Cochrane Library

Cochrane Database of Systematic Reviews

Robot-assisted surgery in gynaecology (Review)

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

Lawrie TA, Liu H, Lu D, Dowswell T, Song H, Wang L, Shi G.
Robot-assisted surgery in gynaecology.
Cochrane Database of Systematic Reviews 2019, Issue 4. Art. No.: CD011422.
DOI: 10.1002/14651858.CD011422.pub2.

www.cochranelibrary.com

WILEY

TABLE OF CONTENTS

[Intervention Review]

Robot-assisted surgery in gynaecology

Theresa A Lawrie[1], Hongqian Liu[2], DongHao Lu[2], Therese Dowswell[3], Huan Song[4], Lei Wang[5], Gang Shi[2]

[1]Cochrane Gynaecological, Neuro-oncology and Orphan Cancer Group, 1st Floor Education Centre, Royal United Hospital, Bath, UK. [2]Department of Obstetrics and Gynecology, West China Second University Hospital, Sichuan University, Chengdu, China. [3]C/o Cochrane Pregnancy and Childbirth Group, Department of Women's and Children's Health, The University of Liverpool, Liverpool, UK. [4]Center of Public Health Sciences, Faculty of Medicine, University of Iceland, Reykjavík, Iceland. [5]Department of Orthopedics, West China Second University Hospital, Sichuan University, Chengdu, China

Contact address: 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.

Editorial group: Cochrane Gynaecological, Neuro-oncology and Orphan Cancer Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 4, 2019.

Citation: Lawrie TA, Liu H, Lu D, Dowswell T, Song H, Wang L, Shi G. Robot-assisted surgery in gynaecology. *Cochrane Database of Systematic Reviews* 2019, Issue 4. Art. No.: CD011422. DOI: 10.1002/14651858.CD011422.pub2.

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 0.77, 95% CI 0.24 to 2.50; participants = 583; studies = 6; I^2 = 37%), postoperative complications (RR 0.81, 95% CI 0.48 to 1.34; participants = 629; studies = 6; I^2 = 44%), and blood transfusions (RR 1.94, 95% CI 0.63 to 5.94; participants = 442; studies = 5; I^2 = 0%). There was no statistical difference between malignant and non-malignant disease subgroups with regard to complication rates. Only one study reported death within 30 days and no deaths occurred (very low-certainty evidence). Researchers reported no survival outcomes.

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)

A single study with a total sample size of 20 women was included in this comparison. For most outcomes, the sample size was insufficient to show any possible differences between groups.

• 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 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.

A single study with a small sample size of 20 women looked at hysterectomy using RAS versus open abdominal surgery; however, the sample size was insufficient to show any possible differences between these surgical techniques. 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 FOR THE MAIN COMPARISON [Explanation]

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	57 per 1000	44 per 1000 (14 to 143)	RR 0.77 (0.24 to 2.50)	583 (6 RCTs)	⊕⊕◯◯ LOW[a,b]	There was a difference between subgroups (malignant vs non-malignant disease) for this outcome, although numbers experiencing complications were relatively small, and within subgroups, differences between robotic and conventional surgery were not significant. Testing for subgroup differences: $Chi^2 = 5.11$, df = 1 (P = 0.02), $I^2 = 80.4\%$

Postoperative complications	172 per 1000	140 per 1000 (83 to 231)	RR 0.81 (0.48 to 1.34)	629 (6 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	40 per 1000 (13 to 121)	RR 1.94 (0.63 to 5.94)	442 (5 RCTs)	⊕⊕◯◯ LOW[a]	No significant differences between subgroups (women treated for malignant vs non-malignant disease)

*__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

[a] Studies contributing data had design limitations.
[b] Wide 95% CI crossing the line of no effect.
[c] Two studies with I^2 of 80%.
[d] Wide 95% CI crossing the line of no effect and small sample size.

[e] Studies contributing data had very serious risk of bias for this outcome.
[f] Studies with small sample sizes.

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 (Degueldre 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 ve 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 paraaortic 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 *meta*Register, 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 Chi^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 Chi² statistic and the P value, as well as the interaction test I² 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.

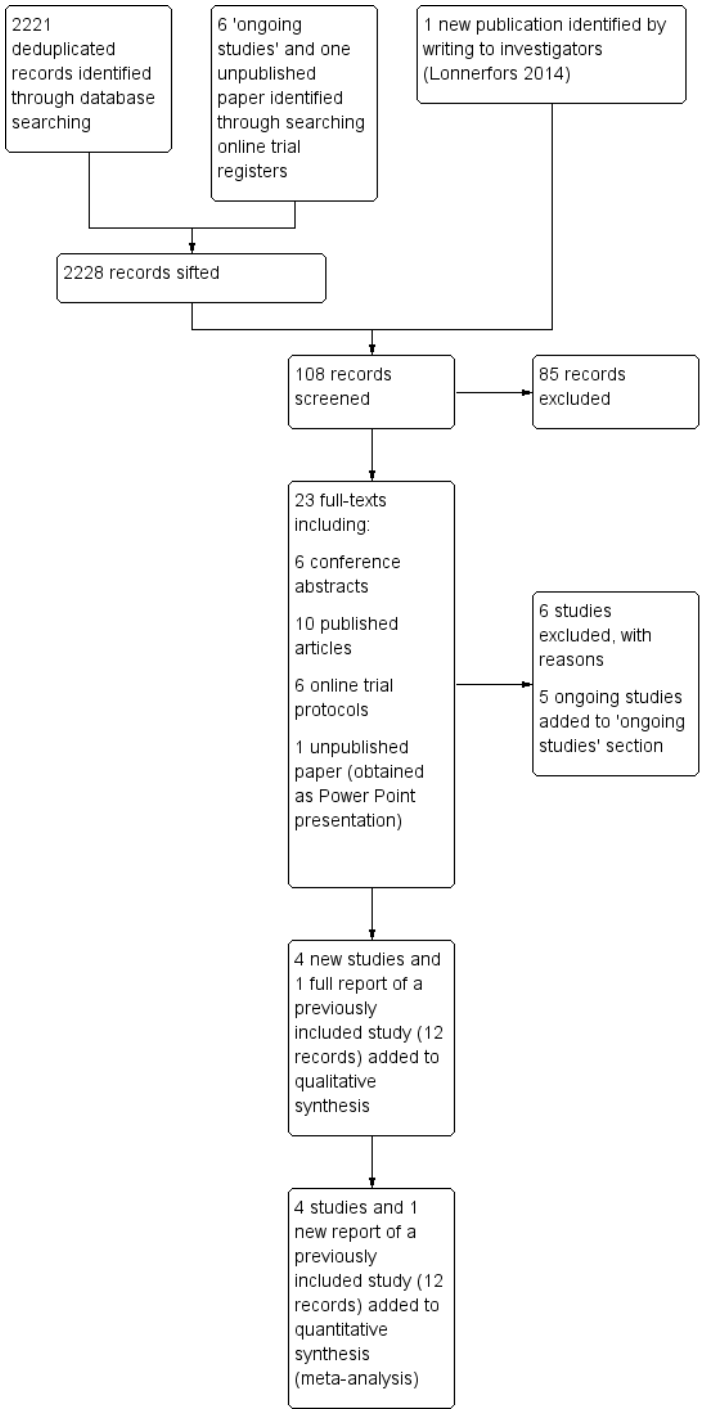
- Liu 2012 (benign gynaecological disease) included Sarlos 2010 (conference abstract only) and Paraiso 2011, and excluded three studies (not RCTs). These previously included studies comprised six citations (five conference abstracts and one full published report).
- Lu 2012 (malignant gynaecological 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; Paraiso 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).

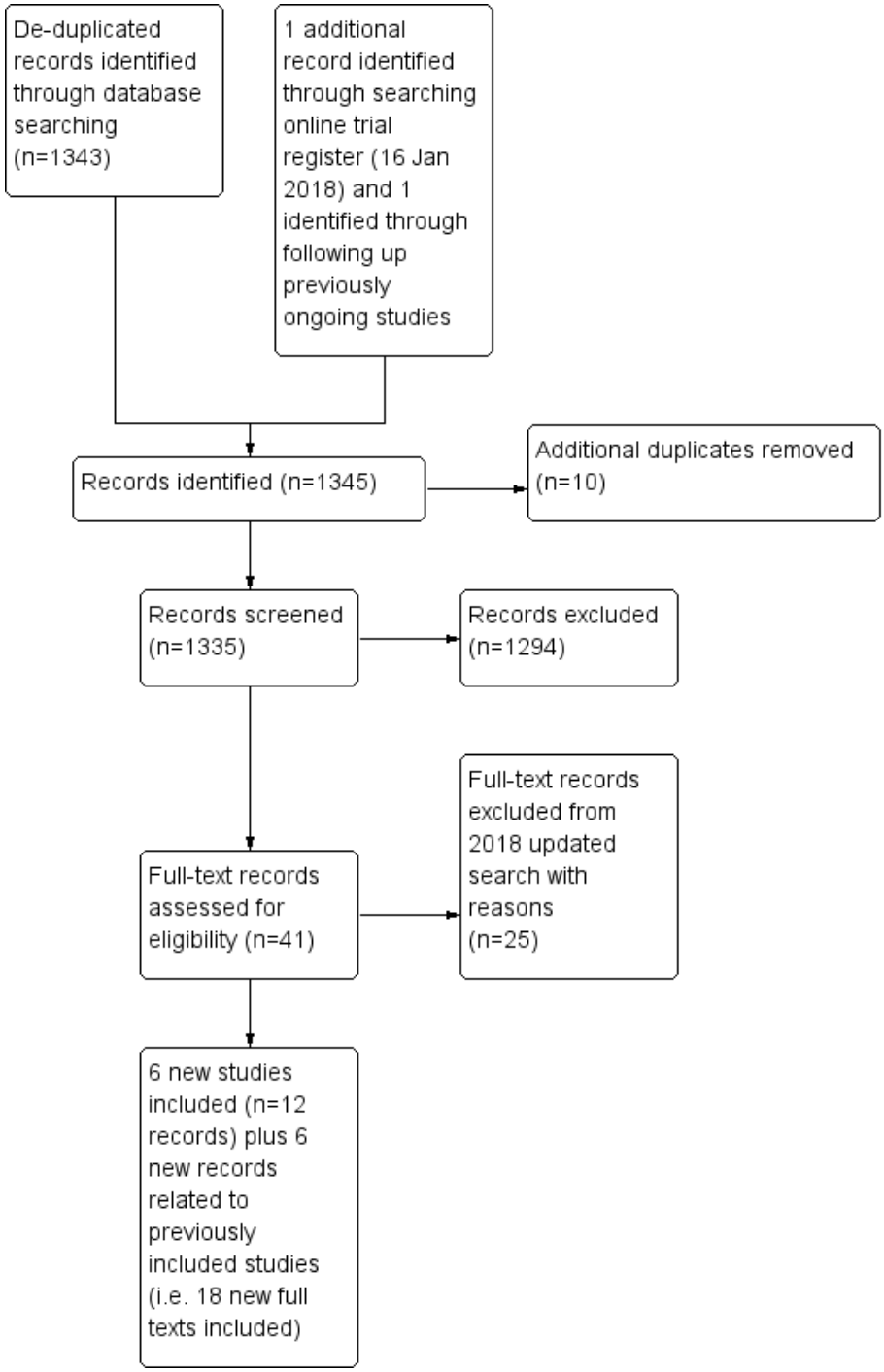


One included study was a conference abstract of a study initially identified as an 'ongoing study' (see study and protocol citation linked to Green 2013). We requested unpublished data from these investigators and received limited data in the form of a Microsoft PowerPoint presentation. We were informed 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 (Kjolhede 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 high-risk 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

One included study compared RAS versus open surgery (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.

