision of endometriosis, were performed with similar frequency between study arms, with four and three women in the RAS and CLS arms, respectively, undergoing more than one concomitant procedure.

In two studies, surgeons had performed a minimum of 10 relevant RAS procedures (Anger 2014; Paraiso 2011), and in three studies, surgeons had performed 20 or more relevant RAS procedures (Lonnerfors 2014; Paraiso 2013; Sarlos 2010). Costantini 2017, Deimling 2017, Maenpaa 2016, and Wijk 2016 describe those performing surgery as 'experienced surgeons'. In the LAROSE 2017 trial of five surgeons undertaking procedures, only 3 carried out both procedures. RASHEC 2013 reported that five surgeons carried out conventional surgery and only one performed RAS. Green 2013 did not describe the experience of the surgeons.

Outcomes

The most common primary outcomes among these studies were cost in Anger 2014 and Lonnerfors 2014, and operating time in Green 2013, Paraiso 2011, Paraiso 2013, and Sarlos 2010. Most studies included complications and length of hospital stay as secondary outcomes (Costantini 2017; Green 2013; Lonnerfors 2014; Maenpaa 2016; Paraiso 2011; RASHEC 2013; Sarlos 2010). Other stated secondary outcomes included blood loss (Anger 2014; Costantini 2017; Green 2013; LAROSE 2017; Lonnerfors 2014; Sarlos 2010), QoL (Anger 2014; Paraiso 2011; Paraiso 2013; Sarlos 2010; Wijk 2016), postoperative pain (Anger 2014; Green 2013; Paraiso 2011; Paraiso 2013), conversion rates (Lonnerfors 2014; Paraiso 2011; Paraiso 2013; Sarlos 2010), and re-intervention (Anger 2014; Lonnerfors 2014; Sarlos 2010).

Excluded studies

Thirty non-randomised studies were excluded from the original reviews. For the 2014 updated review, six additional studies were excluded for the following reasons.

- Quasi-RCT ([Martinez-Maestro 2014](#)).
- Not an RCT ([Desille-Gbaguidi 2013](#); [Gocmen 2013](#)).
- Inappropriate intervention/comparison ([Campos 2013](#); [McNanley 2012](#); [Palmer 2013](#)).

For the 2018 update, we excluded 25 studies for the following reasons.

- Quasi-RCT ([Somashekhar 2014](#)).
- Inappropriate intervention/comparison ([Chen 2015](#); [Diaz-Feijoo 2016](#); [Landeem 2016](#); [Ramirez 2018](#); [Tsafrir 2017](#)).
- Not an RCT (all other exclusions).

Please see the [Characteristics of excluded studies](#) section for additional details.

Risk of bias in included studies

Overall, we considered one study to be at high risk of bias ([Green 2013](#)), and we considered the other studies to be at moderate risk of bias. Risks of bias are summarised in [Figure 3](#) and are detailed below.

Figure 3. 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 of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Funding	Other bias
Anger 2014	+	+	?	?	+	+	+	+
Costantini 2017	+	?	-	-	?	?	?	-
Deimling 2017	+	+	-	?	+	+	?	+
Green 2013	+	?	-	?	-	-	?	-
LAROSE 2017	+	?	-	-	?	+	?	?
Lonnerfors 2014	+	?	-	?	+	?	+	?
Maenpaa 2016	+	?	-	-	-	+	?	+
Paraiso 2011	+	+	?	?	?	+	?	?
Paraiso 2013	+	?	?	?	?	+	?	+
RASHEC 2013	+	?	-	?	?	+	+	-
Sarlos 2010	+	?	-	?	?	?	?	?
Wijk 2016	+	+	-	-	+	+	?	?

Allocation

All studies were RCTs, and the method of sequence generation assessed was low risk in all of them. RCTs that did not describe allocation concealment clearly we assessed as having some risk of selection bias ([Costantini 2017](#); [Green 2013](#); [LAROSE 2017](#); [Lonnerfors 2014](#); [Maenpaa 2016](#); [RASHEC 2013](#); [Sarlos 2010](#)). We considered these studies to be at unclear risk of bias for this item.

Blinding

All of the included studies were at some risk of performance bias, as staff performing surgery would be aware of allocations and this may have had an effect on outcomes. As we described above, two studies were at particular risk of performance bias ([LAROSE 2017](#); [RASHEC 2013](#)), as not all surgeons involved in these studies performed both procedures. Three studies described that they attempted to blind participants and assessors to group allocation ([Anger 2014](#); [Paraíso 2011](#); [Paraíso 2013](#)). However, it is not clear in any of the included studies who had assessed outcomes such as extent of blood loss and length of hospital stay, which normally are determined by the surgeon who performed the procedure, and therefore they are at potentially high risk of bias.

Incomplete outcome data

Four studies reported no or minimal loss to follow-up ([Anger 2014](#); [Deimling 2017](#); [Lonnerfors 2014](#); [Wijk 2016](#)) (low risk of bias). In [Paraíso 2011](#), five women were withdrawn from each study arm after randomisation (unclear risk of bias). In [Paraíso 2013](#), nine women withdrew after randomisation (five in the CLS group and four in the RAS group), one woman allocated for CLS underwent RAS in error (protocol deviation), and one woman in the CLS group was withdrawn as the result of missing data (unclear risk of bias). Quality of life outcomes in [Paraíso 2013](#) and [Sarlos 2010](#) were subject to attrition greater than 20%, so data for this outcome were considered to be at high risk of bias.

In [Green 2013](#), of 113 women initially randomly assigned, 10 women were withdrawn because procedures were cancelled for medical or personal reasons (eight in the CLS group and two in the RAS group), and five women who had undergone alternative procedures were excluded (three in the CLS group and two in the RAS group). This left 98 participants (48 in the CLS group and 50 in the RAS group), representing attrition of 13% of the sample. In addition, 11 protocol deviations were reported. We considered this study to be at high risk of attrition bias.

We assessed [Costantini 2017](#), [LAROSE 2017](#), and [RASHEC 2013](#) as having unclear risk of bias for this domain.

Selective reporting

Most included studies reported expected and/or pre-specified outcomes. We considered [Green 2013](#) to be at high risk of reporting bias because of high attrition and protocol deviations with subsequent reporting of data per protocol. In [Paraíso 2013](#), most expected outcomes were reported; however, no details of complications were provided despite the fact that three women required blood transfusions (unclear risk). In [Lonnerfors 2014](#), outcomes were reported for RAS versus minimally invasive surgery (CLS and vaginal hysterectomy) together and separately. However, as separate baseline data were not reported, it is not possible to determine whether there were differences in the baseline

characteristics of control group women undergoing CLS or vaginal hysterectomy (unclear risk).

Other potential sources of bias

Two studies were early adopters of RAS ([Paraíso 2011](#); [Sarlos 2010](#)). Enrolment for these two studies occurred between 2007 and 2011, and, arguably, data from these studies may have been subject to bias caused by the learning curve, although surgeons in the latter study had performed a minimum of 30 RAS procedures before commencing the trial. Nevertheless, to assess this possibility and to avoid potential bias from early studies in the review findings, we performed sensitivity analyses for most outcomes by excluding these early studies.

In the [Paraíso 2011](#) study report, it is unclear whether participants experienced more than one intraoperative and/or postoperative complication, and it is not possible to determine the direction of any bias as a result. This study also included relatively minor complications (e.g. urinary tract infection), unlike the other studies; this might have contributed heterogeneity to the 'complications' analyses but not bias necessarily. Although we included these data from the analyses, we performed sensitivity analysis by excluding this study.

[Lonnerfors 2014](#) compared RAS with CLS or vaginal hysterectomy, and the comparison intervention was based on the surgeon's choice. As participants were not randomly assigned to CLS and vaginal hysterectomy separately, these separate reported data were potentially subject to significant bias (e.g. a higher percentage of women who underwent CLS had a concomitant procedure (75% CLS, 59% RAS, and 19% vaginal hysterectomy procedures) that would have influenced procedure time, complication rates, length of hospital stay (LOS) and the costs of separate CLS data). Therefore, we extracted combined data, not separate data, from this study. The direction and magnitude of bias resulting from inclusion of these data in this review are unclear.

In [Costantini 2017](#), the mean length of follow-up was different in the two arms of the trial; it is not clear whether women were recruited for different types of surgery at the same time.

In [RASHEC 2013](#), the fact that a single surgeon carried out all RAS procedures while five surgeons carried out the conventional procedure means that data may be at high risk of bias.

Authors of all studies reported no potential conflicts of interest. Although most study reports declared the main study sponsor to be the institution at which the study was undertaken, it was unclear whether study institutions had received financial support from the system manufacturers, directly or indirectly. Therefore, from a funding perspective, we considered most studies to be at potentially high or unclear risk of bias.

As a result of the small number of included studies, we were unable to meaningfully evaluate publication bias as planned; however, one included study with significant protocol deviations remains unpublished ([Green 2013](#)).

Effects of interventions

See: [Summary of findings for the main comparison Robot-assisted surgery compared with conventional laparoscopic surgery for hysterectomy](#); [Summary of findings 2 Robot-assisted](#)

surgery compared with conventional laparoscopic surgery for sacrocolpopexy

1. RAS versus CLS (hysterectomy)

Intraoperative and postoperative complications

No clear differences in complication rates were reported between RAS and CLS arms (risk ratio (RR) 0.92, 95% confidence interval (CI) 0.54 to 1.59; participants = 585; studies = 6; $I^2 = 51\%$; low-certainty evidence; [Analysis 1.1](#)). We downgraded this evidence to 'low' because of study design limitations in studies contributing data and imprecision in the effect estimate. We examined studies including women with non-malignant versus malignant disease separately; we found no clear evidence of differences in effect in these two subgroups (test for subgroup differences: $\text{Chi}^2 = 1.92$, $\text{df} = 1$ ($P = 0.17$), $I^2 = 48.0\%$).

Intraoperative complications only

No clear differences in intraoperative complication rates were found between RAS and CLS arms for women undergoing hysterectomy (RR 1.05, 95% CI 0.31 to 3.56; participants = 487; studies = 5; $I^2 = 28\%$; low-certainty evidence; [Analysis 1.2](#)). Tests for subgroup differences suggest that the treatment effect may be different in women with malignant versus non-malignant disease ($P = 0.08$; $I^2 = 68.4\%$). We downgraded this evidence to 'low' as a result of imprecision and study limitations (risk of bias concerns).

Intraoperative injury

For the specific complication 'intraoperative injury', we noted no clear differences between RAS and CLS arms, with low event rates in both arms (RR 1.62, 95% CI 0.20 to 12.91; participants = 269; studies = 3; $I^2 = 0\%$; low-certainty evidence; [Analysis 1.3](#)). Studies recruiting women with non-malignant disease only reported these outcomes.

Postoperative complications only

With regard to postoperative complications for hysterectomy procedures, researchers found no clear differences between RAS and CLS arms (RR 0.82, 95% CI 0.42 to 1.59; participants = 533; studies = 5; $I^2 = 51\%$; low-certainty evidence; [Analysis 1.4](#)). We downgraded this evidence to 'low' as the result of imprecision and study limitations.

Bleeding complications

For the specific outcome 'bleeding complications' (e.g. vaginal haematoma), researchers found no clear differences between RAS and CLS arms (RR 0.41, 95% CI 0.10 to 1.66; participants = 367; studies = 4; $I^2 = 17\%$; low-certainty evidence; [Analysis 1.5](#)). The point estimate in favour of RAS was heavily influenced by a single study ([Lonnerfors 2014](#)), in which 2 of 61 women in the RAS arm developed vaginal haematoma compared with 11 of 61 women in the CLS arm.

Infection complications

Overall, we noted no significant differences between RAS and CLS arms with regard to average wound infection rates (RR 0.62, 95% CI 0.13 to 2.88; participants = 367; studies = 4; $I^2 = 2\%$; low-certainty evidence; [Analysis 1.6](#)).

Death within 30 days

No studies reported this outcome.

Operating time

Mean total operating time was longer on average in the RAS arm than in the CLS arm, although the difference between groups did not reach statistical significance. We noted high statistical heterogeneity for this outcome, with average operating times varying considerably in the two studies contributing data to this outcome (mean difference (MD) 41.18 minutes, 95% CI -6.17 to 88.53; participants = 148; studies = 2; $I^2 = 80\%$; very low-certainty evidence; [Analysis 1.7](#)). We downgraded evidence for study design limitations, heterogeneity, and imprecision.

Two studies reported this outcome as median (range). Median total operating times reported for the RAS arm versus minimally invasive arms in [Lonnerfors 2014](#) were 76 minutes (43 to 210) versus 86 minutes (29 to 223), respectively ($P = 0.54$). Likewise, for [Green 2013](#), median total operating times were 90 minutes (74 to 104) and 88 minutes (75 to 105), respectively ($P = 0.69$). These individual study data, which shed a favourable light on RAS, were at high risk of bias for the reasons previously mentioned (see [Risk of bias in included studies](#)).