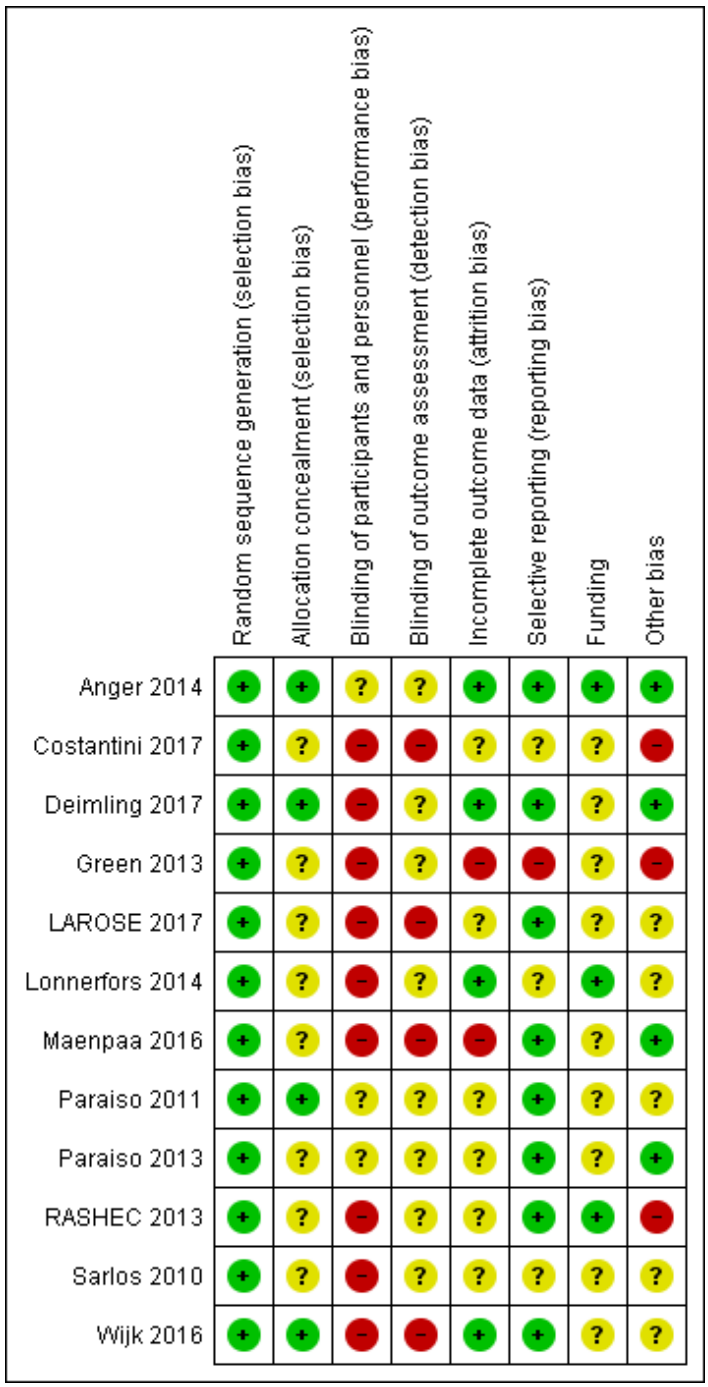
- Quasi-RCT (Somashekhar 2014).
- Inappropriate intervention/comparison (Chen 2015; Diaz-Feijoo 2016; Landeen 2016; Ramirez 2018; Tsafrir 2017).
- Not an RCT (all other exclusions).

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.



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; RASHEC 2013). 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; Paraiso 2011; Paraiso 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 Paraiso 2011, five women were withdrawn from each study arm after randomisation (unclear risk of bias). In Paraiso 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 Paraiso 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 Paraiso 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 (Paraiso 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 Paraiso 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 1.2). 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: Chi^2 = 1.92, 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 0.77, 95% CI 0.24 to 2.50; participants = 583; studies = 6; I^2 = 37%; low-certainty evidence; Analysis 1.3). Tests for subgroup differences suggest that the treatment effect may be different in women with malignant versus non-malignant disease. However, within subgroups, differences between RAS and CLS were not significant (test for subgroup differences: Chi^2 = 5.11, df = 1 (P = 0.02), I^2 = 80.4%) 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 1.4). 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 0.81, 95% CI 0.48 to 1.34; participants = 629; studies = 6; I^2 = 44%; low-certainty evidence; Analysis 1.5). 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; however, the point estimated favoured the RAS arm (RR 0.35, 95% CI 0.11 to 1.07; participants = 463; studies = 5; I^2 = 0%; low-certainty evidence; Analysis 1.6). These results were 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 comparison arm; this finding was not consistent with results from other studies contributing data; although when we temporarily removed this study from the analysis, the difference between RAS and CLS remained non-significant (data not shown).

Infectious 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 1.7).

Death within 30 days

Only RASHEC 2013 reported this outcome; study authors stated that no deaths occurred in either arm of this trial (very low-certainty evidence).

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 1.8). We downgraded evidence for study design limitations, heterogeneity, and imprecision.

Three 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). In the RASHEC 2013 trial, women undergoing surgery had high risk of malignant disease and generally longer operating times; in this study, results favoured conventional surgery; 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).

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 1.9).

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 1.10). Therefore results are difficult to interpret.

For women undergoing hysterectomy for high-risk malignant disease, median length of stay was reported to be shorter in the RAS arm (RAS median 2 days (range 1 to 5 days) vs CLS median 5 days (range 4 to 9 days); P > 0.001). These data are difficult to interpret because a single surgeon carried out all RAS procedures but five (possibly less experienced) surgeons carried out CLS procedures.

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 1.11).

Blood transfusions and blood loss

Five studies reported blood transfusions and noted no statistically significant differences between RAS and CLS arms (RR 1.94, 95% CI 0.63 to 5.94; participants = 442; studies = 5; I^2 = 0%; low-certainty evidence; Analysis 1.13), There was no clear difference in effect between subgroups of women with non-malignant versus malignant disease (testing for subgroup differences: Chi^2 = 0.02, df = 1 (P = 0.88), I^2 = 0%).

RASHEC 2013 reported medians for this outcome and suggested less blood loss in the RAS group; however, as all operations in this group were carried out by a single surgeon who was likely to estimate blood loss himself/herself, these data are at high risk of bias (data not shown).

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 1.14).

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 1.17) or re-admission (RR 0.51, 95% CI 0.21 to 1.25; participants = 316; studies = 3; I^2 = 0%; Analysis 1.18). These data were sparse and were at risk of bias (i.e. very low- to low-certainty evidence).

Cost

Two studies reported overall costs (including equipment setup and maintenance and theatre and hospital admission costs)

(Lonnerfors 2014; RASHEC 2013). We did not pool these data because heterogeneity was substantial (I^2 > 90%). Results were inconsistent in the two studies, and costs varied considerably between the two study sites (Analysis 1.19).

Lymph node yield

In a study examining RAS in malignant disease, lymph node yield was higher in women undergoing conventional surgery (mean yield 15.9 in the RAS group vs 18.8 in the CLS group) (MD -8.00, 95% CI -14.97 to -1.03; participants = 96; low-certainty evidence).

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 1.14). 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 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)

A single study with a total sample size of 20 women is included in this comparison. For most outcomes, the sample size was insufficient to reveal any possible differences between groups. The only outcome that suggested any differences between groups was the finding that at four weeks, more women in the open abdominal surgery group reported some restriction in activities of daily living (RR 0.25, 95% CI 0.07 to 0.90); for other reported outcomes (intraoperative and postoperative complications and re-admission), data were too few to reveal any differences between the two approaches.

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 baselines 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).

ADDITIONAL SUMMARY OF FINDINGS [Explanation]

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 evi- dence (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

[a] Studies contributing data had design limitations.
[b] Serious inconsistencies in study findings (I^2 of 78%).
[c] Wide 95% CI crossing the line of no effect and effect estimate based on small sample size.
[d] Study contributing data had design limitations.
[e] Estimate based on findings from a single study with a small sample size.
[f] Size of difference in effect varied across trials (I^2 of 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.

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). Only one study reported death within 30 days and revealed that no deaths occurred in either arm of this trial (very low-certainty evidence). These researchers reported no survival outcomes.

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). Five 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.

A single study with a total sample size of 20 women examined hysterectomy by RAS versus open abdominal surgery. For most outcomes, the sample size was insufficient to reveal any possible differences between groups.

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.

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 obese women, as included studies did not evaluate the effect of this variable on outcomes.

For malignant disease, we found limited evidence on the effectiveness and safety of RAS compared with CLS or open surgery for endometrial cancer. Neither of these two included studies reported disease-free and overall survival outcomes.

We also found no evidence of the effect of RAS compared with CLS on surgeons' performance and workload outcomes. 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 (Kjolhede 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.

is an operator-dependent, expensive technology, meaning that independent evaluation of the safety of this technology without bias will be challenging.

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

ACKNOWLEDGEMENTS

We are grateful for the contributions of Drs. Zhihong Liu, Dan Liu, and Xiaoyang Zhou to the original review. We also thank Jo Morrison for providing clinical and editorial advice, Joanne Platt for designing the search strategy, and Gail Quinn and Clare Jess for making contributions to the editorial process.

This project was supported by the National Institute for Health Research (NIHR), via Cochrane Infrastructure funding to the Cochrane Gynaecological, Neuro-oncology and Orphan Cancer Group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, the National Health Service (NHS), or the Department of Health.

The review authors and the Cochrane Gynaecological, Neuro-oncology and Orphan Cancers Team are grateful to the following peer reviewers for their time and comments: Sonali Kaushik, Christine Ang, Philipp Harter, and Monique Spillman.

REFERENCES

References to studies included in this review

Anger 2014 ***{published data only}***

Anger J, Mueller E, Tarnay C, Brubaker L, Rosenman A, Smith B. Abdominal colpopexy: comparison of endoscopic surgical strategies. Journal of Urology. 2012 Annual Meeting of the American Urological Association, AUA Atlanta, GA United States. Conference Start: 20120519 Conference End: 20120523. Conference Publication: (var.pagings). 2012:e864.

Anger JT, Mueller ER, Tarnay C, Smith B, Stroupe K, Rosenman A, et al. Erratum: Robotic compared with laparoscopic sacrocolpopexy: a randomized controlled trial (Obstetrics and Gynecology). *Obstetrics and Gynecology* 2014;**124**(1):165.

Anger JT, Mueller ER, Tarnay C, Smith B, Stroupe K, Rosenman A, et al. Robotic compared with laparoscopic sacrocolpopexy: a randomized controlled trial. *Obstetrics and Gynecology* 2014;**123**(1):5–12.

Kenton K, Mueller E, Tarnay C, Brubaker L, Rosenman A, Smith B, et al. Comparative effectiveness of robotic and laparoscopic sacrocolpopexy for apical vaginal prolapse: one year outcomes. Journal of Urology Conference: 2013 Annual Meeting of the American Urological Association, AUA San Diego, CA United States. Conference Start: 20130504 Conference End: 20130508. Conference Publication:(var.pagings). 2013:e877–8.

Kenton K, Mueller ER, Tarney C, Bresee C, Anger JT. One-year outcomes after minimally invasive sacrocolpopexy. *Female Pelvic Medicine & Reconstructive Surgery* 2016;**22**(5): 382–4.

Mueller ER, Kenton K, Anger JT, Bresee C, Tarnay C. Cosmetic appearance of port-site scars 1 year after laparoscopic versus robotic sacrocolpopexy: a supplementary study of the ACCESS clinical trial. *Journal of Minimally Invasive Gynecology* 2016;**23**(6):917–21.

* Mueller ER, Kenton K, Tarnay C, Brubaker L, Rosenman A, Smith B, et al. Abdominal colpopexy: comparison of endoscopic surgical strategies (ACCESS). *Contemporary Clinical Trials* 2012;**33**(5):1011–8.

Tarnay C, Kenton K, Anger J, Bresee C, Brubaker L, Rosenman A, et al. Trocar site appearance one year after robotic vs. laparoscopic sacrocolpopexy. Neurourology and Urodynamics Conference: Society for Urodynamics and Female Urology 2013 Winter Meeting Las Vegas, NV United States. Conference Start: 20130226 Conference End: 20130302. Conference Publication:(var.pagings). 2013:159.

Costantini 2017 ***{published data only}***

Costantini E, Di Biase M, Zucchi A, Cagini R, De Rienzo

G, Di Tonno P, et al. Laparoscopic and robotic assisted laparoscopic sacrocolpopexy: a randomized controlled trial, a comparison of two techniques. *Neurourology and Urodynamics Conference: 41st Annual Congress of the Italian Urodynamic Society Italy* 2017;**36**:S16–S7.

* Costantini E, Zucchi A, Di Biase M, Di Rienzo G, Orcidi D, Carbone A, et al. Laparoscopic and robotic assisted laparoscopic sacrocolpopexy: a randomized controlled trial in the era of minimally invasive surgery. *Neurourology and urodynamics Conference: 47th annual meeting of the international continence society, ICS 2017 Italy* 2017;**36**: S434–S5.

Illiano E, Di Biase M, De Rienzo G, Di Tonno P, Costantini E, Maglia D, et al. Laparoscopic versus robotic assisted sacrocolpopexy: a randomized, controlled trial. *Journal of Urology Conference: 112th Annual Meeting of the American Urological Association, AUA 2017 United States* 2017;**197**(4 Suppl 1):e354–e5.

Deimling 2017 ***{published data only}***

* Deimling TA, Eldridge JL, Riley KA, Kunselman AR, Harkins GJ. Randomized controlled trial comparing operative times between standard and robot-assisted laparoscopic hysterectomy. *International Journal of Gynaecology and Obstetrics* 2017;**136**(1):64–9.

Deimling TA, Eldridge JL, Riley KA, Kunselman AR, Harkins GJ. Standard versus robot-assisted laparoscopic hysterectomy: a prospective randomized trial. *Journal of Minimally Invasive Gynecology* 2015;**22 Suppl 1**(6):S7–S8.

Green 2013 ***{published and unpublished data}***

* Green JL, Deimling T, Tam T, Davies MF, Harkins GJ. A randomized controlled trial comparing conventional laparoscopic hysterectomy with robot-assisted laparoscopic hysterectomy in a teaching institution. Journal of Minimally Invasive Gynecology Conference: 42nd Global Congress of Minimally Invasive Gynecology, AAGL 2013 Washington, DC, United States. Conference Start: 20131110 Conference End: 20131114. Conference Publication:(var.pagings). 2013:S4.

Harkins G. Study of conventional laparoscopic hysterectomy versus robot-assisted laparoscopic hysterectomy at a teaching institution. Clinicaltrials.gov 2012; Vol. http: //clinicaltrials.gov/ct2/show/NCT01581905?term= NCT01581905&rank=1, issue accessed 4 July 2014.