Results for mean operating room time were similar to those for mean total operating time, although the difference (favouring RAS) reached statistical significance (MD 44.35, 95% CI 5.22 to 83.47; participants = 148; studies = 2; $I^2 = 59\%$). This result is based on findings from two studies with design limitations and moderately high heterogeneity and relates to women with non-malignant disease undergoing hysterectomy ([Analysis 1.8](#)).

Length of hospital stay

Mean length of hospital stay in days differed slightly between RAS and CLS (MD -0.30 days, 95% CI -0.53 to -0.07; participants = 192; studies = 2; $I^2 = 0\%$; very low-certainty evidence). However, data for this outcome were derived from two relatively small trials, and length of stay varied considerably in these two studies (mean stay in CLS groups was 3.6 days in [Sarlos 2010](#) vs 1.4 days in the later [Lonnerfors 2014](#) study; [Analysis 1.9](#)). Therefore results are difficult to interpret.

Conversion to another approach

We noted no significant differences between RAS and CLS approaches with regard to rate of conversion (RR 1.17, 95% CI 0.24 to 5.77; participants = 269; studies = 3; $I^2 = 0\%$; low-certainty evidence; [Analysis 1.10](#)).

Blood transfusions and blood loss

Four studies reported blood transfusions and noted no statistically significant differences between RAS and CLS arms (RR 2.49, 95% CI 0.75 to 8.23; participants = 346; studies = 4; $I^2 = 0\%$; low-certainty evidence; [Analysis 1.12](#)). There was no clear difference in effect between subgroups of women with non-malignant versus malignant disease (Tests for subgroup differences: $\text{Chi}^2 = 0.02$, $\text{df} = 1$ ($P = 0.88$), $I^2 = 0\%$).

Pain

Two studies reported postoperative pain at different time points within the first two weeks ([Green 2013](#); [Paraiso 2013](#)). However, only one study provided usable data (means) for meta-analysis ([Paraiso 2013](#)).

[Paraiso 2013](#) reported pain scores during normal activities at two weeks post hysterectomy, with no significant differences between study arms (MD -2.00, 95% CI -16.08 to 12.08; participants = 36; [Analysis 1.13](#)).

[Green 2013](#) (a high risk of bias study) reported median postoperative pain scores and found no significant differences between RAS and CLS arms following hysterectomy ($P = 0.73$).

Quality of life

One study reported quality of life at four to six weeks ([Sarlos 2010](#)), and another study at six months ([Paraiso 2013](#)). None of the studies reporting these data described significant differences in QoL, except for [Sarlos 2010](#). This study initially found a greater change in QoL at six weeks compared with before the operation in the RAS group (MD 8.00, 95% CI 3.12 to 12.88; participants = 95), but this self-reported outcome was subject to significant risk of bias. At six months, a different study found no significant differences between groups (MD 5.00, 95% CI -3.01 to 13.01; participants = 38).

Re-intervention/re-admission

We noted no significant difference between RAS and CLS with regard to the number of cases requiring re-intervention (RR 0.25, 95% CI 0.03 to 2.17; participants = 122; studies = 1; [Analysis 1.16](#)) or re-admission (RR 0.46, 95% CI 0.14 to 1.48; participants = 220; studies = 2; $I^2 = 0\%$; [Analysis 1.17](#)). These data were sparse and were at risk of bias (i.e. very low- to low-certainty evidence).

Cost

One study reported overall costs (including equipment setup and maintenance and theatre and hospital admission costs) ([Lonnerfors 2014](#);) [Analysis 1.18](#)), which were higher for RAS than for CLS.

Lymph node yield

No data were found for this outcome.

2. RAS versus CLS (sacrocolpopexy)

Intraoperative and postoperative complications

Three studies reported this outcome; overall researchers found no clear differences in rates of complications between women undergoing sacrocolpopexy by RAS or CLS (RR 0.95, 95% CI 0.21 to 4.24; participants = 186; studies = 3; $I^2 = 78\%$; very low-certainty evidence). We noted high statistical heterogeneity for this outcome and downgraded results for study design limitations and imprecision.

Intraoperative complications

Researchers reported no clear differences between groups for intraoperative complications (RR 0.82, 95% CI 0.09 to 7.59; participants = 108; studies = 2; $I^2 = 47\%$; very low-certainty evidence; [Analysis 2.2](#)) or intraoperative injuries (RR 0.87, 95% CI 0.28 to 2.70; participants = 186; studies = 3; $I^2 = 4\%$; low-certainty evidence; [Analysis 2.3](#)).

Postoperative complications

One study reported more early postoperative complications in the RAS group; however data were not simple to interpret because it is not clear whether women suffered more than one complication

(RR 3.54, 95% CI 1.31 to 9.56; participants = 68; very low-certainty evidence; [Analysis 2.4](#)). Infection appeared more frequent in the RAS group; data on postoperative complications were sparse and showed no significant differences between groups (RR 1.89, 95% CI 0.63 to 5.68; participants = 68; studies = 1).

Death up to 30 days

Authors of the included trials did not report this outcome.

Total operating time

RAS was associated with increased operating time, although we noted high heterogeneity for this outcome; on average, operating time was 40.53 minutes longer in the RAS group (MD 40.53 minutes, 95% CI 12.06 to 68.99; participants = 186; studies = 3; $I^2 = 73\%$; low-certainty evidence; [Analysis 2.7](#)). Findings for total operating room time were similar, and again we observed high heterogeneity between studies (MD 43.24, 95% CI 0.12 to 86.35; participants = 146; studies = 2; $I^2 = 84\%$; [Analysis 2.8](#)).

Length of hospital stay

Two studies reported length of hospital stay for women undergoing RAS versus CLS for sacrocolpopexy. Very low-certainty evidence suggested little or no difference between the two techniques in terms of duration of stay (MD 0.26 days, 95% CI -0.15 to 0.67; participants = 108; studies = 2; $I^2 = 0\%$; [Analysis 2.9](#)).

Conversion to another approach

Only one study reported conversion to another surgical approach; in the RLS group, 3 of 35 converted to another method, and in the CLS group, 2 of 35 converted. Numbers were too small to permit meaningful conclusions (RR 1.41, 95% CI 0.25 to 7.94).

Blood loss and blood transfusion

Trial authors did not report the number of women undergoing blood transfusion. Two studies reported estimated mean blood loss, which appeared to be slightly reduced in the RAS group, although mean blood loss in both arms was not consistent in the two studies contributing data (MD -15.17, 95% CI -26.43 to -3.91; participants = 118; studies = 2; $I^2 = 0\%$).

Pain

[Anger 2014](#) reported mean pain scores one week postoperatively. Differences in pain scores favoured the CLS arm but were not statistically significant (MD 0.90, 95% CI -0.06 to 1.86; participants = 78; very low-certainty evidence; [Analysis 1.13](#)). Although it did not contribute data to the meta-analysis, another sacrocolpopexy study reported that the RAS group had significantly greater pain at rest and with activity during weeks 3 to 5 and required longer use of non-steroidal anti-inflammatory drugs (NSAIDs) (median 20 days vs 11 days; $P < .005$) ([Paraiso 2011](#)). This low-quality evidence suggests that, when performed for sacrocolpopexy, RAS may be associated with greater postoperative pain than is noted with CLS.

Quality of life

[Anger 2014](#) reported QoL scores at six weeks; mean scores were almost identical in the two arms (MD -0.01, 95% CI -0.06 to 0.04; participants = 78).

[Paraiso 2011](#) also measured QoL at 12 months; however, data were insufficient for meta-analysis.

Re-intervention and re-admission to hospital

Authors of included studies did not report hospital re-admission. Two studies reported the numbers of women requiring re-intervention after the initial surgery. The number of women requiring further surgery was too small to allow meaningful analysis (RR 0.47, 95% CI 0.06 to 3.59; participants = 173; studies = 2; very low-certainty evidence; [Analysis 2.16](#)).

Cost

Two studies reported costs of the two surgical approaches; we noted very high heterogeneity between these studies and did not combine the results. Conventional surgery appeared to be associated with lower costs when compared with RAS (see [Analysis 2.18](#)).

Non-prespecified outcomes

One study reported longer-term complications (sexual dysfunction and urinary tract infection); few women experienced these complications, we noted no clear differences between surgical approaches for either outcome (RR 0.90, 95% CI 0.06 to 13.48; RR 0.18, 95% CI 0.01 to 3.56; participants = 40; studies = 1, respectively).

3. RAS versus open abdominal surgery (hysterectomy)

Only two studies evaluated this comparison, one among 20 women with non-malignant disease ([Wijk 2016](#)), and the other among 120 women with high-risk endometrial cancer ([RASHEC 2013](#)). For most outcomes, only one of these studies contributed data and evidence from [RASHEC 2013](#) was downgraded by two levels for risk of bias (see [Risk of bias in included studies](#)). Evidence for the following outcomes suggesting that there may be little or no difference between the two approaches was rated very low certainty:

- Intraoperative and postoperative complications: [Analysis 3.1](#).
- Intraoperative complications: [Analysis 3.2](#).
- Postoperative complications: [Analysis 3.3](#).
- Death within 30 days: [RASHEC 2013](#) reported that no deaths occurred in either arm within 30 days; [Analysis 3.4](#).
- Bleeding complications: [Analysis 3.5](#)
- Infection complications: [Analysis 3.6](#)
- Blood loss and blood transfusion: [Analysis 3.7](#).
- Re-admission: [Analysis 3.9](#).

Quality of life

One study ([Wijk 2016](#)) reported that, at 4 weeks post-operation, more women in the open abdominal surgery group than in the RAS group reported some restriction in activities of daily living (RR 0.25, 95% CI 0.07 to 0.90; participants = 20; studies = 1; very low certainty evidence, [Analysis 3.8](#)).

Costs

[RASHEC 2013](#) reported cost data from Sweden, which suggest that the average cost of RAS may be about USD 1568 less than open surgery (MD -1568.00 US dollars, 95% CI -3100.75 to -35.25; participants = 96; studies = 1; low certainty evidence, [Analysis 3.10](#)).

Total operating time

In [RASHEC 2013](#) this was reported as mean (range) and the mean operating time was 233 minutes in the RAS group (range 166 to 320

minutes) compared with 187 minutes in the CLS group (range 109 to 300) ($P > 0.001$) (low-certainty evidence).

Hospital stay

[RASHEC 2013](#) reported this outcome as medians (range) and median hospital stay was 2 days (1-5 days) in the RAS group and 5 days (4 to 9 days) in the open surgery group ; i.e findings suggest that hospital stays may be shorter with RAS than with open abdominal surgery (low certainty evidence) These data are difficult to interpret because a single surgeon carried out all RAS procedures but five (possibly less experienced) surgeons carried out the open surgical procedures.

Lymph node yield

Evidence from [RASHEC 2013](#) suggest that para-aortic and pelvic lymph node yields may be lower with RAS than with open abdominal surgery (mean yield 42 in the RAS group vs 50 in the CLS group) (MD -8.00, 95% CI -14.97 to -1.03; participants = 96, studies = 1; low-certainty evidence).

4. RAS versus CLS for endometriosis

A single study that provided data for 73 women is included in this comparison; women with endometriosis underwent procedures ranging from relatively minor endometrial resection through hysterectomy; many of the women included in this study had undergone previous surgery for their condition. For most outcomes, event rates were low and the sample size was insufficient to show potential differences between groups (resulting in very low-certainty to low-certainty evidence).

Intraoperative complications

Researchers found no clear differences between surgical techniques for intraoperative complications (RR 0.36, 95% CI 0.04 to 3.32; participants = 73), which included urethral complications and bowel injury; they reported four events overall.

Postoperative complications

Researchers reported no significant differences in postoperative complications between groups; however results are difficult to interpret because it is not clear from the published results whether an individual woman may have had more than one complication (RR 0.78, 95% CI 0.40 to 1.51; participants = 73). For postoperative infection, it appeared that women undergoing RAS were at lower risk of infection (6/35 vs 12/38 women for the CLS group); although the 95% CI for this outcome was wide, differences between groups did not reach statistical significance (RR 0.54, 95% CI 0.23 to 1.29). Trial authors did not report overall length of hospital stay.

Total operating time

Researchers identified little or no difference in mean operating time between the two surgical approaches (MD 5.00 minutes, 95% CI -20.71 to 30.71; participants = 73). Results for total operating room time were similar (MD 5.90, 95% CI -22.31 to 34.11).

Conversion to another approach

Only one woman (in the CLS group) required conversion to another approach (RR 0.36, 95% CI 0.02 to 8.58; participants = 73).

Hospital re-admission

Event rates were low for this outcome, and researchers provided no clear evidence of any differences in the number of women needing re-admission to hospital (RR 0.72, 95% CI 0.13 to 4.08).