LAROSE 2017 ***{published data only}***

Soto E. Laparoscopy vs. robotic surgery for endometriosis (LAROSE): a prospective randomized controlled trial [NCT01556204]. Clinicaltrials.gov 2012.

Soto E, Luu TH, Liu X, Magrina JF, Einarsson JI, Falcone T. Laparoscopy vs robotic surgery for endometriosis (LAROSE): a multicenter randomized controlled trial. *Human Reproduction Conference: 32nd Annual Meeting of the European Society of Human Reproduction and Embryology Finland* 2016;**31**:i87.

Soto E, Luu TH, Liu X, Magrina JF, Einarsson JI, Falcone T. Laparoscopy vs. robotic surgery for endometriosis (LAROSE): a multicenter randomized controlled trial. *Human Reproduction (Oxford, England)* 2016;**31 Supp1**:i87 Abstract no: O-202.

Soto E, Luu TH, Liu X, Magrina JF, Wasson MN, Einarsson JI, et al. Laparoscopy vs. robotic surgery for endometriosis (LAROSE): a multicenter, randomized, controlled trial. *Fertility and Sterility* 2017;**107**(4):996–1002.e3.

Lonnerfors 2014 ***{published data only}***

* Lonnerfors C, Reynisson P, Persson J. A randomized trial comparing vaginal- and laparoscopic hysterectomy to robot-assisted hysterectomy. *Journal of Minimally Invasive Gynecology* 2014;**Jul 18**:doi: 10.1016/j.jmig.2014.07.010. [Epub ahead of print].

Persson J. Robotic hysterectomy versus vaginal hysterectomy or traditional laparoscopic hysterectomy [NCT01865929]. Clinicaltrials.gov 2013.

Maenpaa 2016 ***{published data only}***

Mäenpää MM, Nieminen K, Tomás EI, Laurila M, Luukkaala TH, Mäenpää JU. Robotic-assisted vs traditional laparoscopic surgery for endometrial cancer: a randomized controlled trial. *American Journal of Obstetrics and Gynecology* 2016;**215**(5):588.e1–7.

Paraiso 2011 ***{published data only}***

Frick AC, Barber MD, Jelovsek JE, Fu Z, Chen G, Paraiso MR. Cost analysis of laparoscopic versus robotic sacrocolpopexy in a randomized controlled trial. *Journal of Pelvic Medicine and Surgery* 2011;**17 Suppl 1**(2):17. 37th Annual Scientific Meeting of the Society of Gynecologic Surgeons, SGS 2011 San Antonio, TX United States]

Paraiso M, Chen C, Jelovsek JE, Frick A, Barber MD. Conventional laparoscopic versus robotic-assisted laparoscopic sacral colpopexy: a randomized controlled trial. *Journal of Pelvic Medicine and Surgery* 2010;**16 Suppl 2**(5):58–9. 31st Annual Scientific Meeting of the American Urogynecologic Society, AUGS Long Beach, CA United States]

Paraiso MF, Chen CC, Jelovsek JE, Frick A, Barber MD. Conventional laparoscopic versus robotic-assisted laparoscopic sacral colpopexy: a randomized controlled trial. *Journal of Minimally Invasive Gynecology* 2010;**17 Suppl 1**(6):25. 39th Global Congress of Minimally Invasive Gynecology, AAGL 2010 Las Vegas, NV United States]

* Paraiso MF, Jelovsek JE, Frick A, Chen CC, Barber MD. Laparoscopic compared with robotic sacrocolpopexy for vaginal prolapse: a randomized controlled trial. *Obstetrics and Gynecology* 2011;**118**(5):1005–13.

Paraiso MF, Jelovsek JE, Frick A, Chen CCG, Barber MD. Laparoscopic versus robotic-assisted laparoscopic sacral colpopexy: a randomized controlled trial. *Neurourology and Urodynamics* 2010;**29**(6):964–5. Joint Annual Meeting of the International Continence Society, ICS and International Urogynecological Association, IUGA Toronto, ON Canada]

Paraiso MFR, Jelovsek JE, Frick A, Chen CCG, Barber MD. Conventional laparoscopic versus robotic-assisted laparoscopic sacral colpopexy: a randomized controlled trial. *International Urogynecology Journal and Pelvic Floor Dysfunction* 2010;**21**:S160–S1.

Paraiso 2013 *{published data only}*

* Paraiso MF, Ridgeway B, Park AJ, Jelovsek JE, Barber MD, Falcone T, et al. A randomized trial comparing conventional and robotically assisted total laparoscopic hysterectomy. *American Journal of Obstetrics and Gynecology* 2013;**208**(5):368.e361–368.e367.

RASHEC 2013 *{published data only}*

Falconer H. Robotic versus abdominal surgery for endometrial cancer (RASHEC) [NCT01847703]. Clinicaltrials.gov 2013.

Salehi S, Avall-Lundqvist E, Legerstam B, Carlson JW, Falconer H. Robot-assisted laparoscopy versus laparotomy for infrarenal paraaortic lymphadenectomy in women with high-risk endometrial cancer: a randomised controlled trial. *European Journal of Cancer* 2017;**79**:81–9.

Sarlos 2010 *{published data only}*

* Sarlos D, Kots L, Stevanovic N, von Felten S, Schar G. Robotic compared with conventional laparoscopic hysterectomy: a randomized controlled trial. *Obstetrics and Gynecology* 2012;**3**:604–11.

Sarlos D, Kots LV, Stevanovic N, Schar G. Robotic hysterectomy versus conventional laparoscopic hysterectomy: costs and preliminary results of a randomized controlled trial. *Archives of Gynecology and Obstetrics* 2010; **282 Suppl**:11–2. 58th Congress of the German Society for Gynecology and Obstetrics (Deutsche Gesellschaft fur Gynakologie und Geburtshilfe, DGGG) Munich Germany]

Wijk 2016 *{published data only}*

Wijk L, Nilsson K, Ljungqvist O. Metabolic and inflammatory responses and subsequent recovery in robotic versus abdominal hysterectomy: a randomised controlled study. *Clinical Nutrition* 2016;**pii: S0261-5614**(16): 31356–5.

References to studies excluded from this review

Advincula 2007 *{published data only}*

Advincula AP, Xiao Xu, Goudeau S, Ransom SB. Robot-assisted laparoscopic myomectomy versus abdominal myomectomy: a comparison of short-term surgical outcomes and immediate costs. *Journal of Minimally Invasive Gynecology* 2007;**14**(6):698–705.

Arms 2015 *{published data only}*

Arms RG 3rd, Sun CC, Burzawa JK, Fleming ND, Nick AM, Rallapalli V, et al. Improvement in quality of life after robotic surgery results in patient satisfaction. *Gynecologic Oncology* 2015;**138**(3):727–30.

Asciutto 2015 *{published data only}*

Asciutto KC, Kalapotharakos G, Löfgren M, Högberg T, Borgfeldt C. Robot-assisted surgery in cervical cancer patients reduces the time to normal activities of daily living. *Acta Obstetricia et Gynecologica Scandinavica* 2015;**94**(3): 260–5.

Bell 2008 *{published data only}*

Bell MC, Torgerson J, Seshadri-Kreaden U, Suttle AW, Hunt S. Comparison of outcomes and cost for endometrial cancer staging via traditional laparotomy, standard laparoscopy and robotic techniques. *Gynecologic Oncology* 2008;**111**(3): 407–11.

Best 2014 *{published data only}*

Best J, Day L, Ingram L, Musgrave B, Rushing H, Schooley B. Comparison of robotic vs standard surgical procedure on postoperative nursing care of women undergoing total abdominal hysterectomy. *Medical-Surgical Nursing* 2014;**23** (6):414–21.

Boggess 2008a *{published data only}*

Boggess JF, Gehrig PA, Cantrell L, Shafer A, Ridgway M, Skinner EN, et al. A case-control study of robot-assisted type III radical hysterectomy with pelvic lymph node dissection compared with open radical hysterectomy. *American Journal of Obstetrics and Gynecology* 2008;**199**(4): 357.e1–7.

Boggess 2008b *{published data only}*

Boggess JF, Gehrig PA, Cantrell L, Shafer A, Ridgway M, Skinner EN, et al. A comparative study of 3 surgical methods for hysterectomy with staging for endometrial cancer: robotic assistance, laparoscopy, laparotomy. *American Journal of Obstetrics and Gynecology* 2008;**199**(4): 360.e1–9.

Bogliolo 2015 *{published data only}*

Bogliolo S, Cassani C, Musacchi V, Babilonti L, Gardella B, Spinillo A. Robotic single-site surgery in management of obese patients with early-stage endometrial cancer. *Journal of Minimally Invasive Gynecology* 2015;**22**(4):697–9.

Campos 2013 *{published data only}*

Campos LS, Limberger LF, Stein AT, Kalil AN. Postoperative pain and perioperative outcomes after laparoscopic radical hysterectomy and abdominal radical hysterectomy in patients with early cervical cancer: a randomised controlled trial. *Trials* 2013;**14**:293.

Cantrell 2010 *{published data only}*

Cantrell LA, Mendivil A, Gehrig PA, Boggess JF. Survival outcomes for women undergoing type III robotic radical hysterectomy for cervical cancer: a 3-year experience. *Gynecologic Oncology* 2010;**117(2)**:260–5.

Cardenas-Goicoechea 2010 *{published data only}*

Cardenas-Goicoechea J, Adams S, Bhat SB, Randall TC. Surgical outcomes of robotic-assisted surgical staging for endometrial cancer are equivalent to traditional laparoscopic staging at a minimally invasive surgical center. *Gynecologic Oncology* 2010;**117**(2):224–8. PUBMED: 20144471]

Chen 2015 *{published data only}*

Chen C, Tanner E, Malpani A, Vedula SS, Fader AN, Scheib SA, et al. Warm-up before robotic hysterectomy does not improve trainee operative performance: a randomized trial. *Journal of Minimally Invasive Gynecology* 2015;**22**(6S):S34.

Chong 2016 *{published data only}*

Chong GO, Lee YH, Hong DG, Cho YL, Lee YS. Long-term efficacy of laparoscopic or robotic adenomyomectomy with or without medical treatment for severely symptomatic adenomyosis. *Gynecologic and Obstetric Investigation* 2016; **81**(4):346–52.

Culligan 2010 *{published data only}*
Culligan PJ, Salamon C, Priestley JL, Scherer J, Shariati A. A double-blind randomized clinical trial comparing porcine dermis and polypropylene mesh for laparoscopic sacrocolpopexy. *Journal of Pelvic Medicine and Surgery* 2010; **16 Suppl 2**(5):93. 31st Annual Scientific Meeting of the American Urogynecologic Society, AUGS Long Beach, CA United States]

DeNardis 2008 *{published data only}*
DeNardis SA, Holloway RW, Bigsby GE 4th, Pikaart DP, Ahmad S, Finkler NJ. Robotically assisted laparoscopic hysterectomy versus total abdominal hysterectomy and lymphadenectomy for endometrial cancer. *Gynecologic Oncology* 2008;**111**(3):412–7. PUBMED: 18834620]

Denstad 2017 *{published data only}*
Denstad SE, Aasen S, Ostrem AM, Bakkeheim V, Fossum GH, Moen MH. Hysterektomi ved St. Olavs Hospital 1989-2014. *Tidsskrift for Den Norske Laegeforening* 2017; **137**:16.

Desille-Gbaguidi 2013 *{published data only}*
Desille-Gbaguidi H, Hebert T, Paternotte-Villemagne J, Gaborit C, Rush E, Body G. Overall care cost comparison between robotic and laparoscopic surgery for endometrial and cervical cancer. *European Journal of Obstetrics, Gynecology, and Reproductive Biology* 2013;**171**(2):348–52.

Diaz-Feijoo 2016 *{published data only}*
Díaz-Feijoo B, Correa-Paris A, Pérez-Benavente A, Franco-Camps S, Sánchez-Iglesias JL, Cabrera S, et al. Prospective randomized trial comparing transperitoneal versus extraperitoneal laparoscopic aortic lymphadenectomy for surgical staging of endometrial and ovarian cancer: the STELLA trial. *Annals of Surgical Oncology* 2016;**23**(9): 2966–74.

Eklind 2015 *{published data only}*
* Eklind S, Lindfors A, Sjöli P, Dahm-Kähler P. A prospective, comparative study on robotic versus open-surgery hysterectomy and pelvic lymphadenectomy for endometrial carcinoma. *International Journal of Gynecological Cancer* 2015;**25**(2):250–6.

Estape 2009 *{published data only}*
Estape R, Lambrou N, Diaz R, Estape E, Dunkin N, Rivera A. A case matched analysis of robotic radical hysterectomy with lymphadenectomy compared with laparoscopy and laparotomy. *Gynecologic Oncology* 2009;**113**(3):357–61. PUBMED: 19345987]

Falik 2017 *{published data only}*
Falik RC. Regarding "Robotic versus laparoscopic staging for early ovarian cancer: a case-matched control study". *Journal of Minimally Invasive Gynecology* 2017;**24**(6):1049.

Gehrig 2008 *{published data only}*
Gehrig PA, Cantrell LA, Shafer A, Abaid LN, Mendivil A, Boggess JF. What is the optimal minimally invasive surgical procedure for endometrial cancer staging in the obese and morbidly obese woman?. *Gynecologic Oncology* 2008;**111** (1):41–5.

Geisler 2010 *{published data only}*
Geisler JP, Orr CJ, Khurshid N, Phibbs G, Manahan KJ. Robotically assisted laparoscopic radical hysterectomy compared with open radical hysterectomy. *International Journal of Gynecological Cancer* 2010;**20**(3):438–42. PUBMED: 20375811]

Gocmen 2013 *{published data only}*
Gocmen A, Sanlikan F, Ucar MG. Comparison of robotic-assisted laparoscopic myomectomy outcomes with laparoscopic myomectomy. *Archives of Gynecology and Obstetrics* 2013;**287**(1):91–6.

Grias 2012 *{published data only}*
Grias I, Della Badia C. Interrupted vicryl suture vs. barbed suture and vaginal cuff complications after robotic hysterectomy. Journal of Minimally Invasive Gynecology Conference: 41st Global Congress of Minimally Invasive Gynecology, AAGL Las Vegas, NV United States. Conference Start: 20121105 Conference End: 20121109. Conference Publication:(var.pagings): S38.. 2012.

Hoekstra 2009 *{published data only}*
Hoekstra AV, Jairam-Thodla A, Rademaker A, Singh DK, Buttin BM, Lurain JR, et al. The impact of robotics on practice management of endometrial cancer: transitioning from traditional surgery. *International Journal of Medical Robotics and Computer Assisted Surgery* 2009;**5**(4):392–7. PUBMED: 19455550]

Iavazzo 2016 *{published data only}*
Iavazzo C, Iavazzo PE, Gkegkes ID. Obese patients with endometrial cancer: is the robotic approach a challenge or a new era of safer and more cost-effective management of such patients?. *Journal of Robotic Surgery* 2016;**10**(2):183–4.

Jung 2010 *{published data only}*
Jung YW, Lee DW, Kim SW, Nam EJ, Kim JH, Kim JW, et al. Robot-assisted staging using three robotic arms for endometrial cancer: comparison to laparoscopy and laparotomy at a single institution. *Journal of Surgical Oncology* 2010;**101**(2):116–21. PUBMED: 19902479]

Kho 2009 *{published data only}*
Kho R. A trial on laparoscopic hysterectomy versus robotic hysterectomy [NCT00895284]. Clinicaltrials.gov 2009; Vol. trial terminated due to lack of funding.

Kim 2015 *{published data only}*
Kim JY, Lee YH, Chong GO, Lee YS, Cho YL, Hong DG. Comparative study between total laparoscopic and total robotic radical hysterectomy for cervical carcinoma: clinical study. *Anticancer Research* 2015;**35**(9):5015–21.

Kivnick 2013 *{published data only}*
Kivnick S, Parker W. Robot-assisted laparoscopic myomectomy compared with standard laparoscopic myomectomy. *Obstetrics and Gynecology* 2013;**121**(1):188.

Ko 2008 *{published data only}*
Ko EM, Muto MG, Berkowitz RS, Feltmate CM. Robotic versus open radical hysterectomy: a comparative study at a single institution. *Gynecologic Oncology* 2008;**111**(3): 425–30. PUBMED: 18929400]

Lambaudie 2008 *{published data only}*
Lambaudie E, Houvenaeghel G, Walz J, Bannier M, Buttarelli M, Gurriet B, et al. Robot-assisted laparoscopy in gynecologic oncology. *Surgical Endoscopy* 2008;**22**(12): 2743–7.

Lambaudie 2010 *{published data only}*
Lambaudie E, Narducci F, Bannier M, Jauffret C, Pouget N, Leblanc E, et al. Role of robot-assisted laparoscopy in adjuvant surgery for locally advanced cervical cancer. *European Journal of Surgical Oncology* 2010;**36**(4):409–13. PUBMED: 20079599]

Landeen 2016 *{published data only}*
Landeen LB, Hultgren EM, Kapsch TM, Mallory PW. Vaginal cuff dehiscence: a randomized trial comparing robotic vaginal cuff closure methods. *Journal of Robotic Surgery* 2016;**10**(4):337–41.

Lonnerfors 2009 *{published data only}*
Lonnerfors C, Persson J. Robot-assisted laparoscopic myomectomy: a feasible technique for removal of unfavorably localized myomas. *Acta Obstetricia et Gynecologica Scandinavica* 2009;**88**(9):994–9.

Madhuri 2017 *{published data only}*
Madhuri TK, Butler-Manuel S. Robotic-assisted vs traditional laparoscopic surgery for endometrial cancer: a randomized controlled trial. *American Journal of Obstetrics and Gynecology* 2017;**216**(6):619.

Maggioni 2009 *{published data only}*
Maggioni A, Minig L, Zanagnolo V, Peiretti M, Sanguineti F, Bocciolone L, et al. Robotic approach for cervical cancer: comparison with laparotomy: a case control study. *Gynecologic Oncology* 2009;**115**(1):60–4. PUBMED: 19638333]

Magrina 2008 *{published data only}*
Magrina JF, Kho RM, Weaver AL, Montero RP, Magtibay PM. Robotic radical hysterectomy: comparison with laparoscopy and laparotomy. *Gynecologic Oncology* 2008; **109**(1):86–91.

Marino 2015 *{published data only}*
Marino P, Houvenaeghel G, Narducci F, Boyer-Chammard A, Ferron G, Uzan C, et al. Cost-effectiveness of conventional vs robotic-assisted laparoscopy in gynecologic oncologic indications. *Internationl Journal of Gynecologic Cancer* 2015;**25**(6):1102–8.

Martinez-Maestro 2014 *{published data only}*
Martinez-Maestre MA, Gambadauro P, Gonzalez-Cejudo C, Torrejon R. Total laparoscopic hysterectomy with and without robotic assistance: a prospective controlled study. *Surgical Innovation* 2014;**21**(3):250–5.

McNanley 2012 *{published data only}*
McNanley A, Perevich M, Glantz C, Duecy EE, Flynn MK, Buchsbaum G. Bowel function after minimally invasive urogynecologic surgery: a prospective randomized controlled trial. *Female Pelvic Medicine & Reconstructive Surgery* 2012;**18**(2):82–5.

Nezhat 2008 *{published data only}*
Nezhat FR, Datta MS, Liu C, Chuang L, Zakashansky K. Robotic radical hysterectomy versus total laparoscopic radical hysterectomy with pelvic lymphadenectomy for treatment of early cervical cancer. *Journal of the Society of Laparoendoscopic Surgeons* 2008;**12**(3):227–37.

Ozgun 2017 *{published data only}*
Ozgun A, Sargin A, Karaman S, Gunusen I, Alper I, Askar FZ. The relationship between the Trendelenburg position and cerebral hypoxia in patients who have undergone robot-assisted hysterectomy and prostatectomy. *Turkish Journal of Medical Sciences* 2017;**47**(6):1797–803.

Paek 2016 *{published data only}*
Paek J, Lee JD, Kong TW, Chang SJ, Ryu HS. Robotic single-site versus laparo-endoscopic single-site surgery for adnexal tumours: a propensity score-matching analysis. *International Journal of Medical Robotics + Computer Assisted Surgery* 2016;**12**(4):694–700.

Palmer 2013 *{published data only}*
* Palmer MM, Dahlman M, Eisenstein D, Theoharis E, Fisher J, Wegienka G. Outcomes of vaginal cuff closure techniques in robotic hysterectomy: a prospective randomized trial. In: Journal of Minimally Invasive Gynecology.Conference: 42nd Global Congress of Minimally Invasive Gynecology, AAGL 2013 Washington, DC United States. Conference Start: 20131110 Conference End: 20131114. Conference Publication:(var.pagings): S33.. 2013.

Persson 2009 *{published data only}*
Persson J, Reynisson P, Borgfeldt C, Kannisto P, Lindahl B, Bossmar T. Robot assisted laparoscopic radical hysterectomy and pelvic lymphadenectomy with short and long term morbidity data. *Gynecologic Oncology* 2009;**113**(2):185–90. PUBMED: 19251308]

Ramirez 2009 *{published data only}*
Ramirez PT. Robotic radical hysterectomy: a new standard of care?. *Future Oncology* 2009;**5**(1):23–5.

Ramirez 2018 *{published data only}*
Obermair A, Gebski V, Frumovitz M, Soliman PT, Schmeler KM, Levenback C. A phase III randomized clinical trial comparing laparoscopic or robotic radical hysterectomy with abdominal radical hysterectomy in patients with early stage cervical cancer [NCT00614211]. *Journal of Minimally Invasive Gynecology* 2008;**15(5)**:584–8.
Ramirez P, Frumowitz M, Pareja R, Lopez A, Viera M, Ribiero R, et al. Minimally invasive versus abdominal radical hysterectomy for cervical cancer. *New England Journal of Medicine* 2018;**379**(20):1895–904.

Reza 2010 *{published data only}*
Reza M, Maeso S, Blasco JA, Andradas E. Meta-analysis of observational studies on the safety and effectiveness of robotic gynaecological surgery. *British Journal of Surgery* 2010;**97**(12):1772–83.

Seamon 2009a *{published data only}*
Seamon LG, Cohn DE, Henretta MS, Kim KH, Carlson MJ, Phillips GS, et al. Minimally invasive comprehensive

surgical staging for endometrial cancer: robotics or laparoscopy?. *Gynecologic Oncology* 2009;**113**(1):36–41. PUBMED: 19168206]

Seamon 2009b *{published data only}*
Seamon LG, Bryant SA, Rheaume PS, Kimball KJ, Huh WK, Fowler JM, et al. Comprehensive surgical staging for endometrial cancer in obese patients: comparing robotics and laparotomy. *Obstetrics and Gynecology* 2009;**114**(1): 16–21. PUBMED: 19546753]

Sert 2007 *{published data only}*
Sert B, Abeler V. Robotic radical hysterectomy in early-stage cervical carcinoma patients, comparing results with total laparoscopic radical hysterectomy cases. The future is now? . *International Journal of Medical Robotics and Computer Assisted Surgery* 2007;**3**(3):224–8.

Sert 2009 *{published data only}*
Sert MB. Robot assisted laparoscopic radical hysterectomy and pelvic lymphadenectomy with short and long term morbidity. Gynecologic Oncology 2009; Vol. 115, issue 1: 164-5; author reply 165-6. PUBMED: 19539356]

Sert 2010 *{published data only}*
Sert MB. Comparison between robot-assisted laparoscopic radical hysterectomy (RRH) and abdominal radical hysterectomy (ARH): a case control study from EIO/Milan. *Gynecologic Oncology* 2010;**117(2)**:389.

Somashekhar 2014 *{published data only}*
Ashwin K. Prospective randomized study comparing robotic-assisted hysterectomy and regional lymphadenectomy with traditional laparotomy for endometrial cancer in India. *European Journal of Surgical Oncology* 2014;**34th Congress of the European Society of Surgical Oncology in partnership with BASO 2014 Liverpool United Kingdom**:S119–20.
* Somashekhar SP, Jaka RC, Zaveri SS. Prospective randomized study comparing robotic-assisted hysterectomy and regional lymphadenectomy with traditional laparotomy for staging of endometrial carcinoma - initial Indian experience. *Indian Journal of Surgical Oncology* 2014;**5**(3): 217–23.

Tsafrir 2017 *{published data only}*
Tsafrir Z, Palmer M, Dahlman M, Nawfal AK, Aoun J, Taylor A, et al. Long-term outcomes for different vaginal cuff closure techniques in robotic-assisted laparoscopic hysterectomy: a randomized controlled trial. *European Journal of Obstetrics and Gynecology and Reproductive Biology* 2017;**210**:7–12.

Veljovich 2008 *{published data only}*
Veljovich DS, Paley PJ, Drescher CW, Everett EN, Shah C, Peters WA III. Robotic surgery in gynecologic oncology: program initiation and outcomes after the first year with comparison with laparotomy for endometrial cancer staging. *American Journal of Obstetrics and Gynecology* 2008;**198**(6): 679.e1–10.

Vizza 2014 *{published data only}*
Vizza E, Corrado G, Zanagnolo V, Tomaselli T, Cutillo G, Mancini E, et al. Neoadjuvant chemotherapy followed by robotic radical hysterectomy in locally advanced cervical cancer: a multi-institution study. *Gynecologic Oncology* 2014;**133**(2):180–5.

Westermann 2017 *{published data only}*
Westermann LB, Crisp CC, Mazloomdoost D, Kleeman SD, Pauls RN. Comparative perioperative pain and recovery in women undergoing vaginal reconstruction versus robotic sacrocolpopexy. *Obstetrical & Gynecological Survey* 2017;**72** (9):535–6.

Yoo 2015 *{published data only}*
Yoo HN, Kim TJ, Lee YY, Choi CH, Lee JW, Bae DS, et al. Single-site robotic surgery in gynecologic cancer: a pilot study. *Journal of Gynecologic Oncology* 2015;**26**(1):62–7.

References to ongoing studies

Kjolhede 2012 *{published data only}*
Kjölhede P. RCT comparing robot assisted laparoscopic hysterectomy to abdominal hysterectomy in endometrial cancer [NCT01526655]. Clinicaltrials.gov 2012.

Lauszus 2017 *{published data only}*
Lauszus FF. Robotic-assisted hysterectomy: single- vs. multi-port laparoscopic access [NCT03373513]. Clinicaltrials.gov 2017.