Blood loss

Trial authors did not report the number of women requiring blood transfusion. The mean estimated blood loss for women undergoing surgery via different approaches was not significantly different (MD 57.10, 95% CI -20.08 to 134.28; participants = 73). These data are very difficult to interpret because the standard deviations (SDs) were very high in both arms of the trial; this study included women with a broad range of severity of disease who were undergoing surgery, with some women undergoing extensive surgery.

Quality of life

Researchers reported unadjusted QoL scores at six weeks and at six months. It appears that QoL scores were higher in the CLS group at six weeks post surgery; however these results are difficult to interpret because baseline scores were also higher in the CLS group than in the RAS group (MD -2.30, 95% CI -3.79 to -0.81; participants = 73). Scores at six months were very similar in both arms of the trial, and no significant differences were evident between groups (MD 1.30, 95% CI -0.58 to 3.18; participants = 73).

Pain

Trial authors reported pain scores at six months and noted no clear differences between groups (MD 3.30, 95% CI -8.31 to 14.91; participants = 73).

DISCUSSION

Summary of main results

This is the second update of this review. We included 12 randomised controlled trials (RCTs) involving 1016 women. Studies were at moderate to high overall risk of bias, and we downgraded evidence mainly due to concerns about risk of bias among studies contributing data and imprecision of effect estimates. Procedures performed were hysterectomy (eight studies) and sacrocolpopexy (three studies). Two studies of hysterectomy involved women with endometrial cancer. In addition, one trial examined surgical treatment for endometriosis, which included resection or hysterectomy.

For the comparison RAS versus CLS for hysterectomy, researchers found no clear differences in complication rates between robot-assisted surgery (RAS) and conventional laparoscopy surgery (CLS) arms (low-certainty evidence). We examined separately studies including women with non-malignant versus malignant disease and found no clear evidence of a difference in effect between subgroups, with only one study contributing data to the malignant disease subgroup of this comparison.

Review authors noted no clear differences in intraoperative complication rates between RAS and CLS arms (low-certainty evidence). Testing for subgroup differences suggests that the treatment effect may be different for women with malignant versus non-malignant disease; however, the difference between RAS and CLS was not significant in either group. For postoperative

complications, we noted no statistically significant differences between RAS and CLS arms (low-certainty evidence).

Pooled data from two studies suggest that mean total operating time was longer on average in the RAS arm than in the CLS arm, although the difference between groups did not reach statistical significance. We noted high statistical heterogeneity for this outcome, with average operating times varying considerably in the two studies contributing data (very low-certainty evidence). Three studies reported this outcome as median values (range), but their results were not consistent. Mean length of hospital stay in days differed slightly between RAS and CLS arms (very low-certainty evidence). However, data for this outcome were derived from two relatively small trials, for which length of stay varied considerably (mean stay in CLS groups 3.6 days in one study vs 1.4 days in a later study). Four studies reported blood transfusions and revealed no statistically significant differences between RAS and CLS arms (low-certainty evidence).

For the comparison RAS versus CLS for sacrocolpopexy, three studies reported intraoperative and postoperative complications. Overall researchers found no clear difference in rates of these complications between women undergoing sacrocolpopexy by RAS or CLS (very low-certainty evidence), and no clear differences in intraoperative complications between these groups (very low-certainty evidence). In one study, early postoperative complications were higher in the RAS group; however, these data are difficult to interpret because it is not clear whether women suffered more than one complication (very low-certainty evidence). None of the included studies reported death up to 30 days.

RAS was associated with increased operating time, although heterogeneity for this outcome was high; on average, operating time was 40.53 minutes longer in the RAS group (low-certainty evidence). Two studies reported length of stay for women undergoing RAS versus CLS for sacrocolpopexy. Very low-certainty evidence suggests there was little or no difference between the two techniques in terms of duration of stay. Researchers did not report the number of women undergoing blood transfusion.

Only two studies evaluated RAS against open surgery, one among 20 women with non-malignant disease and the other among 96 women with high-risk endometrial cancer. For most outcomes, only one of these studies contributed data and the evidence was mostly of a very low certainty. Low-certainty evidence from the study among women with endometrial cancer suggests that lymph node yields may be lower with RAS, operating time may be longer, hospital stays may be shorter, and overall costs may be less than open surgery; survival outcomes were not reported.

For RAS versus CLS for endometriosis, a single study with 73 women contributed data. Women in this study underwent procedures ranging from relatively minor endometriosis resection through hysterectomy, and many women had undergone previous surgery for their condition. For most outcomes, event rates were low, and the sample size was insufficient to show potential differences between groups.

Neither of the studies conducted among women with endometrial cancer reported survival outcomes.

Comprehensive economic analysis was beyond the scope of this review; this aspect of RAS requires further independent evaluation.

Overall completeness and applicability of evidence

Evidence related to non-malignant gynaecological disease is incomplete overall, and available evidence is applicable only to hysterectomy and sacrocolpopexy procedures. In addition, we are not sure whether review findings apply to all women requiring these procedures or selected groups of women, as inclusion and exclusion criteria varied across the studies.

For malignant disease, we found little evidence on the effectiveness and safety of RAS compared with CLS or open surgery for endometrial cancer. Neither of the two included studies reported disease-free and overall survival outcomes. In one study, one surgeon performed all the RAS procedures and five different surgeons performed all the comparison procedures, so it was not possible to distinguish the effects of RAS from the effects of the surgeon/s on the outcomes reported and these findings may not be applicable to other surgeons and settings.

Increased postoperative pain with RAS for sacrocolpopexy procedures, as observed in [Paraiso 2011](#) and [Anger 2014](#), which may have been due to the extra port (RAS required five ports), larger size or different locations of trocars, longer operating time, or robotic rather than manual manipulation of trocars throughout a longer procedure, requires further investigation.

Quality of the evidence

Much uncertainty remains regarding the estimate of several important effects of RAS versus CLS, and we most commonly assessed the certainty of review findings as low or very low. The main reasons for downgrading the certainty of evidence for these outcomes were inconsistency and imprecision of results across the small number of included studies, which, in general, could not be attributed to differences in the types of procedures undertaken. Given the limited data for the different procedures included, the average effect of one study could have had a large potential effect on the size and direction of the overall effect estimate. We therefore expect that further research will have an important impact on review findings and will likely change the estimate of effects for intraoperative and postoperative complications, among others.

Potential biases in the review process

We conducted a rigorous process to identify all relevant studies; we therefore consider this review to be comprehensive in identifying all eligible studies. After a thorough discussion of the merits and implications for risk of bias, we excluded one quasi-RCT conducted in women requiring hysterectomy ([Martinez-Maestro 2014](#)). Women in this study were allocated to RAS or CLS "according to the position on the hospital waiting list and the availability of the robot on the day of surgery"; investigators reported that "neither the researchers nor the surgeons had the possibility to interfere with the allocation". Slight imbalances in age (slightly older participants in the CLS group) and in uterine weight (slightly smaller in the RAS group) might have been due to chance.

The original reviews included only two studies between them: [Sarlos 2010](#) and [Paraiso 2011](#). It has been suggested that studies conducted by early robot adopters may be subject to bias ([Lonnerfors 2014](#)). Surgeons in the two early studies had performed a minimum of 10 and 30 RAS procedures, respectively. [Sarlos 2010](#) reported the need to undock the robot in six women to cut the uterus into piecemeal sizes for removal. The other included studies

did not describe this procedure, and it is not clear how, if at all, similar problems were overcome by other researchers. We did not pre-specify technical issues as an outcome; however, we presume these would have an impact on procedure time.

Extracted data for intraoperative and postoperative complications were investigator-defined. We used these data as reported, without censoring for minor complications (e.g. urinary tract infection). This may have accounted for some of the heterogeneity observed among the included studies.

To our knowledge, two studies identified as ongoing in the 2014 version of this review have not yet published results ([Kjølhed 2012](#); [Narducci 2010](#)). We were unable to obtain a status report from contact authors, and further investigation of this potential source of reporting bias was not possible.

Agreements and disagreements with other studies or reviews

The learning curve for RAS in gynaecology has been addressed in several studies, which show that it may vary according to the type of procedure involved. Learning curve analyses for benign disease suggest that competency (for which operating time is frequently a surrogate marker) is gained upon completion of approximately 20 procedures ([Bell 2009](#)), whereas for radical hysterectomy in women with cervical cancer, proficiency might be achieved after 28 procedures have been performed ([Yim 2013](#)).

Several studies have suggested that the learning curve for RAS is shorter than for CLS, and therefore gynaecological surgeons who are inexperienced in CLS should consider performing RAS ([Green 2013](#)). Findings of a shorter operating time with RAS versus CLS in a quasi-RCT with surgeons relatively inexperienced in both approaches might support this suggestion ([Martinez-Maestro 2014](#)). However, a report from a setting in the USA where RAS accounted for almost 23% of all hysterectomies in 2011 stated that resident doctor involvement in RAS was less with the robotic approach than with any other route ([Jeppson 2014](#)). Thus the impact of this technology on surgical training of young doctors appears considerably uncertain.

A large RCT of minimally invasive versus abdominal radical hysterectomy for early cervical cancer has reported results showing that minimally invasive surgery was associated with higher rates of death and recurrence when compared with open surgery ([Ramirez 2018](#)). Unfortunately, this study did not fit our review criteria, as only 15.6% of minimally invasive procedures in the experimental arm of the study were robot-assisted, the others were done by laparoscopy, and allocation to RAS or laparoscopy was not randomised (see [Characteristics of excluded studies](#)). This trial closed for this reason before the full sample size had been accrued (631/740 participants had been accrued). However, its overall findings suggest that minimally invasive techniques might not be equally effective for malignant disease, which generally involves more extensive surgery and greater surgical experience. Further research is needed to test the robustness of this single study and to understand the extent to which biological or surgical factors might affect outcomes for cervical cancer surgery.

An economic evaluation of RAS in gynaecology was beyond the scope of this review. However, a recent economic evaluation of RAS for hysterectomy concluded that without longer-term or functional

outcome data, the additional expense of RAS may not be justified in a budget-constrained health system (Teljeur 2014). In the light of our findings, current evidence related to the clinical effectiveness of RAS across a range of gynaecological procedures remains of low certainty or unproven. Once effectiveness is proved, additional indirect factors such as the surgeon's well-being, particularly with respect to physically demanding laparoscopic and open surgery for gynaecological cancers, may become important cost considerations. However, without more robust evidence on clinical effectiveness and safety, it will not be possible to accurately assess the cost-effectiveness of RAS in gynaecology.

AUTHORS' CONCLUSIONS

Implications for practice

Evidence on the effectiveness and safety of robot-assisted surgery (RAS) compared with conventional laparoscopic surgery (CLS) for non-malignant disease (hysterectomy and sacrocolpopexy) is of low certainty but suggests that surgical complication rates might be comparable. Evidence on the effectiveness and safety of RAS compared with CLS or open surgery for malignant disease is more uncertain because survival data are lacking; therefore, until further evidence becomes available, its use in this context might be appropriate only in clinical trials. Other practical implications, such as the potential for under-skilling of surgical trainees and future surgeons in essential surgical skills, should be carefully considered in broader discussions around the use of RAS.

Implications for research

The effectiveness and safety of RAS remain uncertain, so more evidence on whether it should be used for gynaecological procedures is needed, as is independent evaluation of cost-effectiveness. RAS is an operator-dependent, expensive technology, meaning that independent evaluation of the safety of this technology without bias will be challenging.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Anger 2014

Methods	<p>2-Centre RCT</p> <p>Setting: academic teaching hospitals (UCLA , Los Angeles, and Loyola University, Chicago)</p> <p>Country: USA</p> <p>Groups: robot-assisted sacrocolpopexy vs conventional laparoscopic sacrocolpopexy</p> <p>Period: 2009 to 2011</p>
Participants	<p>Number: 78 women randomly assigned</p> <p>Diagnosis: women with symptomatic stage POP II or greater, including significant spiral support loss</p> <p>Included: a clinical indication for sacrocolpopexy in women with symptomatic stage 2 or greater pelvic organ prolapse to 1 cm on either side of the introitus, including apical support loss to half total vaginal length</p> <p>Excluded: pregnancy or pregnancy in the past 12 months, plans for future childbearing, inability to give informed consent.</p> <p>Age (years): 58.5 ± 10.5/60.6 ± 9.2</p> <p>BMI (kg/m²): 28.3 ± 6.6/27.7 ± 4.7</p> <p>Overall 42% of the women had a prior hysterectomy (similar between groups)</p>
Interventions	<p>RAS (40) vs CLS (38)</p> <p>Procedure: laparoscopic sacrocolpopexy</p> <p>Follow-up: 12 months</p>
Outcomes	<ul style="list-style-type: none"> Intraoperative and postoperative complications: adverse events reported Quality of life: reported

Robot-assisted surgery in gynaecology (Review)

Anger 2014 (Continued)

- Total operating time: reported
- Instrument setup time: NR
- Length of hospital stay: NR
- Estimated blood loss, or transfusion: reported
- Rate of conversion: NR
- Early and late mortality: NR
- Cost: reported (primary outcome)