Narducci 2010 *{published data only}*
Narducci F. Perioperative morbidity in gyneco-oncology according to the procedure: coelioscopy vs robot-assisted coelioscopy [NCT01247779]. Clinicaltrials.gov 2010.

Additional references

Advincula 2004
Advincula AP, Song A, Burke W, Reynolds RK. Preliminary experience with robot-assisted laparoscopic myomectomy. *Journal of the American Association of Gynecologic Laparoscopists* 2004;**11**:511–8.

Bell 2009
Bell MC, Torgerson JL, Kreaden U. The first 100 da Vinci hysterectomies: an analysis of the learning curve for a single surgeon. *South Dakota Medical* 2009;**62**(91):93–5.

Cadiere 2001
Cadiere GB, Himpens J, Germay O, Izizaw R, Degueldre M, Vandromme J, et al. Feasibility of robotic laparoscopic surgery: 146 cases. *World Journal of Surgery* 2001;**25**: 1467–77.

Cela 2013
Cela V, Freschi L, Simi G, Tana R, Russo N, Artini PG, et al. Fertility and endocrine outcome after robot-assisted laparoscopic myomectomy (RALM). *Gynecological Endocrinology* 2013;**29**(1):79–82.

Cho 2009
Cho JE, Nezhat FR. Robotics and gynecologic oncology: review of the literature. *Journal of Minimally Invasive Gynecology* 2009;**16(6)**:669–81.

Coronado 2012
Coronado PJ, Herraiz MA, Magrina JF, Fasero M, Vidart JA. Comparison of perioperative outcomes and cost of

robotic-assisted laparoscopy, laparoscopy and laparotomy for endometrial cancer. *European Journal of Obstetrics, Gynecology, and Reproductive Biology* 2012;**165**(2):289–94.

da Vinci 2014
Intuitive Surgical Inc. The da Vinci surgery experience. http://www.davincisurgery.com/ (accessed 25 June 2014).

Degueldre 2000
Degueldre M, Vandromme J, Huong PT, Cadiere GB. Robotically assisted laparoscopic microsurgical tubal reanastomosis: a feasibility study. *Fertility and Sterility* 2000;**74**:1020–3.

DerSimonian 1986
DerSimonian R, Laird N. Meta-analysis in clinical trials. *Controlled Clinical Trials* 1986;**7**:177–88.

Dharia 2008
Dharia Patel SP, Steinkampf MP, Whitten SJ, Malizia BA. Robotic tubal anastomosis: surgical technique and cost effectiveness. *Fertility and Sterility* 2008;**90**:1175–9.

Diaz 2008
Diaz JP, Sonoda Y, Leitao MM, Zivanovic O, Brown CL, Chi DS, et al. Oncologic outcome of fertility-sparing radical trachelectomy versus radical hysterectomy for stage IB1 cervical carcinoma. *Gynecologic Oncology* 2008;**111(2)**: 255–60.

Dimitri 2010
Sarlos D, Kots L, Stevanovic N, Schaer G. Robotic hysterectomy versus conventional laparoscopic hysterectomy: outcome and cost analyses of a matched case-control study. *European Journal of Obstetrics, Gynecology, and Reproductive Biology* 2010;**150**:92–6.

Falcone 2000
Falcone T, Goldberg JM, Margossian H, Stevens L. Robotic-assisted laparoscopic microsurgical tubal anastomosis: a human pilot study. *Fertility and Sterility* 2000;**73**(5): 1040–2.

Fanning 2008
Fanning J, Fenton B, Purohit M. Robotic radical hysterectomy. *American Journal of Obstetrics and Gynecology* 2008;**198(6)**:649.e1–4.

Field 2007
Field JB, Benoit MF, Dinh TA, Diaz-Arrastia C. Computer-enhanced robotic surgery in gynecologic oncology. *Surgical Endoscopy* 2007;**21(2)**:244–6.

Finger 2014
Finger TN, Nezhat FR. Robotic-assisted fertility-sparing surgery for early ovarian cancer. *Journal of the Society of Laparoendoscopic Surgeons* 2014;**18**(2):308–13.

Galaal 2018
Galaal K, Donkers H, Bryant A, Lopes AD. Laparoscopy versus laparotomy for the management of early stage endometrial cancer. *Cochrane Database of Systematic Reviews* 2018, Issue 10. DOI: 10.1002/14651858.CD006655.pub3

Geisler 2008
Geisler JP, Orr CJ, Manahan KJ. Robotically assisted total laparoscopic radical trachelectomy for fertility sparing in stage IB1 adenosarcoma of the cervix. *Journal of Laparoendoscopic & Advanced Surgical Techniques. Part A* 2008;**18(5)**:727–9.

GRADE 2008
GRADEpro [Computer program]. Jan Brozek, Andrew Oxman, Holger Schünemann. Version 3.6 for Windows 2008.

Hemal 2008
Hemal AK, Kolla SB, Wadhwa P. Robotic reconstruction for recurrent supratriginal vesicovaginal fistulas. *Journal of Urology* 2008;**180**:981–5.

Higgins 2011
Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. www.cochrane-handbook.org.

Holloway 2009a
Holloway RW, Patel SD, Ahmad S. Robotic surgery in gynecology. *Scandinavian Journal of Surgery* 2009;**98**(2): 96–109.

Holloway 2009b
Holloway RW, Ahmad S, DeNardis SA, Peterson LB, Sultana N, Bigsby GE 4th, et al. Robotic-assisted laparoscopic hysterectomy and lymphadenectomy for endometrial cancer: analysis of surgical performance. *Gynecologic Oncology* 2009;**115(3)**:447–52.

Hyst 2013
The Hysterectomy Association. Hysterectomy statistics-an infographic for the UK. http://www.hysterectomy-association.org.uk/latest-news/hysterectomy-statistics-an-infographic-for-the-uk/ 2013 (accessed 6 August 2014).

Jemal 2011
Jemal A, Bray F, Center MM, Ferlay J, Ward E, Forman D. Global cancer statistics. *CA: a Cancer Journal for Clinicians* 2011;**61(2)**:69–90.

Jeppson 2014
Jeppson PC, Rahimi S, Gattoc L, Westermann L, Cichowski S, Raker CA, et al. Impact of robotic technology on hysterectomy route and associated implications for resident education. Journal of Minimally Invasive Gynecology Conference: 40th Annual SGS Scientific Meeting Scottsdale, AZ United States. Conference Start: 20140323 Conference End: 20140326. Conference Publication: (var.pagings):S4. 2014.

Kilgore 2013
Kilgore JE, Jackson AL, Ko EM, Soper JT, Van Le L, Gehrig PA, et al. Recurrence-free and 5-year survival following robotic-assisted surgical staging for endometrial carcinoma. *Gynecologic Oncology* 2013;**129**(1):49–53.

Kim 2008
Kim YT, Kim SW, Hyung WJ, Lee SJ, Nam EJ, Lee WJ. Robotic radical hysterectomy with pelvic lymphadenectomy for cervical carcinoma: a pilot study. *Gynecologic Oncology* 2008;**108(2)**:312–6.

Kucukmetin 2013
Kucukmetin A, Biliatis I, Naik R, Bryant A. Laparoscopically assisted radical vaginal hysterectomy versus radical abdominal hysterectomy for the treatment of early cervical cancer. *Cochrane Database of Systematic Reviews* 2013, Issue 10. DOI: 10.1002/14651858.CD006651.pub3

Lawrie 2013
Lawrie TA, Medeiros LRF, Rosa DD, da Rosa MI, Edelweiss MI, Stein AT, et al. Laparoscopy versus laparotomy for FIGO stage I ovarian cancer. *Cochrane Database of Systematic Reviews* 2013, Issue 2. DOI: 10.1002/14651858.CD005344.pub3

Lenihan 2008
Lenihan JP, Kovanda C, Sheshadri-Kreaden U. What is the learning curve for robotic assisted gynaecologic surgery?. *Journal of Minimally Invasive Gynecology* 2008;**15**:589–94.

Lowe 2009
Lowe MP, Chamberlain DH, Kamelle SA, Johnson PR, Tillmanns TD. A multi-institutional experience with robotic-assisted radical hysterectomy for early stage cervical cancer. *Gynecologic Oncology* 2009;**113(2)**:191–4.

Madhuri 2012
Madhuri TK, Hamzawala I, Tailor A, Butler-Manuel S. Robot assisted surgery in gynaecologic oncology-starting a program and initial learning curve from a UK tertiary referral centre: the Guildford perspective. *International Journal of Medical Robotics and Computer Assisted Surgery: MRCAS* 2012;**8**(4):496–503.

Medeiros 2009
Medeiros LRF, Rosa DD, Bozzetti MC, Fachel JMG, Furness S, Garry R, et al. Laparoscopy versus laparotomy for benign ovarian tumour. *Cochrane Database of Systematic Reviews* 2009, Issue 2. DOI: 10.1002/14651858.CD004751.pub3

Melamud 2005
Melamud O, Eichel L, Turbow B, Shanberg A. Laparoscopic vesicovaginal fistula repair with robotic reconstruction. *Urology* 2005;**65**:163–6.

Mettler 1998
Mettler L, Ibrahim M, Jonat W. One year of experience working with the aid of a robotic assistant (the voice-controlled optic holder AESOP) in gynaecological endoscopic surgery. *Human Reproduction* 1998;**3**(10):2748–50.

Moy 2010
Moy ML, Byun SY. Role of robotic surgery in urogynecologic surgery. *Current Opinion in Urology* 2010;**20(1)**:70–4.

Nezhat 2006
Nezhat C, Saberi NS, Shahmohamady B, Nezhat F. Robotic-assisted laparoscopy in gynecological surgery. *Journal of Strategic Information Systems* 2006;**10**:317–20.

Nezhat 2009
Nezhat C, Lavie O, Hsu S, Watson J, Barnett O, Lemyre M. Robotic assisted laparoscopic myomectomy compared with standard laparoscopic myomectomy-a retrospective matched control study. *Fertility and Sterility* 2009;**91**:556–9.

Nieboer 2014
Nieboer TE, Aarts JW. Robotic compared with laparoscopic sacrocolpopexy: a randomized controlled trial. *Obstetrics and Gynecology* 2014;**123**(6):1357–8.

O'Neill 2013
O'Neill M, Moran PS, Teljeur C, O'Sullivan OE, O'Reilly BA, Hewitt M, et al. Robot-assisted hysterectomy compared to open and laparoscopic approaches: systematic review and meta-analysis. [Review]. *Archives of Gynecology and Obstetrics* 2013;**287**(5):907–18.

Parmar 1998
Parmar MK, Torri V, Stewart L. Extracting summary statistics to perform meta-analyses of the published literature for survival endpoints. *Statistics in Medicine* 1998;**17**(24):2815–34.

Persson 2008
Persson J, Kannisto P, Bossmar T. Robot-assisted abdominal laparoscopic radical trachelectomy. *Gynecologic Oncology* 2008;**111(3)**:564–7.

Plante 2008
Plante M. Vaginal radical trachelectomy: an update. *Gynecologic Oncology* 2008;**111 Suppl 1**(2):105–10.

Ramsey 2012
Ramsey C, Pickard R, Robertson C, Close A, Vale L, Armstrong N, et al. Systematic review and economic modelling of the relative clinical benefit and cost-effectiveness of laparoscopic surgery and robotic surgery for removal of the prostate in men with localised prostate cancer. *NIHR Health Technology Assessment Programme: Executive Summaries* 2012;**16**(41):1–313.

RevMan 2014 [Computer program]
The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

Reynisson 2013
Reynisson P, Persson J. Hospital costs for robot-assisted laparoscopic radical hysterectomy and pelvic lymphadenectomy. *Gynecologic Oncology* 2013;**130**(1):95–9.

Reynolds 2005
Reynolds RK, Burke WM, Advincula AP. Preliminary experience with robot-assisted laparoscopic staging of gynecologic malignancies. *Journal of the Society of Laparoendoscopic Surgeons/Society of Laparoendoscopic Surgeons* 2005;**9(2)**:149–58.

Reynolds 2006
Reynolds RK, Advincula AP. Robot-assisted laparoscopic hysterectomy: technique and initial experience. *American Journal of Surgery* 2006;**191**:555–60.

Rodgers 2007
Rodgers AK, Goldberg JM, Hammel JP, Falcone T. Tubal anastomosis by robotic compared with outpatient

minilaparotomy. *Obstetrics and Gynecology* 2007;**109**: 1375–80.

Schiavone 2012
Schiavone M, Kuo E, Naumann R, Burke W, Lewin S, Herzog T, et al. The commercialization of robotic surgery: unsubstantiated marketing of gynecologic surgery by hospitals. Gynecologic Oncology Conference: 2012 Annual Meeting on Women's Cancer Austin, TX, United States. Conference Start: 20120324 Conference End: 20120327. Conference Publication:(var.pagings):772. 2012.

Schimpf 2007
Schimpf MO, Morgenstern JH, Tulikangas PK, Wagner JR. Vesicovaginal fistula repair without intentional cystotomy using the laparoscopic robotic approach: a case report. *Journal of the Society of Laparoendoscopic Surgeons* 2007;**11**: 378–80.