Notes

Surgeons' experience: All surgeons had performed a minimum of 10 procedures of each type

58% of women underwent a hysterectomy at the same time (25/40 vs 20/38 for RAS and CLS, respectively)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation: "based on site and need for concurrent hysterectomy"
Allocation concealment (selection bias)	Low risk	Allocation was concealed before surgical randomisation (performed by uploading the treatment allocation to a password-protected website)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and study co-ordinator "were blinded to the assignment for the first 6 weeks of the study" Surgeons performing surgery and other staff providing care would not be blind to assignment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Study assessor was blinded to surgery assignment Surgeons performing surgery would not be blind to group assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Three women were lost to follow-up at 6 months (1 CLS and 2 RAS)
Selective reporting (reporting bias)	Low risk	All prespecified outcomes were reported
Funding	Low risk	Funded by a National Institute of Biomedical Imaging and Bioengineering Recovery Act Limited Competition Grant Study authors reported no potential conflicts of interest
Other bias	Low risk	None noted

Costantini 2017

Methods

1-Centre RCT

Setting: Department of Urology, tertiary hospital (not clear), Italy

Country: Italy

Groups: robot-assisted sacrocolpopexy vs laparoscopic sacrocolpopexy

Costantini 2017 (Continued)

Period: women recruited May 2013 to April 2016

Participants	<p>Number: 40 women randomised (21/19)</p> <p>Diagnosis: women with advanced pelvic organ prolapse (symptomatic POP stage > II)</p> <p>Included: women with advanced pelvic organ prolapse (symptomatic POP stage > II) requiring sacro-colpopexy. Other inclusion criteria not described</p> <p>Excluded: not described</p> <p>Age (years): (mean, SD not reported) 63.5; 58.82</p> <p>BMI (kg/m²): (mean, SD not reported) 24.59; 25.41</p>
Interventions	<p>RAS (21) vs laparoscopic surgery</p> <p>Procedure: laparoscopic sacrocolpopexy</p> <p>Follow-up: 12 months (although long-term outcomes not reported)</p>
Outcomes	<ul style="list-style-type: none"> • Intraoperative and postoperative complications: reported • Quality of life: NR • Total operating time: reported • Instrument setup time: NR • Length of hospital stay: reported • Estimated blood loss, or transfusion: reported • Cost: NR • Rate of conversion: NR • Early and late mortality: NR
Notes	<p>Surgeons' experience: "All procedures were performed by 2 senior surgeons, with standardized technique"</p> <p>Data were extracted from 2 brief conference abstracts. It is not clear if these are pilot or interim results. Mean follow-up time appeared different for the 2 procedures (15.5 months for RAS vs 32.05 months for CLS). It is not clear why there was this discrepancy. Most of the data collected were not reported</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Reported via a predetermined computer-generated code
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and staff would be aware of the technique
Blinding of outcome assessment (detection bias) All outcomes	High risk	All reported outcomes would be subject to observer bias
Incomplete outcome data (attrition bias)	Unclear risk	Denominators were not reported in the tables

Costantini 2017 (Continued)

All outcomes

Selective reporting (reporting bias)	Unclear risk	No protocol is available Only a limited number of outcomes were reported
Funding	Unclear risk	Not reported
Other bias	High risk	Methods were described very briefly and women in the 2 groups were not followed up at the same time Due to the discrepancy in follow-up times between the 2 study arms, reviewers believe it is possible that women were recruited to the 2 procedures at different times

Deimling 2017

Methods	1-Centre RCT Setting: Penn State Hershey Medical Center, Pennsylvania Country: USA Groups: robot-assisted hysterectomy vs conventional laparoscopic hysterectomy Period: April to October 2014
Participants	Number: 144 women randomly assigned Diagnosis: pelvic pain, endometriosis, abnormal uterine bleeding, fibroids, previous failure of ablation treatment Included: scheduled to undergo hysterectomy at the study institution; aged 18 to 80 years Excluded: medical conditions contraindicating pneumoperitoneum or proper ventilation during anaesthesia, pregnant, pelvic organ prolapse allowing for a vaginal approach, anticipated to undergo combined surgical procedure (other than coincidental appendectomy) Age (years): 42.3 ± 8.0/43.2 ± 8.5 BMI (kg/m²): 30.6 ± 7.8/32.1 ± 9.3
Interventions	RAS (72) vs CLS (72) Procedure: laparoscopic hysterectomy Follow-up: 12 weeks
Outcomes	<ul style="list-style-type: none"> • Intraoperative and postoperative complications: adverse events reported • Total operating time: reported • Length of hospital stay: reported • Estimated blood loss (≥ 50 mL): reported • Postoperative pain score: reported
Notes	Surgeons' experience: The primary surgeon had a high-volume surgical case load (> 300 total hysterectomies each year) that included both standard laparoscopic and robot-assisted laparoscopic techniques

Deimling 2017 (Continued)

81% (RAS group)/88% (CLS group) of women underwent an oophorectomy at the same time, 24%/30% unilateral oophorectomy, 25%/21% appendectomy, 7%/18% lysis of adhesions, 22%/4% resection of endometriosis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number generator: "randomization was performed using a random number generator"
Allocation concealment (selection bias)	Low risk	Treatment allocations were sealed in opaque envelopes, numbered consecutively, and given to participants in sequential order on the day of surgery
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and study investigators were unmasked to group assignments
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of study assessor was not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Although 1 participant in the CLS group did not receive the allocated intervention (hysterectomy aborted: underwent laparoscopic lysis of adhesions), intention-to-treat outcome data for all randomised participants were reported
Selective reporting (reporting bias)	Low risk	All prespecified outcomes were reported
Funding	Unclear risk	Study was reported to be funded in part through the Penn State Clinical and Translational Research Institute, Pennsylvania State University. One study author was a proctor for Ethicon and Intuitive Surgical during the study period, and another study author owns stock in Merck; no other potential conflicts of interest were reported
Other bias	Low risk	None noted

Green 2013

Methods	<p>Single-centre RCT, open-label</p> <p>Setting: Cleveland Clinic, Ohio (academic teaching hospital)</p> <p>Country: USA</p> <p>Groups: conventional laparoscopic vs robot-assisted laparoscopic hysterectomy</p> <p>Period: NR</p>
Participants	<p>Number: 113 randomly assigned, 98 analysed</p> <p>Diagnosis: pelvic pain, endometriosis/adenomyosis, DUB, fibroids</p> <p>Included: "all women between 18 and 80 years of age requiring hysterectomy that were also candidates for laparoscopy"</p>

Green 2013 (Continued)

Excluded: medical conditions not allowing for pneumoperitoneum; medical conditions preventing proper ventilation during laparoscopy; uterine size precluding access to the uterine arteries; pelvic organ prolapse amenable to a vaginal approach

Age (median years): 42 (36 to 46)/45 (37 to 48)

BMI (median kg/m²): 32 (25.3 to 36.1)/29.6 (26.6 to 36.4)

Uterine weight (grams): 119 (90 to 174.8)/151 (110 to 217)

Interventions	RAS (59) vs CLS (54) Procedure: laparoscopic hysterectomy
Outcomes	<ul style="list-style-type: none"> • Intraoperative and postoperative complications: reported • Quality of life: NR • Total operating time: reported (primary outcome) • Instrument setup time: NR • Length of hospital stay: reported • Estimated blood loss, or transfusion: reported • Rate of conversion: NR • Early and late mortality: NR • Cost: NR
Notes	<p>This study is currently published only as a conference abstract (NCT01581905). The conference presentation including tabled results was obtained from the investigators (Gerald Harkins) on 22 July 2014. A full report of this study may yet be published (personal communication). Accrual appears to have been closed early (online protocol states a sample size of 400)</p> <p>15 women were withdrawn from the study (11 in CLS group and 4 in RAS group). In addition, 11 women in the CLS arm had RAS, resulting in 37 women in the CLS arm and 61 in the RAS arm Per-protocol analysis was performed</p> <p>Uterine weight tended to be less in the RAS arm (P = 0.09)</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Stated: performed "using a random number generator program"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Open-label
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	High risk	<p>10 women were withdrawn because procedures were cancelled for medical or personal reasons (8 in CLS and 2 in RAS groups), and 5 women underwent alternative procedures (3 in CLS group and 2 in RAS group)</p> <p>11 women in CLS arm underwent RAS instead</p>

Green 2013 (Continued)

Selective reporting (reporting bias)	High risk	11 women in the CLS arm underwent RAS; per-protocol analysis was performed, resulting in 37 women in the CLS arm and 61 in the RAS arm
Funding	Unclear risk	Milton S. Hershey Medical Center; potential conflicts of interest not disclosed
Other bias	High risk	Study appears to have been closed early (online protocol states sample size of 400)

LAROSE 2017

Methods	<p>RCT, multi-centre, parallel, open-label (Cleveland Clinic, Cleveland, Ohio, Mayo Clinic, Scottsdale, Arizona; Brigham and Women's Hospital, Boston, Massachusetts)</p> <p>Country: USA</p> <p>Period: March 2012 to July 2015</p> <p>Groups: RAS (superficial and deep resection for endometriosis) vs CLS</p>	
Participants	<p>Number: 74 participants (73 followed up: RAS 35, CLS 38)</p> <p>Diagnosis: presumed endometriosis</p> <p>Included: women aged 18 or over undergoing laparoscopic treatment for pain and infertility with presumed endometriosis determined by operating surgeon and/or ultrasound finding of endometrioma(s)</p> <p>Excluded: suspected malignancy, medical illness precluding laparoscopy, inability to give informed consent, morbid obesity (BMI > 44), need for concomitant bowel resection and/or ureteral re-anastomosis</p> <p>Age: 34.3 (SD 7.2); 34.5 (SD 8.5)</p> <p>BMI: 26.1 (SD 5.2); 24.8 (SD 5.9)</p> <p>Previous laparoscopy: reported as mean, SD, and n; 1.2 (1.3)/35; 1.2 (1.4)/38</p> <p>Previous abdominal surgery: 14/35 vs 12/38</p> <p>Physical health at baseline score (mean (SD)): 41.5 (4.8) vs 42.7 (6.4)</p>	
Interventions	<p>Procedure: surgery for endometriosis (superficial and deep endometriosis resection). Lesions suspicious for endometriosis were completely resected until non-diseased peritoneal margins were visible in surrounding tissue. Cystectomy was performed for endometrioma(s), along with additional procedures as needed (including hysterectomy)</p> <p>Follow-up: 6 months</p> <p>Surgeon experience: 5 surgeons carried out the procedures (3 carried out both procedures, 1 performed conventional, and another performed robot-assisted surgery only). Each site had experience in both procedures</p>	
Outcomes	<p>Primary outcomes</p> <ul style="list-style-type: none"> Operating time (skin incision to skin closure) <p>Secondary outcomes</p> <ul style="list-style-type: none"> Pain and activity (assessed at 2 weeks, 6 weeks, and 6 months) Total operating room time Surgeon estimated blood loss 	

LAROSE 2017 (Continued)

- Intraoperative and postoperative complications
- Re-admission
- Quality of life (SF-12 and EHP-30) (assessed at 6 weeks and at 6 months)

Notes This study examines resection for endometriosis and seems to incorporate both relatively limited and extensive surgical excision and resection

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation schedule with random numbers table
Allocation concealment (selection bias)	Unclear risk	Stated that randomisation was prospective at the time of surgery scheduling by a research nurse with a computer randomisation schedule No other information provided
Blinding of participants and personnel (performance bias) All outcomes	High risk	Although it was stated that women were not aware of allocation until the day of surgery, all staff would have been aware
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcomes were recorded by staff aware of allocations
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	For perioperative outcomes, data were available for 73/74 women (an abstract mentioned 1 woman dropped out after randomisation). For longer-term outcomes, unclear There was some loss to follow-up but this was balanced across groups
Selective reporting (reporting bias)	Low risk	Registered trial (NCT015562014); expected outcomes reported
Funding	Unclear risk	All study authors reported no conflicts of interest Funding not clear
Other bias	Unclear risk	It is not clear how important surgeon allocation is In this study of 5 surgeons, only 3 carried out both procedures; it is not clear whether they were equally experienced in both procedures

Lonnerfors 2014

Methods Single-centre RCT, open-label

Online protocol ID: NCT01865929

Setting: Skåne University Hospital

Country: Sweden

Groups: robot-assisted laparoscopic hysterectomy vs conventional laparoscopic or vaginal hysterectomy

Lonnerfors 2014 (Continued)

Period: January 2010 to June 2013

Participants	<p>Number: 122 randomly assigned</p> <p>Diagnosis: women with uterine size ≤ 16 weeks planned for minimally invasive hysterectomy for benign disease</p> <p>Included: indication for hysterectomy for benign disease or prophylactic surgery due to hereditary cancer; size of uterus and vagina allows for retrieval by the vaginal route; maximum uterine size equivalent to 16 weeks of pregnancy; informed consent</p> <p>Excluded: malignant disease; known extensive intra-abdominal adhesions; anaesthesiological contraindications to laparoscopic surgery; women with pacemaker or other implants for whom electro-surgery is to be avoided; immunocompetence; simultaneous need for prolapse surgery; known defects of haemostasis; allergies towards metronidazole and doxycycline; referred for vaginal surgery; inability to understand patient information</p> <p>Age (median, years): 47 (27 to 65)/46 (29 to 69)</p> <p>BMI (median, kg/m²): 24.9 (17 to 39.2)/24.9 (17.6 to 42)</p> <p>Uterine weight (median, grams): 180 (54 to 1114)/154 (30 to 694)</p>
Interventions	<p>RAS vs other minimally invasive surgery (CLS or vaginal approach)</p> <p>Procedure: hysterectomy</p> <p>Follow-up: 4 months</p>
Outcomes	<ul style="list-style-type: none"> • Intraoperative and postoperative complications: reported • Quality of life: NR • Total operating time: reported • Length of hospital stay: reported • Estimated blood loss, or transfusion: reported • Rate of conversion: reported • Early and late mortality: NR • Cost: reported (primary outcome)
Notes	<p>RAS was compared with CLS or vaginal hysterectomy (comparison intervention was based on surgeon's choice); therefore we extracted combined data, not separate data, for CLS and the vaginal approach. Separate data were potentially subject to significant bias</p> <p>Surgeons' experience: "All six surgeons were consultants experienced in both vaginal and laparoscopic surgery and four were gynaecological oncologists experienced in robotic surgery....The least experienced robotic surgeon had performed 49 robotic hysterectomies prior to the study"</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Envelopes containing the assigned surgical method in the proportion of 1:1 were closed, shuffled and thereafter numbered"
Allocation concealment (selection bias)	Unclear risk	Opaque envelopes were opened in consecutive numbered sequence, and participant names and allocations were entered into the study register. Study arms were RAS vs other minimally invasive approach (CLS or vaginal hysterectomy). For the latter, the surgeon chose the route. See "Other bias" below

Lonnerfors 2014 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Open-label
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Primary outcome of cost depends mainly on "length of surgery...which is expected to be independent of whether or not the study was blinded"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals or losses to follow-up were reported
Selective reporting (reporting bias)	Unclear risk	Prespecified and expected outcomes were reported. Outcomes were reported for RAS vs minimally invasive surgery (CLS and vaginal hysterectomy) together and separately. Separate baseline data were not reported; therefore it is not possible to determine whether there were differences in the characteristics of control women receiving CLS or vaginal hysterectomy
Funding	Low risk	Study authors stated no conflicts of interest No financial support was received for this study
Other bias	Unclear risk	"The route of traditional minimally invasive surgery was chosen by the designated surgeon with vaginal hysterectomy as first choice, followed by laparoscopic hysterectomy", i.e. women were not randomly assigned to CLS and vaginal hysterectomy but, rather, were allocated at surgeon's discretion. This resulted in a greater proportion of women undergoing concomitant procedures with CLS vs RAS and vaginal hysterectomy, which would have influenced procedure time, complication rates, LOS, and cost of CLS only data. We therefore used only combined (randomised) data in our meta-analyses. Direction and magnitude of bias associated with use of these data are unclear

Maenpaa 2016

Methods	1-Centre RCT Setting: Tampere University Hospital Country: Finland Groups: robot-assisted hysterectomy vs conventional laparoscopic hysterectomy Period: December 2010 to October 2013
Participants	Number: 101 women randomly assigned Diagnosis: endometrial cancer Included: low-grade (grade 1 or 2) endometrial carcinoma, scheduled for laparoscopic surgical staging, i.e. for a laparoscopic hysterectomy along with bilateral salpingo-oophorectomy and pelvic lymphadenectomy Excluded: narrow vagina or uterus too large to be removed through vagina; patient's condition not allowing for a deep Trendelenburg position Age (years): 67 (43 to 84)/70 (48 to 83)

Maenpaa 2016 (Continued)

BMI (kg/m²): 29 (20 to 46)/29 (20 to 45)

Interventions	RAS (50) vs CLS (51) Procedure: hysterectomy, bilateral salpingo-oophorectomy, and pelvic lymphadenectomy In both groups, lymphadenectomy was omitted in 2 cases due to disseminated disease for all 4 patients Follow-up: 6 months	
Outcomes	<ul style="list-style-type: none">• Intraoperative and postoperative complications: reported• Total operating time: reported• Length of hospital stay: reported• Estimated blood loss: reported• Blood transfusions: reported• Postoperative pain score: reported• Number of lymph nodes harvested: reported• Conversions: reported	
Notes	Surgeons' experience: All operations were performed by gynaecological oncologists with several years of experience in laparoscopic surgery. Thus, a learning curve was not included for the operations	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomization was made with the minimization software for allocating patients to treatments in clinical trials"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of participants was not reported Staff would be aware of assignment
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of study assessor was not reported Staff recording some outcomes would be aware of assignment
Incomplete outcome data (attrition bias) All outcomes	High risk	2 participants in the CLS group were diverted to a laparotomy for anaesthesiological reasons and were excluded from the analysis 1 participant in the CLS group was operated on with the aid of the robot, chosen by a consultant outside the study team. This participant is included in the CLS group in the intention-to-treat analysis
Selective reporting (reporting bias)	Low risk	All prespecified outcomes were reported
Funding	Unclear risk	Source of funding was not reported One study author was proctor for robotic surgery from October 2010 to October 2014 Remaining study authors reported no conflicts of interest

Maenpaa 2016 (Continued)

Other bias	Low risk	None noted
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Paraiso 2011

Methods	<p>RCT, single-centre, single-blinded</p> <p>Setting: Cleveland Clinic, Ohio (academic teaching hospital)</p> <p>Country: USA</p> <p>Groups: robot-assisted laparoscopic sacrocolpopexy vs conventional laparoscopic sacrocolpopexy</p> <p>Period: January 2007 to December 2009</p>
Participants	<p>Number: randomly assigned: 78 participants (38/40); evaluated: 68 participants (33/35)</p> <p>Diagnosis: apical vaginal prolapse stages 2 to 4</p> <p>Included: ≥ 21 years of age; had post-hysterectomy vaginal apex prolapse with overall POP-Q stages 2 to 4 and desired a minimally invasive approach to sacrocolpopexy</p> <p>Excluded: not a candidate for general anaesthesia; underwent prior sacrocolpopexy or rectopexy; had a suspicious adnexal mass or other factors that may indicate pelvic malignancy; reported a history of pelvic inflammatory disease; morbidly obese; scheduled for concomitant laparoscopic rectopexy with or without sigmoid resection</p> <p>Age (years): $60 \pm 11/61 \pm 9$</p> <p>BMI (kg/m²): $29 \pm 5/29 \pm 5$</p> <p>Uterine weight (grams): NR</p> <p>Most women had had a prior hysterectomy ($> 90\%$)</p> <p>Withdrawals: 5 in RAS arm (1 not eligible and 4 for personal choice) and 5 in CLS arm (3 not eligible and 2 for medical illness)</p>
Interventions	<p>RAS vs CLS</p> <p>Procedure: laparoscopic sacrocolpopexy</p> <p>Follow-up: 1 year</p>
Outcomes	<ul style="list-style-type: none"> • Intraoperative and postoperative complications: reported (including urinary tract infection) • Quality of life: reported • Total operating time: reported (primary outcome) • Instrument setup time: reported • Length of hospital stay: reported • Estimated blood loss, or transfusion: NR • Cost: reported • Rate of conversion: reported • Early and late mortality: NR
Notes	<p>Surgeons' experience: 2 surgeons involved; each had performed at least 10 robotic hysterectomies before participating in the study</p>

Risk of bias

Paraiso 2011 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation schedule
Allocation concealment (selection bias)	Low risk	Consecutively numbered, opaque, sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were blinded to treatment assignment for 12 months. Surgeons would not be blind to assignment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Research staff administering and collecting data were blinded to participants' treatment groups for the entire duration of the study Intraoperative outcomes may have been affected by observer bias (surgeons would be aware of assignment)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	5/38 were withdrawn from intervention group; 5/40 were withdrawn from control group
Selective reporting (reporting bias)	Low risk	All expected outcomes were reported
Funding	Unclear risk	Funded by the Cleveland Clinic Research Program Council and the Cleveland Clinic Center for Surgical Innovation, Technology, and Education Study authors did not report any potential conflicts of interest
Other bias	Unclear risk	It is not clear from the report whether study participants experienced more than 1 intraoperative and/or postoperative complication; the direction of potential bias was unclear Early RAS adopters may contribute to review bias Only 10 RAS hysterectomies were performed by surgeons before the study

Paraiso 2013

Methods	2-Centre RCT Setting: Cleveland Clinic, Ohio; Brigham and Women's Hospital, Boston (academic teaching hospitals) Country: USA Groups: robot-assisted laparoscopic vs conventional laparoscopic hysterectomy Period: June 2007 to March 2011
Participants	Number: 62 randomly assigned, 53 underwent procedure Diagnosis: benign gynaecological conditions, including fibroid tumours, abnormal bleeding, pelvic pain, endometriosis, and ovarian cysts (80% had more than 1 reason for hysterectomy) Included: women over 18 years of age who were to undergo laparoscopic hysterectomy for benign indications

Paraiso 2013 (Continued)

Excluded: suspected malignancy, illness that precludes laparoscopy, inability to give consent, morbid obesity

Age (years): 43.8 vs 45.6 (NS)

BMI (kg/m²): 29.9 vs 31.4 (NS)

Uterine weight (grams): 282.9 ± 214.7/293.9 ± 299.9

Withdrawals: 9 participants withdrew before surgery (5 CLS and 4 RAS)

Interventions	<p>RAS (26) vs CLS (27)</p> <p>Procedure: laparoscopic hysterectomy</p> <p>Follow-up: 6 months</p>
Outcomes	<ul style="list-style-type: none"> • Intraoperative and postoperative complications: reported • Quality of life: reported • Total operating time: reported (primary outcome) • Instrument setup time: reported • Length of hospital stay: reported • Estimated blood loss, or transfusion: reported • Cost: NR • Rate of conversion: reported • Early and late mortality: NR
Notes	<p>Surgeons' experience: all 5 surgeons had performed 75 to 400 total laparoscopic hysterectomies and at least 20 RAS procedures</p> <p>1 woman in the CLS arm required laparotomy because of bleeding and inability to maintain a pneumoperitoneum</p> <p>2 women for RAS were converted to laparoscopy: 1 because of robot malfunction, and the other because she could not be ventilated</p> <p>No intraoperative transfusions or bladder, ureteral, rectal, or small-bowel injuries were reported in either group</p> <p>No postoperative complications occurred; however, 3 women required blood transfusions during the postoperative period (2 after RAS; 1 after CLS)</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Computer generated randomisation schedule with block sizes"; stratified by surgeon and by uterine size
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	All participants were blinded to assignment Staff would be aware of assignment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinded assessment at 4 weeks and at 6 weeks Intraoperative outcomes may have been subject to observer bias

Paraiso 2013 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	9 women withdrew after random assignment (5 to the CLS group and 4 to the RAS group); 1 woman put down for CLS underwent RAS in error (protocol deviation), and 1 woman in the CLS group was withdrawn as the result of missing data. 2 women for RAS were converted to laparoscopy. The report states that 26 women were analysed in each group, but denominators are not specifically given for each outcome. More than 20% of data on pain and activity outcomes were missing; therefore, high risk was assigned for these outcomes
Selective reporting (reporting bias)	Low risk	All expected outcomes were reported ITT analysis was performed
Funding	Unclear risk	Funded by a grant from the Cleveland Clinic Center for Surgical Innovation, Technology, and Education Study authors did not report any potential conflicts of interest
Other bias	Low risk	None noted

RASHEC 2013

Methods	<p>RCT, parallel, open-label, single-centre</p> <p>Setting: Department of Obstetrics and Gynecology, Karolinska University Hospital, Stockholm, Sweden</p> <p>Country: Sweden</p> <p>Period: May 2013 to July 2016</p> <p>Groups: robot-assisted vs open surgery</p>
Participants	<p>Number: 120 women randomised (113 in ITT analysis and 96 in per-protocol analyses)</p> <p>Diagnosis: women with high-risk endometrial cancer (FIGO stage I or II preoperative high-risk tumour (with FIGO grade 3 endometrioid, or grade 2 with > 50% myometrial invasion or tumour invasion in the cervical stroma)</p> <p>Included: 18 to 75 years of age; high-risk endometrial cancer</p> <p>Excluded: ongoing anti-tumour treatment (apart from tamoxifen or aromatase inhibitors); preoperative imaging indicating extrauterine spread; medically unfit for surgery; disseminated disease diagnosed during surgery or inability to comply with the protocol; WHO performance > 1; severe comorbidity; ASA > 3; inability to understand information</p>
Interventions	<p>Procedure: complete surgical staging (hysterectomy, BSO, and pelvic and para-aortic lymphadenectomy)</p> <p>Follow-up: 3 years</p>
Outcomes	<p>Primary outcome measures</p> <ul style="list-style-type: none"> Lymph node yield <p>Secondary outcome measures</p> <ul style="list-style-type: none"> Recurrence of cancer Lymphatic side effects Quality of life