Sener 2006
Sener A, Chew BH, Duvdevani M, Brock GB, Vilos GA, Pautler SE. Combined transurethral and laparoscopic partial cystectomy and robot-assisted bladder repair for the treatment of bladder endometrioma. *Journal of Minimally Invasive Gynecology* 2006;**13**:245–8.

Shafer 2008
Shafer A, Boggess JF. Robotic-assisted endometrial cancer staging and radical hysterectomy with the da Vinci surgical system. *Gynecologic Oncology* 2008;**111 Suppl**(2):18–23.

Soliman 2013
Soliman PT, Langley G, Munsell MF, Vaniya HA, Frumovitz M, Ramirez PT. Analgesic and antiemetic requirements after minimally invasive surgery for early cervical cancer: a comparison between laparoscopy and robotic surgery. *Annals of Surgical Oncology* 2013;**20**(4):1355–9.

Sundaram 2006
Sundaram BM, Kalidasan G, Hemal AK. Robotic repair of vesicovaginal fistula: case series of five patients. *Urology* 2006;**67**:970–3.

Teljeur 2014
Teljeur C, O'Neill M, Moran P, Harrington P, Flattery M, Murphy L, et al. Economic evaluation of robot-assisted hysterectomy: a cost-minimisation analysis. BJOG 2014 May 9; Vol. Epub ahead of print.

Vergote 2008
Vergote I, Pouseele B, Van Gorp T, Vanacker B, Leunen K, Cadron I, et al. Robotic retroperitoneal lower para-aortic lymphadenectomy in cervical carcinoma: first report on the technique used in 5 patients. *Acta Obstetricia et Gynecologica Scandinavica* 2008;**87(7)**:783–7.

Verheijen 2012
Verheijen R, Zweemer R. Robotic surgery for gynaecologic cancer: an overview. *Current Oncology Reports* 2012;**14**(6): 544–9.

Yim 2013
Yim GW, Kim SW, Nam EJ, Kim S, Kim YT. Learning curve analysis of robot-assisted radical hysterectomy for cervical cancer: initial experience at a single institution. *Journal of Gynecologic Oncology* 2013;**24**(4):303–12.

References to other published versions of this review

Liu 2012
Liu H, Lu D, Wang L, Shi G, Song H, Clarke J. Robotic surgery for benign gynaecological disease. *Cochrane Database of Systematic Reviews* 2012, Issue 2. DOI: 10.1002/14651858.CD008978.pub2

Lu 2012
Lu D, Liu Z, Shi G, Liu D, Zhou X. Robotic assisted surgery for gynaecological cancer. *Cochrane Database of Systematic Reviews* 2012, Issue 1. DOI: 10.1002/14651858.CD008640.pub2

* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Anger 2014

Methods	2-Centre RCT **Setting:** academic teaching hospitals (UCLA , Los Angeles, and Loyola University, Chicago) **Country:** USA **Groups:** robot-assisted sacrocolpopexy vs conventional laparoscopic sacrocolpopexy **Period:** 2009 to 2011
Participants	**Number:** 78 women randomly assigned **Diagnosis:** women with symptomatic stage POP II or greater, including significant spiral support loss **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 **Excluded:** pregnancy or pregnancy in the past 12 months, plans for future childbearing, inability to give informed consent **Age (years):** 58.5 ± 10.5/60.6 ± 9.2 **BMI (kg/m^2):** 28.3 ± 6.6/27.7 ± 4.7 Overall 42% of the women had a prior hysterectomy (similar between groups)
Interventions	**RAS (40) vs CLS (38)** **Procedure:** laparoscopic sacrocolpopexy **Follow-up:** 12 months
Outcomes	• Intraoperative and postoperative complications: adverse events reported • Quality of life: reported • 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**

Anger 2014 (*Continued*)

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 **Period:** women recruited May 2013 to April 2016
Participants	**Number:** 40 women randomised (21/19) **Diagnosis:** women with advanced pelvic organ prolapse (symptomatic POP stage > II) **Included:** women with advanced pelvic organ prolapse (symptomatic POP stage > II) requiring sacrocolpopexy. Other inclusion criteria not described **Excluded:** not described **Age (years):** (mean, SD not reported) 63.5; 58.82 **BMI (kg/m^2):** (mean, SD not reported) 24.59; 25.41

Costantini 2017 (*Continued*)

Interventions	**RAS (21) vs laparoscopic surgery** **Procedure:** laparoscopic sacrocolpopexy **Follow-up:** 12 months (although long-term outcomes not reported)
Outcomes	• 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	**Surgeons' experience:** "All procedures were performed by 2 senior surgeons, with standardized technique" 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

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) All outcomes	Unclear risk	Denominators were not reported in the tables
Selective reporting (reporting bias)	Unclear risk	No protocol is available Only a limited number of outcomes were reported
Funding	Unclear risk	Not reported

Costantini 2017 (*Continued*)

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/m^2):** 30.6 ± 7.8/32.1 ± 9.3
Interventions	**RAS (72) vs CLS (72)** **Procedure:** laparoscopic hysterectomy **Follow-up:** 12 weeks
Outcomes	• 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 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	

Deimling 2017 (*Continued*)

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	Single-centre RCT, open-label **Setting:** Cleveland Clinic, Ohio (academic teaching hospital) **Country:** USA **Groups:** conventional laparoscopic vs robot-assisted laparoscopic hysterectomy **Period:** NR
Participants	**Number:** 113 randomly assigned, 98 analysed **Diagnosis:** pelvic pain, endometriosis/adenomyosis, DUB, fibroids **Included:** "all women between 18 and 80 years of age requiring hysterectomy that were also candidates for laparoscopy" **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/m^2):** 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	• 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	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) 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 Uterine weight tended to be less in the RAS arm (P = 0.09)

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

Green 2013 (*Continued*)

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	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) 11 women in CLS arm underwent RAS instead
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	RCT, multi-centre, parallel, open-label (Cleveland Clinic, Cleveland, Ohio, Mayo Clinic, Scottsdale, Arizona; Brigham and Women's Hospital, Boston, Massachusetts) **Country:** USA **Period:** March 2012 to July 2015 **Groups:** RAS (superficial and deep resection for endometriosis) vs CLS
Participants	**Number:** 74 participants (73 followed up: RAS 35, CLS 38) **Diagnosis:** presumed endometriosis **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) **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 **Age:** 34.3 (SD 7.2); 34.5 (SD 8.5) **BMI:** 26.1 (SD 5.2); 24.8 (SD 5.9) **Previous laparoscopy:** reported as mean, SD, and n; 1.2 (1.3)/35; 1.2 (1.4)/38 **Previous abdominal surgery:** 14/35 vs 12/38

LAROSE 2017 (*Continued*)

	Physical health at baseline score (mean (SD)): 41.5 (4.8) vs 42.7 (6.4)
Interventions	**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) **Follow-up:** 6 months **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
Outcomes	**Primary outcomes** • Operating time (skin incision to skin closure) **Secondary outcomes** • Pain and activity (assessed at 2 weeks, 6 weeks, and 6 months) • Total operating room time • Surgeon estimated blood loss • 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,

LAROSE 2017 (*Continued*)

		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 **Period:** January 2010 to June 2013
Participants	**Number:** 122 randomly assigned **Diagnosis:** women with uterine size ≤ 16 weeks planned for minimally invasive hysterectomy for benign disease **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 **Excluded:** malignant disease; known extensive intra-abdominal adhesions; anaesthesiological contraindications to laparoscopic surgery; women with pacemaker or other implants for whom electrosurgery 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 **Age (median, years):** 47 (27 to 65)/46 (29 to 69) **BMI (median, kg/m²):** 24.9 (17 to 39.2)/24.9 (17.6 to 42) **Uterine weight (median, grams):** 180 (54 to 1114)/154 (30 to 694)
Interventions	**RAS vs other minimally invasive surgery (CLS or vaginal approach)** **Procedure:** hysterectomy **Follow-up:** 4 months

Outcomes	• 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	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 **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"

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
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

Lonnerfors 2014 (*Continued*)

		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) **BMI (kg/m^2):** 29 (20 to 46)/29 (20 to 45)

Maenpaa 2016 (*Continued*)

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	• 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

Maenpaa 2016 (*Continued*)

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
Other bias	Low risk	None noted

Paraiso 2011

Methods	RCT, single-centre, single-blinded **Setting:** Cleveland Clinic, Ohio (academic teaching hospital) **Country:** USA **Groups:** robot-assisted laparoscopic sacrocolpopexy vs conventional laparoscopic sacrocolpopexy **Period:** January 2007 to December 2009
Participants	**Number:** randomly assigned: 78 participants (38/40); evaluated: 68 participants (33/35) **Diagnosis:** apical vaginal prolapse stages 2 to 4 **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 **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 **Age (years):** 60 ± 11/61 ± 9 **BMI (kg/m^2):** 29 ± 5/29 ± 5 **Uterine weight (grams):** NR Most women had had a prior hysterectomy (> 90%) **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)
Interventions	**RAS vs CLS** **Procedure:** laparoscopic sacrocolpopexy **Follow-up:** 1 year
Outcomes	• 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

Paraiso 2011 (*Continued*)

	• Rate of conversion: reported • Early and late mortality: NR
Notes	**Surgeons' experience:** 2 surgeons involved; each had performed at least 10 robotic hysterectomies before participating in the study

Risk of bias

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

Paraiso 2011 (*Continued*)

		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 **Excluded:** suspected malignancy, illness that precludes laparoscopy, inability to give consent, morbid obesity **Age (years):** 43.8 vs 45.6 (NS) **BMI (kg/m^2):** 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	**RAS (26) vs CLS (27)** **Procedure:** laparoscopic hysterectomy **Follow-up:** 6 months
Outcomes	• 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	**Surgeons' experience:** all 5 surgeons had performed 75 to 400 total laparoscopic hysterectomies and at least 20 RAS procedures 1 woman in the CLS arm required laparotomy because of bleeding and inability to maintain a pneumoperitoneum 2 women for RAS were converted to laparoscopy: 1 because of robot malfunction, and the other because she could not be ventilated No intraoperative transfusions or bladder, ureteral, rectal, or small-bowel injuries were reported in either group No postoperative complications occcurred; however, 3 women required blood transfu-

Paraiso 2013 (*Continued*)

	sions during the postoperative period (2 after RAS; 1 after CLS)	
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
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	RCT, parallel, open-label, single-centre **Setting:** Department of Obstetrics and Gynecology, Karolinska University Hospital, Stockholm, Sweden **Country:** Sweden **Period:** May 2013 to July 2016 **Groups:** robot-assisted vs open surgery
Participants	**Number:** 120 women randomised (113 in ITT analysis and 96 in per-protocol analyses) **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) **Included:** 18 to 75 years of age; high-risk endometrial cancer **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
Interventions	**Procedure:** complete surgical staging (hysterectomy, BSO, and pelvic and para-aortic lymphadenectomy) **Follow-up:** 3 years **Surgeon experience:** "five surgeons performed all open surgeries and one performed all the RALs"
Outcomes	**Primary outcome measures** • Lymph node yield **Secondary outcome measures** • Recurrence of cancer • Lymphatic side effects • Quality of life • Healthcare costs • Perioperative outcomes
Notes	Email correspondence with Dr. Falconer on 25 June 2014 confirmed that 45 women had been enrolled to date; primary results are expected late 2015/early 2016 Data extraction based on 2017 published report

Risk of bias

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)	High risk	Masking was not performed A single surgeon carried out all robot-as-

RASHEC 2013 (*Continued*)

All outcomes		sisted 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 **BMI (kg/m^2):** 25.7 ± 5/26 ± 5.3 **Uterine weight (g):** 254.5 ± 147.3/247 ± 190
Interventions	**Procedure:** total hysterectomy **Follow-up:** 6 weeks
Outcomes	• 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	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 **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

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	5 participants did not complete the study or undergo the procedure "missing values were replaced by the median of available measurements in the respective study arm" "quality of life only evaluated on 75 women as a result of non-completion of questionnaires" Denominators not consistently reported, so not always possible to determine whether data were missing
Selective reporting (reporting bias)	Unclear risk	Denominators not consistently reported
Funding	Unclear risk	Sponsor stated as Kantonsspital Aarau Study authors did not report any potential conflicts of interest
Other bias	Unclear risk	Early RAS adopters may contribute to review bias

Wijk 2016

Methods	Single-centre RCT (NCT02291406) **Setting:** Department of Gynaecology and Obstetrics, Orebro University Hospital **Country:** Sweden **Groups:** robot-assisted laparoscopic hysterectomy vs open abdominal hysterectomy **Period:** October 2014 to May 2015; 8 months
Participants	**Number:** 20 women randomised (10/10); all included in analyses **Diagnosis:** women with an indication for hysterectomy with either benign or malignant disease and suitable for both techniques **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 **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 **Age (years):** (median/range) 52 (41 to 66); 50 (41 to 67) **BMI (kg/m^2):** (median/range) 26 (21 to 38); 26 (18 to 38)
Interventions	**Procedure:** total hysterectomy with or without salpingo-oophorectomy **Follow-up:** 30 days
Outcomes	• 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 Primary outcome was metabolic response (insulin resistance)
Notes	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 **Surgeons' experience:** "All hysterectomies were performed by experienced gynaecologic surgeons, all as the first patient of the morning"

Risk of bias

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 par-

Wijk 2016 (*Continued*)

		ticipate 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
Asciutto 2015	Prospective cohort study
Bell 2008	CCT
Best 2014	Retrospective chart review
Boggess 2008a	CCT
Boggess 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

(*Continued*)

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
Kho 2009	CCT
Kim 2015	Retrospective cohort study
Kivnick 2013	Letter/Commentary
Ko 2008	CCT
Lambaudie 2008	CCT
Lambaudie 2010	CCT
Landeen 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

(*Continued*)

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
Sert 2010	Letter
Somashekhar 2014	Quasi-randomised: "Fifty consecutive patients were alternatively allotted"
Tsafrir 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]*

Kjolhede 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** • 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 postoperatively **Secondary outcomes** • Changes in biomarkers for tissue damage (C-reactive protein, creatinine kinase, high-mobility group protein B1, amino acids) • 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/m², 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	• 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)
Methods	RCT, multi-centre, parallel, open-label **Country:** France **Groups:** laparoscopic gynaecological surgery vs robot-assisted laparoscopic gynaecological surgery
Participants	**Number:** 374 participants **Diagnosis:** malignant gynaecological disease (ovary, uterus, and cervix) **Included:** women > 18 years of age requiring surgery for ovarian, uterine, or cervical cancer **Excluded:** metastatic disease
Interventions	**Procedure:** gynaecological surgery for malignant gynaecological disease (surgical staging procedures) **Follow-up:** 2 years **Endpoint:** safety
Outcomes	**Primary outcomes** • Intraoperative and postoperative complications **Secondary outcomes** • Postoperative analgesia • Surgeon's ergonomy (Borg and NASA-TLX scales) • Quality of life (SF-36)

Narducci 2010 (*Continued*)

	• Operating time • Progression-free survival (2 years) • Number of lymph nodes removed • Positive surgical margins
Starting date	December 2010
Contact information	Dr. Fabrice Narducci Centre Oscar Lambret, Lille, France; 59000f-narducci@o-lambret.fr
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 Death within 30 days	1	96	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
1.1 Hysterectomy for malignant disease	1	96	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2 Intraoperative and postoperative complications	6	585	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.54, 1.59]
2.1 Hysterectomy for non-malignant disease	5	486	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.38, 1.53]
2.2 Hysterectomy for malignant disease	1	99	Risk Ratio (M-H, Random, 95% CI)	1.47 [0.79, 2.72]
3 Intraoperative complications	6	583	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.24, 2.50]
3.1 Hysterectomy for non-malignant disease	4	388	Risk Ratio (M-H, Random, 95% CI)	1.66 [0.76, 3.61]
3.2 Hysterectomy for malignant disease	2	195	Risk Ratio (M-H, Random, 95% CI)	0.19 [0.03, 1.05]
4 Complications: intraoperative injury	3	269	Risk Ratio (M-H, Random, 95% CI)	1.62 [0.20, 12.91]
4.1 Hysterectomy for non-malignant disease	3	269	Risk Ratio (M-H, Random, 95% CI)	1.62 [0.20, 12.91]
5 Postoperative complications	6	629	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.48, 1.34]
5.1 Hysterectomy for non-malignant disease	4	434	Risk Ratio (M-H, Random, 95% CI)	0.61 [0.34, 1.09]
5.2 Hysterectomy for malignant disease	2	195	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.44, 2.77]
6 Complications: bleeding	5	463	Risk Ratio (M-H, Random, 95% CI)	0.35 [0.11, 1.07]
6.1 Hysterectomy for non-malignant disease	4	367	Risk Ratio (M-H, Random, 95% CI)	0.41 [0.10, 1.66]
6.2 Hysterectomy for malignant disease	1	96	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.01, 7.98]
7 Complications: infection	4	367	Risk Ratio (M-H, Random, 95% CI)	0.62 [0.13, 2.88]
7.1 Hysterectomy for non-malignant disease	4	367	Risk Ratio (M-H, Random, 95% CI)	0.62 [0.13, 2.88]
8 Total operating time	2	148	Mean Difference (IV, Random, 95% CI)	41.18 [-6.17, 88.53]
8.1 Hysterectomy for non-malignant disease	2	148	Mean Difference (IV, Random, 95% CI)	41.18 [-6.17, 88.53]
9 Operating room time [min]	2	148	Mean Difference (IV, Random, 95% CI)	44.35 [5.22, 83.47]
9.1 Hysterectomy for non-malignant disease	2	148	Mean Difference (IV, Random, 95% CI)	44.35 [5.22, 83.47]
10 Overall hospital stay	2	192	Mean Difference (IV, Random, 95% CI)	-0.30 [-0.53, -0.07]
10.1 Hysterectomy for non-malignant disease	2	192	Mean Difference (IV, Random, 95% CI)	-0.30 [-0.53, -0.07]
11 Conversion to another approach	3	269	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.24, 5.77]

11.1 Hysterectomy	3	269	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.24, 5.77]
12 Blood transfusions	5	442	Risk Ratio (M-H, Random, 95% CI)	1.94 [0.63, 5.94]
12.1 Hysterectomy for non-malignant disease	3	247	Risk Ratio (M-H, Random, 95% CI)	1.94 [0.30, 12.76]
12.2 Hysterectomy for malignant disease	2	195	Risk Ratio (M-H, Random, 95% CI)	1.56 [0.22, 10.88]
13 Estimated blood loss	1	95	Mean Difference (IV, Random, 95% CI)	7.0 [-18.26, 32.26]
13.1 Hysterectomy for non-malignant disease	1	95	Mean Difference (IV, Random, 95% CI)	7.0 [-18.26, 32.26]
14 Pain at 1 to 2 weeks	1	36	Mean Difference (IV, Random, 95% CI)	-2.0 [-16.08, 12.08]
14.1 Hysterectomy for non-malignant disease	1	36	Mean Difference (IV, Random, 95% CI)	-2.0 [-16.08, 12.08]
15 Quality of life (6 weeks)	1	95	Mean Difference (IV, Random, 95% CI)	8.0 [3.12, 12.88]
15.2 Hysterectomy for non-malignant disease	1	95	Mean Difference (IV, Random, 95% CI)	8.0 [3.12, 12.88]
16 Quality of life (6 months)	1	38	Mean Difference (IV, Random, 95% CI)	5.0 [-3.01, 13.01]
16.1 Hysterectomy for non-malignant disease	1	38	Mean Difference (IV, Random, 95% CI)	5.0 [-3.01, 13.01]
17 Re-intervention	1	122	Risk Ratio (M-H, Random, 95% CI)	0.25 [0.03, 2.17]
17.1 Hysterectomy for non-malignant disease	1	122	Risk Ratio (M-H, Random, 95% CI)	0.25 [0.03, 2.17]
18 Re-admission	3	316	Risk Ratio (M-H, Random, 95% CI)	0.51 [0.21, 1.25]
18.1 Hysterectomy for non-malignant disease	2	220	Risk Ratio (M-H, Random, 95% CI)	0.46 [0.14, 1.48]
18.2 Hysterectomy for malignant disease	1	96	Risk Ratio (M-H, Random, 95% CI)	0.6 [0.15, 2.37]
19 Overall cost	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
19.1 Hysterectomy for non-malignant disease	1	97	Mean Difference (IV, Random, 95% CI)	1564.0 [1079.57, 2048.43]
19.2 Hysterectomy for malignant disease	1	96	Mean Difference (IV, Random, 95% CI)	-1568.0 [-3100.75, -35.25]
20 Lymph node yield	1	96	Mean Difference (IV, Random, 95% CI)	-8.0 [-14.97, -1.03]
20.1 Hysterectomy for malignant disease	1	96	Mean Difference (IV, Random, 95% CI)	-8.0 [-14.97, -1.03]

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
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, Fixed, 95% CI)	0.18 [0.01, 3.56]
20 Complications: sexual dysfunction	1	40	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.06, 13.48]

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]
2 Intraoperative complications	1	20	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
3 Complications: intraoperative injury	0	0	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4 Postoperative complications	1	20	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.02, 7.32]
5 Complications: bleeding	0		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
6 Complications: infection	1	20	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.02, 7.32]
7 Total operating time	0	0	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
8 Operating room time [min]	0	0	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
9 Overall hospital stay	0		Mean Difference (IV, Random, 95% CI)	Subtotals only
10 Conversion to another approach	0	0	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
11 Blood transfusions	0		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
12 Estimated blood loss	0	0	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
13 Pain at 1 to 2 weeks	0	0	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
14 Quality of life (4 weeks)	1	20	Risk Ratio (M-H, Random, 95% CI)	0.25 [0.07, 0.90]
15 Quality of life (6 months)	0		Mean Difference (IV, Random, 95% CI)	Totals not selected
16 Re-intervention	0	0	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
17 Re-admission	1	20	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.02, 7.32]
18 Overall cost	0		Mean Difference (IV, Random, 95% CI)	Totals not selected

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 and postoperative complications	0	0	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2 Intraoperative complications	1	73	Risk Ratio (M-H, Random, 95% CI)	0.36 [0.04, 3.32]
3 Complications: intraoperative injury	0	0	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4 Postoperative complications	1	73	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.40, 1.51]
5 Complications: bleeding	0		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
6 Complications: infection	1	73	Risk Ratio (M-H, Random, 95% CI)	0.54 [0.23, 1.29]
7 Total operating time	1	73	Mean Difference (IV, Random, 95% CI)	5.0 [-20.71, 30.71]
8 Operating room time [min]	1	73	Mean Difference (IV, Random, 95% CI)	5.90 [-22.31, 34.11]
9 Blood transfusions	0		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
10 Overall hospital stay	0		Mean Difference (IV, Random, 95% CI)	Subtotals only
11 Conversion to another approach	1	73	Risk Ratio (M-H, Random, 95% CI)	0.36 [0.02, 8.58]
12 Estimated blood loss	1	73	Mean Difference (IV, Random, 95% CI)	57.10 [-20.08, 134.28]
13 Pain at 1 to 2 weeks	0	0	Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
14 Quality of life (6 weeks)	1	73	Mean Difference (IV, Random, 95% CI)	-2.30 [-3.79, -0.81]
15 Quality of life (6 months)	1	73	Mean Difference (IV, Random, 95% CI)	1.30 [-0.58, 3.18]
16 Re-intervention	0	0	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
17 Re-admission	1	73	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.13, 4.08]
18 Overall cost	0		Mean Difference (IV, Random, 95% CI)	Totals not selected
19 Pain at 6 months	1	73	Mean Difference (IV, Fixed, 95% CI)	3.30 [-8.31, 14.91]

Analysis 1.1. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 1 Death within 30 days.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 1 Death within 30 days

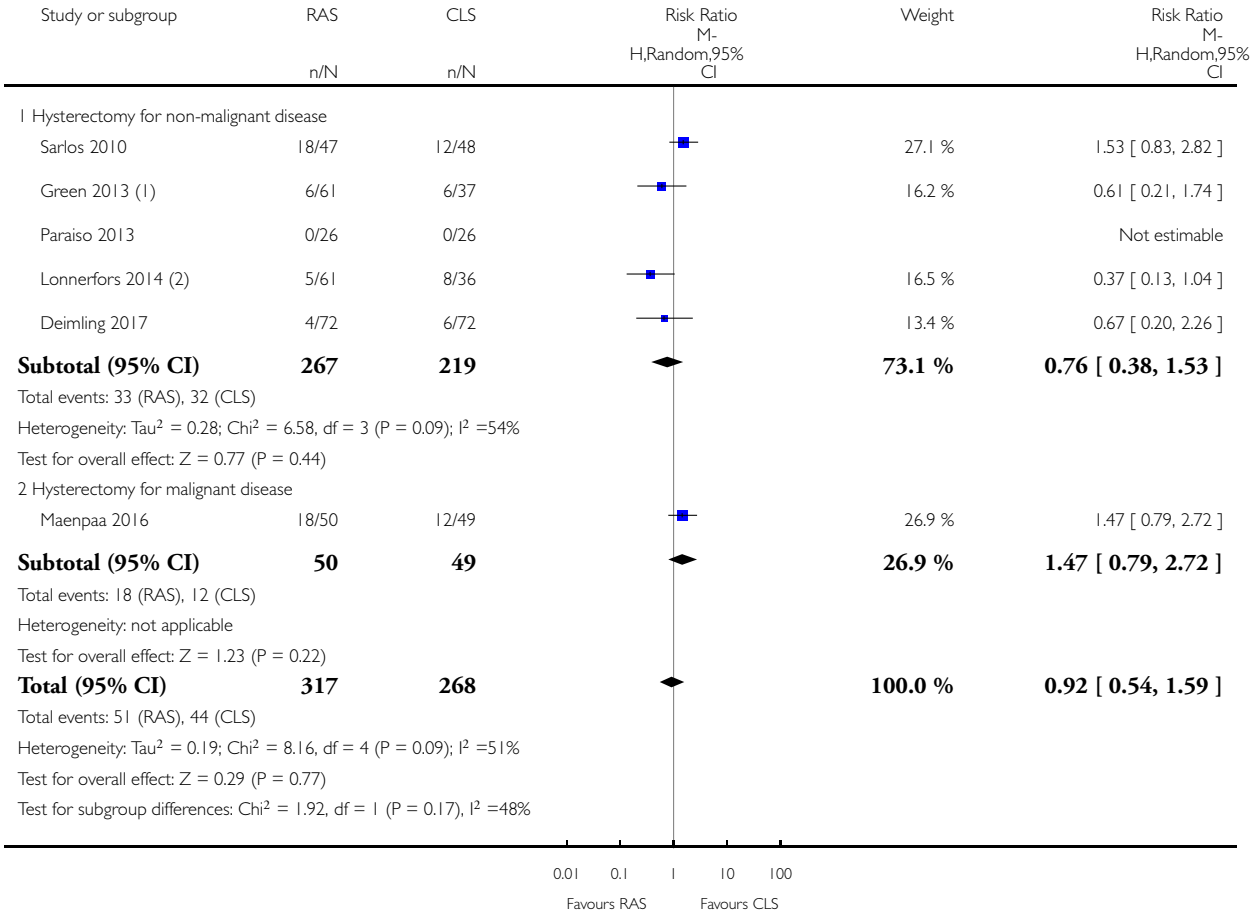
Study or subgroup	RAS n/N	CLS n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Hysterectomy for malignant disease					
RASHEC 2013	0/48	0/48			Not estimable
Total (95% CI)	**48**	**48**			**Not estimable**
Total events: 0 (RAS), 0 (CLS)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Test for subgroup differences: Chi^2 = 0.0, df = -1 (P = 0.0), I^2 =0.0%					