RASHEC 2013 (Continued)

- Healthcare costs
- Perioperative outcomes

Notes	Surgeon experience: "five surgeons performed all open surgeries and one performed all the RALs"	
	Data extraction based on 2017 published report	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Probably low risk; a block design was used (20 per block)
Allocation concealment (selection bias)	Unclear risk	Allocations were in sealed envelopes with "the patient drawing a sealed envelope"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Masking was not performed A single surgeon carried out all robot-assisted procedures
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The lymph node harvest may not have been subject to detection bias, but other outcomes were recorded by staff aware of allocations
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There were exclusions after randomisation; although these appeared balanced across groups, it is not clear whether exclusions affected outcomes 120 randomised; 96 included in reported analyses
Selective reporting (reporting bias)	Low risk	Expected outcomes reported
Funding	Low risk	Funded by grants from the Stockholm County Council
Other bias	High risk	Surgeons were not randomised; 1 surgeon performed ALL of the RALs

Sarlos 2010

Methods	Single-centre RCT (NCT00683293) Setting: University Hospital, Basel Country: Switzerland Groups: robot-assisted or conventional laparoscopic hysterectomy Period: June 2007 to May 2009
Participants	Number: 100 participants (50/50) Diagnosis: benign gynaecological disease Included: included if vaginal hysterectomy not possible (i.e. large fibroids, nulliparity, uterus < 500 g) Excluded: excluded if vaginal hysterectomy indicated Age (years): 46.3 ± 4.2/45.8 ± 6

Robot-assisted surgery in gynaecology (Review)

Sarlos 2010 (Continued)

BMI (kg/m²): 25.7 ± 5/26 ± 5.3

Uterine weight (g): 254.5 ± 147.3/247 ± 190

Interventions	Procedure: total hysterectomy Follow-up: 6 weeks
Outcomes	<ul style="list-style-type: none"> • Intraoperative and postoperative complications: reported • Quality of life: reported • Total operating time: reported (primary outcome) • Instrument setup time: reported • Length of hospital stay: reported • Estimated blood loss, or transfusion: reported • Cost: reported • Rate of conversion: NR • Early and late mortality: NR
Notes	<p>For 5 women in the RAS group, the robot had to be undocked as the result of a large uterus, and the uterus cut into extractable pieces and removed vaginally</p> <p>Surgeons' experience: 2 senior surgeons had performed an average of 50 laparoscopic hysterectomies per year and had performed 30 robotic hysterectomies before the study was begun</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated: "randomisation scheme was generated by using the web-site www.randomisation.com"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Not blinded because the robot was situated in a different building of the hospital complex"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	<p>5 participants did not complete the study or undergo the procedure</p> <p>"missing values were replaced by the median of available measurements in the respective study arm"</p> <p>"quality of life only evaluated on 75 women as a result of non-completion of questionnaires"</p> <p>Denominators not consistently reported, so not always possible to determine whether data were missing</p>
Selective reporting (reporting bias)	Unclear risk	Denominators not consistently reported
Funding	Unclear risk	Sponsor stated as Kantonsspital Aarau

Sarlos 2010 (Continued)

Study authors did not report any potential conflicts of interest

Other bias	Unclear risk	Early RAS adopters may contribute to review bias
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Wijk 2016

Methods	<p>Single-centre RCT (NCT02291406)</p> <p>Setting: Department of Gynaecology and Obstetrics, Orebro University Hospital</p> <p>Country: Sweden</p> <p>Groups: robot-assisted laparoscopic hysterectomy vs open abdominal hysterectomy</p> <p>Period: October 2014 to May 2015; 8 months</p>
Participants	<p>Number: 20 women randomised (10/10); all included in analyses</p> <p>Diagnosis: women with an indication for hysterectomy with either benign or malignant disease and suitable for both techniques</p> <p>Included: women with benign and malignant disease; over 18; adequate knowledge of Swedish language; assessed as suitable for both techniques and possible for uterus to be removed vaginally without morcellation; most common indications bleeding and/or myoma</p> <p>Excluded: metabolic disease including diabetes mellitus or medication causing insulin resistance; severe inflammatory disease, chronic pain, or receiving regular pain medication; known severe adhesions in the abdomen; allergy or contraindications to NSAIDs; mental disability or psychiatric disease</p> <p>Age (years): (median/range) 52 (41 to 66); 50 (41 to 67)</p> <p>BMI (kg/m²): (median/range) 26 (21 to 38); 26 (18 to 38)</p>
Interventions	<p>Procedure: total hysterectomy with or without salpingo-oophorectomy</p> <p>Follow-up: 30 days</p>
Outcomes	<ul style="list-style-type: none"> Intraoperative and postoperative complications: infection Quality of life: activity (WHO score 1) Total operating time: time of surgery reported (median/range) Instrument setup time: NR Length of hospital stay: reported Estimated blood loss, or transfusion: reported (median/range) Cost: NR Rate of conversion: NR Early and late mortality: NR <p>Primary outcome was metabolic response (insulin resistance)</p>
Notes	<p>This is a study with a small sample size looking at 2 different surgical techniques - RA laparoscopic vs open abdominal hysterectomy - although it is stated in the introduction that laparoscopic techniques are now recommended when suitable. The small sample size means that for most outcomes, the study was unlikely to detect differences between groups</p> <p>Surgeons' experience: "All hysterectomies were performed by experienced gynaecologic surgeons, all as the first patient of the morning"</p>

Risk of bias

Robot-assisted surgery in gynaecology (Review)

Wijk 2016 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computerised randomisation sequence produced by staff at the university statistical department who did not otherwise participate in the study
Allocation concealment (selection bias)	Low risk	"The allocated mode of operation was sealed in opaque consecutively numbered envelopes" Envelopes were opened after inclusion, just before the preoperative clamp was applied
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and staff would be aware of the different surgical techniques applied
Blinding of outcome assessment (detection bias) All outcomes	High risk	Most review outcomes may have been affected by lack of blinding There was an attempt to blind the outcome assessor for interpretation of the study primary outcome
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data were reported for all women randomised (20)
Selective reporting (reporting bias)	Low risk	Registered trial Purpose of the study was primarily to examine insulin resistance and inflammatory response
Funding	Unclear risk	Study was supported by a grant from the Research Committee of the Orebro County Council, Nyckelfonden, Stiftelsen Gynekologisk Onkologi, and Lisa och Goran Gronbergs Stiftelse COI: 1 of the study authors had an advisory appointment with Danone Research, a commercial company that produced the carbohydrate drink used as part of the study Other investigators reported no conflicts of interest
Other bias	Unclear risk	Perioperative blood loss was significantly different between groups. This was reported as a baseline characteristic (and was higher in the abdominal hysterectomy group) and may have affected other outcomes

ASA = American Society of Anesthesiologists; BMI = body mass index; BSO = bilateral salpingo-oophorectomy; CLS = conventional laparoscopic surgery; DUB = dysfunctional uterine bleeding; EHP-30 = Endometriosis Health Profile Questionnaire; FIGO = International Federation of Gynecology and Obstetrics; ITT = intention-to-treat; LOS = length of stay; NR = not reported; NS = not significant; NSAID = non-steroidal anti-inflammatory drug; POP = pelvic organ prolapse; POP-Q = pelvic organ prolapse quantification; RAS = robot-assisted surgery; RCT = randomised controlled trial; SD = standard deviation; SF-12 = Short Form 12; WHO = World Health Organization.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Advincula 2007	Benign disease
Arms 2015	Prospective cohort study

Robot-assisted surgery in gynaecology (Review)

Study	Reason for exclusion
Asciutto 2015	Prospective cohort study
Bell 2008	CCT
Best 2014	Retrospective chart review
Bogges 2008a	CCT
Bogges 2008b	CCT
Bogliolo 2015	Letter to editor describing a cohort study
Campos 2013	CCT; not a study of robot-assisted laparoscopy (CLS vs open surgery for radical hysterectomy)
Cantrell 2010	CCT
Cardenas-Goicoechea 2010	CCT
Chen 2015	Robot-assisted surgery with or without warm-up using a robotic simulator
Chong 2016	Prospective cohort study
Culligan 2010	Different reconstructive materials were compared when laparoscopic or robotic surgery was performed
DeNardis 2008	CCT
Denstad 2017	Retrospective chart review
Desille-Gbaguidi 2013	CCT
Diaz-Feijoo 2016	Participants were randomised to trans-peritoneal or extra-peritoneal aortic lymphadenectomy. This was performed with robot-assisted or standard laparoscopic surgery. There were no specific selection criteria for laparoscopic or robotic approaches
Eklind 2015	Prospective cohort study
Estape 2009	CCT
Falik 2017	Letter/Commentary
Gehrig 2008	CCT
Geisler 2010	CCT
Gocmen 2013	CCT
Grias 2012	RCT of different types of suture material in RAS
Hoekstra 2009	CCT
Iavazzo 2016	Letter/Commentary
Jung 2010	CCT

Study	Reason for exclusion
Kho 2009	CCT
Kim 2015	Retrospective cohort study
Kivnick 2013	Letter/Commentary
Ko 2008	CCT
Lambaudie 2008	CCT
Lambaudie 2010	CCT
Landeem 2016	Both groups underwent robot-assisted surgery; different closure techniques were compared: single-layer continuous closure vs single-layer continuous closure with 3 additional sutures
Lonnerfors 2009	Observational study
Madhuri 2017	Letter/Commentary
Maggioni 2009	CCT
Magrina 2008	CCT
Marino 2015	Prospective observational study
Martinez-Maestro 2014	Quasi-RCT comparing RAS vs CLS in women requiring hysterectomy
McNanley 2012	RCT of postoperative bowel regimens following RAS
Nezhat 2008	CCT
Ozgun 2017	Prospective observational study
Paek 2016	Prospective observational study
Palmer 2013	RCT comparing different robotic surgical techniques for vaginal cuff closure
Persson 2009	Case series
Ramirez 2009	Comment on Ko 2008a
Ramirez 2018	This RCT compared minimally invasive surgery vs abdominal surgery for early-stage cervical cancer; however, only 15.6% of the minimally invasive arm underwent robot-assisted surgery; the rest underwent laparoscopy
Reza 2010	Meta-analysis
Seamon 2009a	CCT
Seamon 2009b	CCT
Sert 2007	CCT
Sert 2009	Letter

Study	Reason for exclusion
Sert 2010	Letter
Somashekhar 2014	Quasi-randomised: "Fifty consecutive patients were alternatively allotted"
Tsafir 2017	All groups received the same robot-assisted surgery; vaginal cuff closure techniques were compared: barbed vs interrupted vs continuous sutures
Veljovich 2008	CCT
Vizza 2014	Retrospective cohort study
Westermann 2017	Prospective cohort study
Yoo 2015	Prospective cohort study

CCT = controlled clinical trial; CLS = conventional laparoscopic surgery; RAS = robot-assisted surgery; RCT = randomised controlled trial.

Characteristics of ongoing studies [ordered by study ID]

Kjohde 2012

Trial name or title	Robot-assisted laparoscopic hysterectomy versus abdominal hysterectomy in endometrial cancer (NCT01526655)
Methods	RCT, single-centre, parallel, open-label Country: Sweden Groups: RAS vs open surgery
Participants	Number: 50 participants Diagnosis: low-risk endometrial cancer (FIGO stage 1, grade 1/2, with diploid DNA profile) Included: over 18 years of age, total hysterectomy + bilateral salpingo-oophorectomy (BSO) and peritoneal lavage indicated, WHO performance status ≤ 2 , proficiency in Swedish, informed consent, operation should be considered possible to be performed laparoscopically and by laparotomy through a low transverse abdominal wall incision Excluded: operation anticipated to comprise more than hysterectomy/BSO and lavage, midline laparotomy incision planned, spinal anaesthesia contraindicated
Interventions	Procedure: total hysterectomy, BSO, and peritoneal lavage Follow-up: 6 weeks Endpoint: efficacy
Outcomes	Primary outcome <ul style="list-style-type: none"> Quality of life: 6-week follow-up: EuroQol form (EQ-5D) and Short Form 36 (SF-36). EQ-5D form is filled in on 1 occasion 1 week preoperatively, then daily for a week from the evening after surgery, then once weekly for 5 additional weeks. SF-36 is filled in 1 week preoperatively and 6 weeks post-operatively Secondary outcomes <ul style="list-style-type: none"> Changes in biomarkers for tissue damage (C-reactive protein, creatinine kinase, high-mobility group protein B1, amino acids)

Kjölhede 2012 (Continued)

- Changes in cytokines and chemokines
- Changes in quantities and functions of T, B, and NK lymphocytes
- Postoperative symptoms
- Consumption of analgesics
- Health economics
- Adverse events and serious adverse events

Starting date	January 2012
Contact information	Dr. Preben Kjölhede Preben.Kjolhede@lio.se
Notes	Email correspondence with Dr. Kjölhede on 24 June 2014 confirmed that 40% of sample size had been accrued to date Estimated primary completion date was December 2015

Lauszus 2017

Trial name or title	Robotic-assisted hysterectomy: single- versus multi-port laparoscopic access (NCT03373513)
Methods	RCT, single-centre, parallel, open-label Country: Denmark Groups: robot-assisted single incision hysterectomy vs multi-port laparoscopic hysterectomy
Participants	Number: 124 participants Diagnosis: benign indications Included: women with BMI < 35 kg/m ² , uterine size < 300 g Excluded: adhesions, prior extensive abdominal surgery, prior midline incision, cutis laxa for abdominal surgery, endometriosis, more than 1 cesarean section, malignant disease
Interventions	Procedure: hysterectomy Follow-up: 6 months
Outcomes	<ul style="list-style-type: none"> • Return to work • Pain
Starting date	May 2018
Contact information	Dr. Finn F. Lauszus Gynecology Dept. Herning Hospital, Herning, Denmark; finlau@rm.dk
Notes	

Narducci 2010

Trial name or title	Coelioscopy (laparoscopy) versus robot-assisted coelioscopy in cervical, uterine, and ovarian cancer (NCT01247779)
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Narducci 2010 (Continued)

Methods	<p>RCT, multi-centre, parallel, open-label</p> <p>Country: France</p> <p>Groups: laparoscopic gynaecological surgery vs robot-assisted laparoscopic gynaecological surgery</p>
Participants	<p>Number: 374 participants</p> <p>Diagnosis: malignant gynaecological disease (ovary, uterus, and cervix)</p> <p>Included: women > 18 years of age requiring surgery for ovarian, uterine, or cervical cancer</p> <p>Excluded: metastatic disease</p>
Interventions	<p>Procedure: gynaecological surgery for malignant gynaecological disease (surgical staging procedures)</p> <p>Follow-up: 2 years</p> <p>Endpoint: safety</p>
Outcomes	<p>Primary outcomes</p> <ul style="list-style-type: none"> • Intraoperative and postoperative complications <p>Secondary outcomes</p> <ul style="list-style-type: none"> • Postoperative analgesia • Surgeon's ergonomics (Borg and NASA-TLX scales) • Quality of life (SF-36) • Operating time • Progression-free survival (2 years) • Number of lymph nodes removed • Positive surgical margins
Starting date	December 2010
Contact information	<p>Dr. Fabrice Narducci</p> <p>Centre Oscar Lambret, Lille, France; 59000f-narducci@o-lambret.fr</p>
Notes	Email correspondence with Dr. Narducci on 24 June 2014 confirmed that 320 of 374 participants had been enrolled to date, and the estimated primary completion date was mid-2015

BMI = body mass index; BSO = bilateral salpingo-oophorectomy; EQ-5D = EuroQol form; FIGO = International Federation of Gynecology and Obstetrics; NASA-TLX = NASA Task Load Index; RAS = robot-assisted surgery; RCT = randomised controlled trial; SF-36 = Short Form 36; WHO = World Health Organization.

DATA AND ANALYSES

Comparison 1. Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intraoperative and postoperative complications	6	585	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.54, 1.59]
1.1 Hysterectomy for non-malignant disease	5	486	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.38, 1.53]
1.2 Hysterectomy for malignant disease	1	99	Risk Ratio (M-H, Random, 95% CI)	1.47 [0.79, 2.72]
2 Intraoperative complications	5	487	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.31, 3.56]
2.1 Hysterectomy for non-malignant disease	4	388	Risk Ratio (M-H, Random, 95% CI)	1.66 [0.76, 3.61]
2.2 Hysterectomy for malignant disease	1	99	Risk Ratio (M-H, Random, 95% CI)	0.11 [0.01, 1.97]
3 Complications: intraoperative injury	3	269	Risk Ratio (M-H, Random, 95% CI)	1.62 [0.20, 12.91]
3.1 Hysterectomy for non-malignant disease	3	269	Risk Ratio (M-H, Random, 95% CI)	1.62 [0.20, 12.91]
4 Postoperative complications	5	533	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.42, 1.59]
4.1 Hysterectomy for non-malignant disease	4	434	Risk Ratio (M-H, Random, 95% CI)	0.61 [0.34, 1.09]
4.2 Hysterectomy for malignant disease	1	99	Risk Ratio (M-H, Random, 95% CI)	1.76 [0.91, 3.43]
5 Complications: bleeding	4	367	Risk Ratio (M-H, Random, 95% CI)	0.41 [0.10, 1.66]
5.1 Hysterectomy for non-malignant disease	4	367	Risk Ratio (M-H, Random, 95% CI)	0.41 [0.10, 1.66]
6 Complications: infection	4	367	Risk Ratio (M-H, Random, 95% CI)	0.62 [0.13, 2.88]
6.1 Hysterectomy for non-malignant disease	4	367	Risk Ratio (M-H, Random, 95% CI)	0.62 [0.13, 2.88]
7 Total operating time	2	148	Mean Difference (IV, Random, 95% CI)	41.18 [-6.17, 88.53]
7.1 Hysterectomy for non-malignant disease	2	148	Mean Difference (IV, Random, 95% CI)	41.18 [-6.17, 88.53]
8 Operating room time [min]	2	148	Mean Difference (IV, Random, 95% CI)	44.35 [5.22, 83.47]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 Hysterectomy for non-malignant disease	2	148	Mean Difference (IV, Random, 95% CI)	44.35 [5.22, 83.47]
9 Overall hospital stay	2	192	Mean Difference (IV, Random, 95% CI)	-0.30 [-0.53, -0.07]
9.1 Hysterectomy for non-malignant disease	2	192	Mean Difference (IV, Random, 95% CI)	-0.30 [-0.53, -0.07]
10 Conversion to another approach	3	269	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.24, 5.77]
11 Blood transfusions	4	346	Risk Ratio (M-H, Random, 95% CI)	2.49 [0.75, 8.23]
11.1 Hysterectomy for non-malignant disease	3	247	Risk Ratio (M-H, Random, 95% CI)	1.94 [0.30, 12.76]
11.2 Hysterectomy for malignant disease	1	99	Risk Ratio (M-H, Random, 95% CI)	2.94 [0.62, 13.87]
12 Estimated blood loss	1	95	Mean Difference (IV, Random, 95% CI)	7.0 [-18.26, 32.26]
12.1 Hysterectomy for non-malignant disease	1	95	Mean Difference (IV, Random, 95% CI)	7.0 [-18.26, 32.26]
13 Pain at 1 to 2 weeks	1	36	Mean Difference (IV, Random, 95% CI)	-2.0 [-16.08, 12.08]
13.1 Hysterectomy for non-malignant disease	1	36	Mean Difference (IV, Random, 95% CI)	-2.0 [-16.08, 12.08]
14 Quality of life (6 weeks)	1	95	Mean Difference (IV, Random, 95% CI)	8.0 [3.12, 12.88]
14.2 Hysterectomy for non-malignant disease	1	95	Mean Difference (IV, Random, 95% CI)	8.0 [3.12, 12.88]
15 Quality of life (6 months)	1	38	Mean Difference (IV, Random, 95% CI)	5.0 [-3.01, 13.01]
15.1 Hysterectomy for non-malignant disease	1	38	Mean Difference (IV, Random, 95% CI)	5.0 [-3.01, 13.01]
16 Re-intervention	1	122	Risk Ratio (M-H, Random, 95% CI)	0.25 [0.03, 2.17]
16.1 Hysterectomy for non-malignant disease	1	122	Risk Ratio (M-H, Random, 95% CI)	0.25 [0.03, 2.17]
17 Re-admission	2	220	Risk Ratio (M-H, Random, 95% CI)	0.46 [0.14, 1.48]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
17.1 Hysterectomy for non-malignant disease	2	220	Risk Ratio (M-H, Random, 95% CI)	0.46 [0.14, 1.48]
18 Overall cost	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
18.1 Hysterectomy for non-malignant disease	1	97	Mean Difference (IV, Random, 95% CI)	1564.0 [1079.57, 2048.43]
18.2 Hysterectomy for malignant disease	0	0	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 1 Intraoperative and postoperative complications.

Analysis 1.2. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 2 Intraoperative complications.

Analysis 1.3. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 3 Complications: intraoperative injury.

Analysis 1.4. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 4 Postoperative complications.

Analysis 1.5. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 5 Complications: bleeding.

Analysis 1.6. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 6 Complications: infection.

Analysis 1.7. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 7 Total operating time.

Analysis 1.8. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 8 Operating room time [min].

Analysis 1.9. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 9 Overall hospital stay.

Analysis 1.10. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 10 Conversion to another approach.

Analysis 1.11. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 11 Blood transfusions.

Analysis 1.12. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 12 Estimated blood loss.

Analysis 1.13. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 13 Pain at 1 to 2 weeks.

Analysis 1.14. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 14 Quality of life (6 weeks).

Analysis 1.15. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 15 Quality of life (6 months).

Analysis 1.16. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 16 Re-intervention.

Analysis 1.17. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 17 Re-admission.

Analysis 1.18. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 18 Overall cost.

Study or subgroup	RAS		CLS		Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
	N	Mean(SD)	N	Mean(SD)			
Subtotal ***	0		0				Not estimable
Heterogeneity: Not applicable							
Test for overall effect: Not applicable							
Test for subgroup differences: Not applicable							
<div style="text-align: center;"> Favours RAS -1000 -500 0 500 1000 Favours CLS </div>							

Comparison 2. Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy))

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intraoperative and postoperative complications	3	186	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.21, 4.24]
2 Intraoperative complications	2	108	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.09, 7.59]
3 Complications: intraoperative injury	3	186	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.28, 2.70]
4 Postoperative complications	1	68	Risk Ratio (M-H, Random, 95% CI)	3.54 [1.31, 9.56]
5 Complications: bleeding	0		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
6 Complications: infection	1	68	Risk Ratio (M-H, Random, 95% CI)	1.89 [0.63, 5.68]
7 Total operating time	3	186	Mean Difference (IV, Random, 95% CI)	40.53 [12.06, 68.99]
8 Operating room time [min]	2	146	Mean Difference (IV, Random, 95% CI)	43.24 [0.12, 86.35]
9 Overall hospital stay	2	108	Mean Difference (IV, Random, 95% CI)	0.26 [-0.15, 0.67]
10 Conversion to another approach	1	68	Risk Ratio (M-H, Random, 95% CI)	1.41 [0.25, 7.94]
11 Blood transfusions	0		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
12 Estimated blood loss	2	118	Mean Difference (IV, Random, 95% CI)	-15.17 [-26.43, -3.91]
13 Pain at 1 to 2 weeks	1	78	Mean Difference (IV, Random, 95% CI)	0.90 [-0.06, 1.86]
14 Quality of life (6 weeks)	1	78	Mean Difference (IV, Random, 95% CI)	-0.01 [-0.06, 0.04]
15 Quality of life (6 months)	0		Mean Difference (IV, Random, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
16 Re-intervention	2	173	Risk Ratio (M-H, Random, 95% CI)	0.47 [0.06, 3.59]
17 Re-admission	0		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
18 Overall cost	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
19 Complications: urinary incontinence	1	40	Risk Ratio (M-H, Random, 95% CI)	0.18 [0.01, 3.56]
20 Complications: sexual dysfunction	1	40	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.06, 13.48]

Analysis 2.1. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 1 Intraoperative and postoperative complications.

Analysis 2.2. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 2 Intraoperative complications.

Analysis 2.3. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 3 Complications: intraoperative injury.

Analysis 2.4. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 4 Postoperative complications.

Analysis 2.6. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 6 Complications: infection.

Analysis 2.7. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy), Outcome 7 Total operating time.

Analysis 2.8. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 8 Operating room time [min].

Analysis 2.9. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 9 Overall hospital stay.

Analysis 2.10. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 10 Conversion to another approach.

Analysis 2.12. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 12 Estimated blood loss.

Analysis 2.13. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 13 Pain at 1 to 2 weeks.

Analysis 2.14. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 14 Quality of life (6 weeks).

Analysis 2.16. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 16 Re-intervention.

Analysis 2.18. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 18 Overall cost.

Analysis 2.19. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 19 Complications: urinary incontinence.

Analysis 2.20. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 20 Complications: sexual dysfunction.

Comparison 3. Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intraoperative and postoperative complications	1	20	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.02, 7.32]
1.1 Hysterectomy for non-malignant disease	1	20	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.02, 7.32]
2 Intraoperative complications	1	96	Risk Ratio (M-H, Random, 95% CI)	0.25 [0.03, 2.16]
2.1 Hysterectomy for non-malignant disease	0	0	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2.2 Hysterectomy for malignant disease	1	96	Risk Ratio (M-H, Random, 95% CI)	0.25 [0.03, 2.16]
3 Postoperative complications	2	116	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.35, 1.27]
3.1 Hysterectomy for non-malignant disease	1	20	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.02, 7.32]
3.2 Hysterectomy for malignant disease	1	96	Risk Ratio (M-H, Random, 95% CI)	0.69 [0.36, 1.32]
4 Death within 30 days	1	96	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4.1 Hysterectomy for malignant disease	1	96	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
5 Complications: bleeding	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.1 Hysterectomy for malignant disease	1	96	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.01, 7.98]
6 Complications: infection	1	20	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.02, 7.32]
6.1 Hysterectomy for non-malignant disease	1	20	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.02, 7.32]
7 Blood transfusions	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 Hysterectomy for malignant disease	1	96	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.01, 7.98]
8 Quality of life (4 weeks)	1	20	Risk Ratio (M-H, Random, 95% CI)	0.25 [0.07, 0.90]
8.1 Hysterectomy for non-malignant disease	1	20	Risk Ratio (M-H, Random, 95% CI)	0.25 [0.07, 0.90]
9 Re-admission	2	116	Risk Ratio (M-H, Random, 95% CI)	0.54 [0.16, 1.91]
9.1 Hysterectomy for non-malignant disease	1	20	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.02, 7.32]
9.2 Hysterectomy for malignant disease	1	96	Risk Ratio (M-H, Random, 95% CI)	0.6 [0.15, 2.37]
10 Overall cost	1	96	Mean Difference (IV, Random, 95% CI)	-1568.0 [-3100.75, -35.25]
10.1 Hysterectomy for malignant disease	1	96	Mean Difference (IV, Random, 95% CI)	-1568.0 [-3100.75, -35.25]
11 Lymph node yield	1	96	Mean Difference (IV, Random, 95% CI)	-8.0 [-14.97, -1.03]
11.1 Hysterectomy for malignant disease	1	96	Mean Difference (IV, Random, 95% CI)	-8.0 [-14.97, -1.03]

Analysis 3.1. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 1 Intraoperative and postoperative complications.

Analysis 3.2. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 2 Intraoperative complications.

Analysis 3.3. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 3 Postoperative complications.

Analysis 3.4. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 4 Death within 30 days.

Study or subgroup	RAS n/N	CLS n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
3.4.1 Hysterectomy for malignant disease					
RASHEC 2013	0/48	0/48			Not estimable
Subtotal (95% CI)	48	48			Not estimable
Total events: 0 (RAS), 0 (CLS)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
Total (95% CI)	48	48			Not estimable
Total events: 0 (RAS), 0 (CLS)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					

Favours RAS 0.01 0.1 1 10 100 Favours CLS

Analysis 3.5. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 5 Complications: bleeding.

Study or subgroup	RAS n/N	Open surgery n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
3.5.1 Hysterectomy for malignant disease					
RASHEC 2013	0/48	1/48		100%	0.33[0.01,7.98]
Subtotal (95% CI)	48	48		100%	0.33[0.01,7.98]
Total events: 0 (RAS), 1 (Open surgery)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.68(P=0.5)					

Favours RAS 0.01 0.1 1 10 100 Favours open surgery

Analysis 3.6. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 6 Complications: infection.

Study or subgroup	RAS n/N	Open surgery n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
3.6.1 Hysterectomy for non-malignant disease					
Wijk 2016	0/10	1/10		100%	0.33[0.02,7.32]
Subtotal (95% CI)	10	10		100%	0.33[0.02,7.32]
Total events: 0 (RAS), 1 (Open surgery)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.7(P=0.49)					
Total (95% CI)	10	10		100%	0.33[0.02,7.32]
Total events: 0 (RAS), 1 (Open surgery)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.7(P=0.49)					

Favours RAS 0.01 0.1 1 10 100 Favours open surgery

Analysis 3.7. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 7 Blood transfusions.

Analysis 3.8. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 8 Quality of life (4 weeks).

Analysis 3.9. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 9 Re-admission.

Analysis 3.10. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 10 Overall cost.

Analysis 3.11. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 11 Lymph node yield.

Comparison 4. Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intraoperative complications	1	73	Risk Ratio (M-H, Random, 95% CI)	0.36 [0.04, 3.32]
2 Postoperative complications	1	73	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.40, 1.51]
3 Complications: infection	1	73	Risk Ratio (M-H, Random, 95% CI)	0.54 [0.23, 1.29]
4 Total operating time	1	73	Mean Difference (IV, Random, 95% CI)	5.0 [-20.71, 30.71]
5 Operating room time [min]	1	73	Mean Difference (IV, Random, 95% CI)	5.90 [-22.31, 34.11]
6 Conversion to another approach	1	73	Risk Ratio (M-H, Random, 95% CI)	0.36 [0.02, 8.58]
7 Estimated blood loss	1	73	Mean Difference (IV, Random, 95% CI)	57.10 [-20.08, 134.28]
8 Quality of life (6 weeks)	1	73	Mean Difference (IV, Random, 95% CI)	-2.30 [-3.79, -0.81]
9 Quality of life (6 months)	1	73	Mean Difference (IV, Random, 95% CI)	1.30 [-0.58, 3.18]
10 Re-admission	1	73	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.13, 4.08]
11 Pain at 6 months	1	73	Mean Difference (IV, Fixed, 95% CI)	3.30 [-8.31, 14.91]

Analysis 4.1. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 1 Intraoperative complications.

Analysis 4.2. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 2 Postoperative complications.

Analysis 4.3. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 3 Complications: infection.

Analysis 4.4. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 4 Total operating time.

Analysis 4.5. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 5 Operating room time [min].

Analysis 4.6. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 6 Conversion to another approach.

Analysis 4.7. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 7 Estimated blood loss.

Analysis 4.8. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 8 Quality of life (6 weeks).

Analysis 4.9. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 9 Quality of life (6 months).

Analysis 4.10. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 10 Re-admission.

Analysis 4.11. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 11 Pain at 6 months.

APPENDICES

Appendix 1. MEDLINE search strategy

1 Robotics/
2 Surgery, Computer-Assisted/
3 (robot* or da Vinci or Aesop or Zeus or (remote* adj5 surgery)).mp.
4 1 or 2 or 3
5 exp Gynecologic Surgical Procedures/
6 (hysterectom* or myomectom* or (tub* adj (reanastomos?s or re-anastomos?s)) or sterilization reversal or oophorectom* or ovariectom* or sacrocolpopexy).mp.
7 exp Genital Diseases, Female/

8 ((gyne* or gynae* or female genital) adj5 (disease* or disorder* or benign*)).mp.
9 (fibroid* or leiomyoma* or endometriosis or adenomyos?s or (ovar* adj5 cyst*) or female infertility or (pelvic adj5 pain*) or ((uter* or vagin*) adj5 prolapse) or vesicovaginal fistula* or menorrhagia or metrorrhagia or (uter* adj5 bleed*)).mp.
10 exp Genital Neoplasms, Female/
11 ((endometr* or uter* or cervi* or ovar* or vagin* or fallopian* or vulva* or gynae* or gyne*) adj5 (cancer* or neoplas* or neoplas* or carcinom* or malignan* or tumor* or tumour*)).mp.
12 5 or 6 or 7 or 8 or 9 or 10 or 11
13 4 and 12

key:

mp= [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

Appendix 2. Embase search strategy

1 robotics/
2 computer assisted surgery/
3 (robot* or da Vinci or Aesop or Zeus or (remote* adj5 surgery)).mp.
4 1 or 2 or 3
5 exp gynecologic surgery/
6 (hysterectom* or myomectom* or (tub* adj (reanastomos?s or re-anastomos?s)) or sterili?ation reversal or oophorectom* or ovariectom* or sacrocolpopexy).mp.
7 exp gynecologic disease/
8 ((gyne* or gynae* or female genital) adj5 (disease* or disorder* or benign*)).mp.
9 (fibroid* or leiomyoma* or endometriosis or adenomyos?s or (ovar* adj5 cyst*) or female infertility or (pelvic adj5 pain*) or ((uter* or vagin*) adj5 prolapse) or vesicovaginal fistula* or menorrhagia or metrorrhagia or (uter* adj5 bleed*)).mp.
10 exp female genital tract tumor/
11 ((endometr* or uter* or cervi* or ovar* or vagin* or fallopian* or vulva* or gynae* or gyne*) adj5 (cancer* or neoplas* or neoplas* or carcinom* or malignan* or tumor* or tumour*)).mp.
12 5 or 6 or 7 or 8 or 9 or 10 or 11
13 4 and 12

key:

[mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

Appendix 3. CENTRAL search strategy

#1 MeSH descriptor: [Robotics] this term only
#2 MeSH descriptor: [Surgery, Computer-Assisted] this term only
#3 (robot* or da Vinci or Aesop or Zeus or (remote* adj5 surgery))
#4 #1 or #2 or #3
#5 MeSH descriptor: [Gynecologic Surgical Procedures] explode all trees
#6 (hysterectom* or myomectom* or (tub* adj (reanastomos?s or re-anastomos?s)) or sterili?ation reversal or oophorectom* or ovariectom* or sacrocolpopexy)
#7 MeSH descriptor: [Genital Diseases, Female] explode all trees
#8 ((gyne* or gynae* or female genital) near/5 (disease* or disorder* or benign*))
#9 (fibroid* or leiomyoma* or endometriosis or adenomyos?s or (ovar* adj5 cyst*) or female infertility or (pelvic adj5 pain*) or ((uter* or vagin*) near/5 prolapse) or vesicovaginal fistula* or menorrhagia or metrorrhagia or (uter* adj5 bleed*))
#10 MeSH descriptor: [Genital Neoplasms, Female] explode all trees
#11 ((endometr* or uter* or cervi* or ovar* or vagin* or fallopian* or vulva* or gynae* or gyne*) near/5 (cancer* or neoplas* or neoplas* or carcinom* or malignan* or tumor* or tumour*))
#12 #5 or #6 or #7 or #8 or #9 or #10 or #11
#13 #4 and #12

WHAT'S NEW

Date	Event	Description
19 September 2019	Feedback has been incorporated	Following feedback, the RASHEC 2013 data has been moved from the 'malignant disease' subgroup of comparison 1 to the

Date	Event	Description
		corresponding comparison 3 subgroup and the results revised accordingly. The main findings and conclusions are unchanged.
19 September 2019	Amended	Review amended following feedback.

HISTORY

Review first published: Issue 12, 2014

Date	Event	Description
29 March 2019	New citation required but conclusions have not changed	Order of authors updated.
1 October 2018	New search has been performed	Review updated and six new studies added.
1 April 2015	Amended	Contact details updated
11 February 2015	Amended	Contact details updated
12 September 2014	New search has been performed	Updates of Liu 2012 and Lu 2012 merged

CONTRIBUTIONS OF AUTHORS

For the 2018 update, study selection was performed by the Cochrane Response team as part of a commissioned Rapid Review on RAS for hysterectomy, and these studies were shared with the review team. TL and TD performed data extraction and entry and prepared the first draft of the updated review. All review authors approved the final version.

For the 2014 update, TL selected studies, extracted and entered data, and prepared the first draft of the review. DL selected studies, extracted data, checked data entry, and contributed to the text. HL contributed to the text of the review, including interpretation of findings. All review authors approved the final version. For contributions of authors to the original reviews, see [Liu 2012](#) and [Lu 2012](#).

DECLARATIONS OF INTEREST

Hongqian Liu: none known.
Theresa A. Lawrie: none known.
DongHao Lu: none known.
Therese Dowswell: none known.
Huan Song: none known.
Lei Wang: none known.
Gang Shi: none known.

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Internal sources

- Department of Obstetrics & Gynaecology, West China Second University Hospital, Sichuan University, China, Other.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

This updated review provides a combined update of two originally separate reviews of robot-assisted surgery for benign and malignant gynaecological disease ([Liu 2012](#); [Lu 2012](#)). These original reviews were conducted by the same review author team, and the methodology

of these reviews was similar. The Trial Search Co-ordinator for the Cochrane Gynaecological Cancer Group, Jane Hayes, designed a new combined search strategy to capture all eligible records for the updated combined review. Differences between methods of the original reviews and of the combined review include the following changes to the updated review.

- Primary outcomes are intraoperative and postoperative complications, with quality of life (QoL) and survival outcomes moved to secondary outcomes.
- Outcomes related to surgeons' performance and workload assessment were added.
- Risk ratios instead of odds ratios were calculated for meta-analyses of dichotomous data.
- Data have been subgrouped according to type of procedure.

INDEX TERMS

Medical Subject Headings (MeSH)

Genital Diseases, Female [*surgery]; Genital Neoplasms, Female [*surgery]; Hysterectomy [instrumentation] [methods]; Laparoscopy [instrumentation] [*methods]; Randomized Controlled Trials as Topic; Robotic Surgical Procedures [*methods]

MeSH check words

Female; Humans