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 2 Intraoperative and postoperative complications



(1) Per protocol data

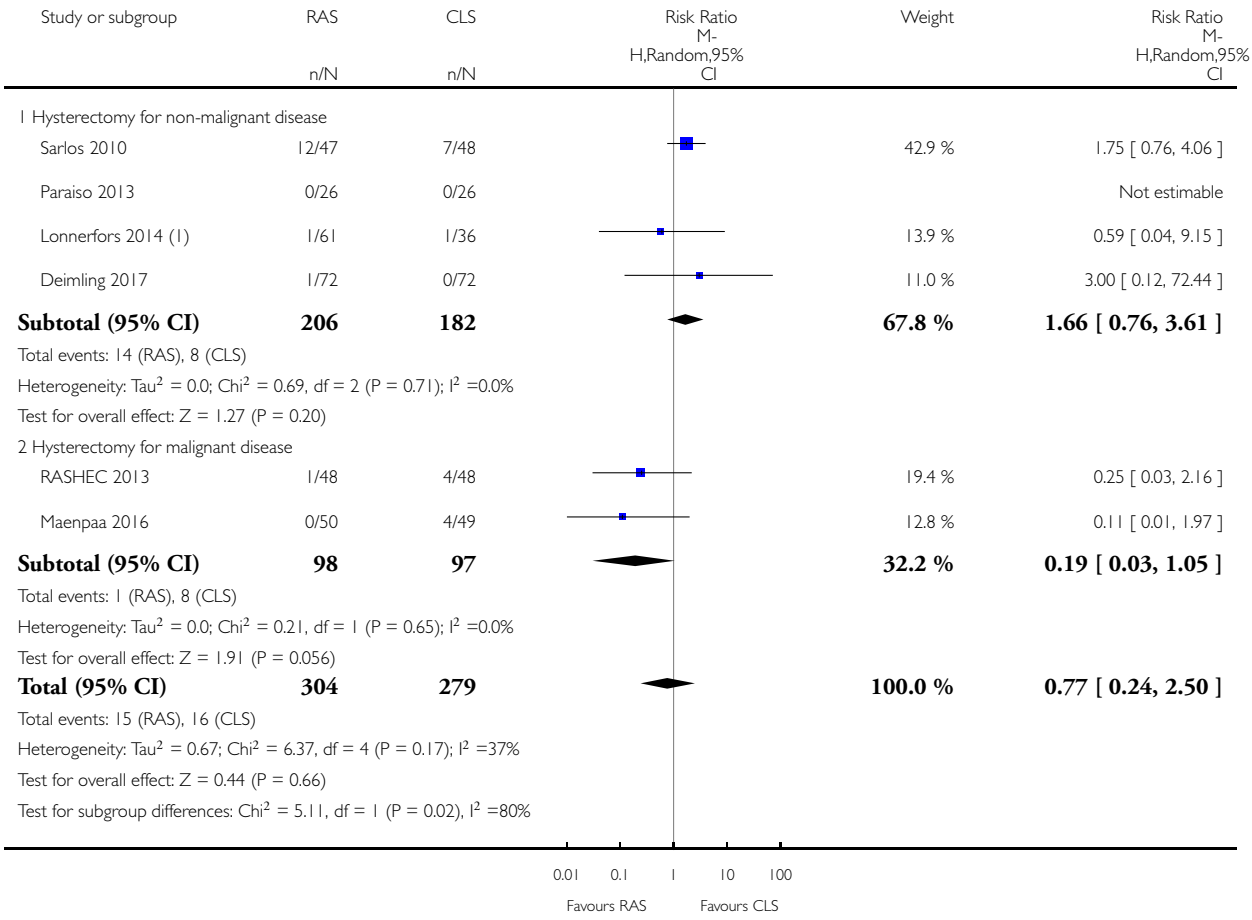
(2) Excluding 25 women who underwent a vaginal hysterectomy in the control arm

Analysis 1.3. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 3 Intraoperative complications.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 3 Intraoperative complications



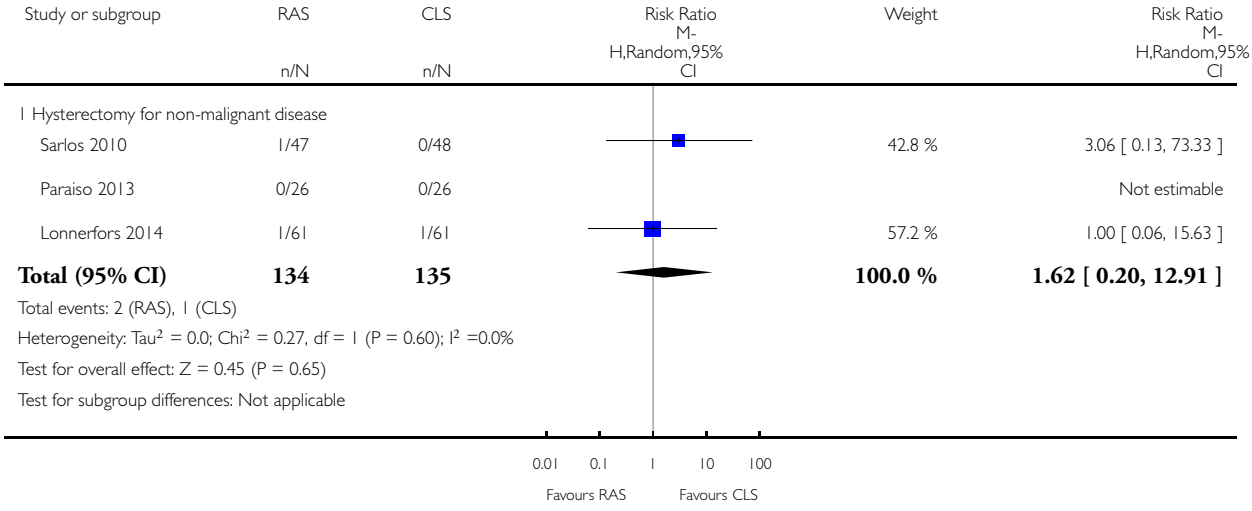
(1) Excluding 25 women who underwent a vaginal hysterectomy in the control arm

Analysis 1.4. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 4 Complications: intraoperative injury.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 4 Complications: intraoperative injury



Analysis 1.5. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 5 Postoperative complications.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 5 Postoperative complications

Study or subgroup	RAS n/N	CLS n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Hysterectomy for non-malignant disease					
Sarlos 2010	6/47	5/48		13.7 %	1.23 [0.40, 3.74]
Green 2013 (1)	6/61	6/37		14.8 %	0.61 [0.21, 1.74]
Lonnerfors 2014 (2)	4/61	7/36		13.1 %	0.34 [0.11, 1.07]
Deimling 2017	3/72	6/72		10.6 %	0.50 [0.13, 1.92]
Subtotal (95% CI)	**241**	**193**		**52.2 %**	**0.61 [0.34, 1.09]**
Total events: 19 (RAS), 24 (CLS)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 2.59, df = 3 (P = 0.46); I^2 =0.0%					
Test for overall effect: Z = 1.67 (P = 0.094)					
2 Hysterectomy for malignant disease					
RASHEC 2013 (3)	11/48	16/48		24.1 %	0.69 [0.36, 1.32]
Maenpaa 2016	18/50	10/49		23.8 %	1.76 [0.91, 3.43]
Subtotal (95% CI)	**98**	**97**		**47.8 %**	**1.10 [0.44, 2.77]**
Total events: 29 (RAS), 26 (CLS)					
Heterogeneity: Tau^2 = 0.33; Chi^2 = 3.91, df = 1 (P = 0.05); I^2 =74%					
Test for overall effect: Z = 0.20 (P = 0.84)					
Total (95% CI)	**339**	**290**		**100.0 %**	**0.81 [0.48, 1.34]**
Total events: 48 (RAS), 50 (CLS)					
Heterogeneity: Tau^2 = 0.17; Chi^2 = 8.88, df = 5 (P = 0.11); I^2 =44%					
Test for overall effect: Z = 0.83 (P = 0.41)					
Test for subgroup differences: Chi^2 = 1.12, df = 1 (P = 0.29), I^2 =11%					

(1) High risk of bias (per protocol data). [Infection (1 vs 3), bleeding (1 vs 0), vaginal cuff dehiscence (3 vs 3), other (1 vs 1)]

(2) Excluding 25 women who underwent a vaginal hysterectomy in the control arm

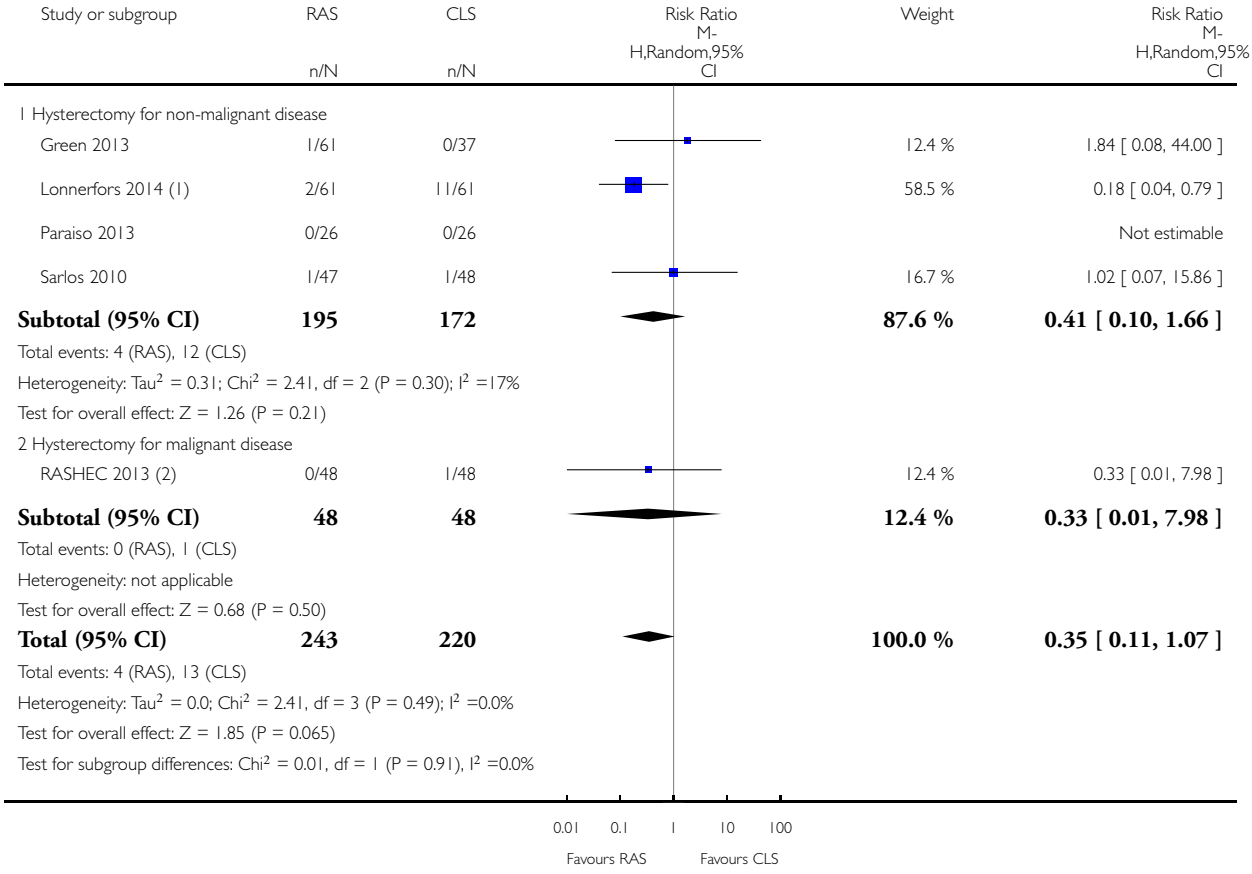
(3) Any grade of complication

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 6 Complications: bleeding



(1) Vaginal cuff haematomas. CLS arm included 25 women who underwent vaginal hysterectomy.

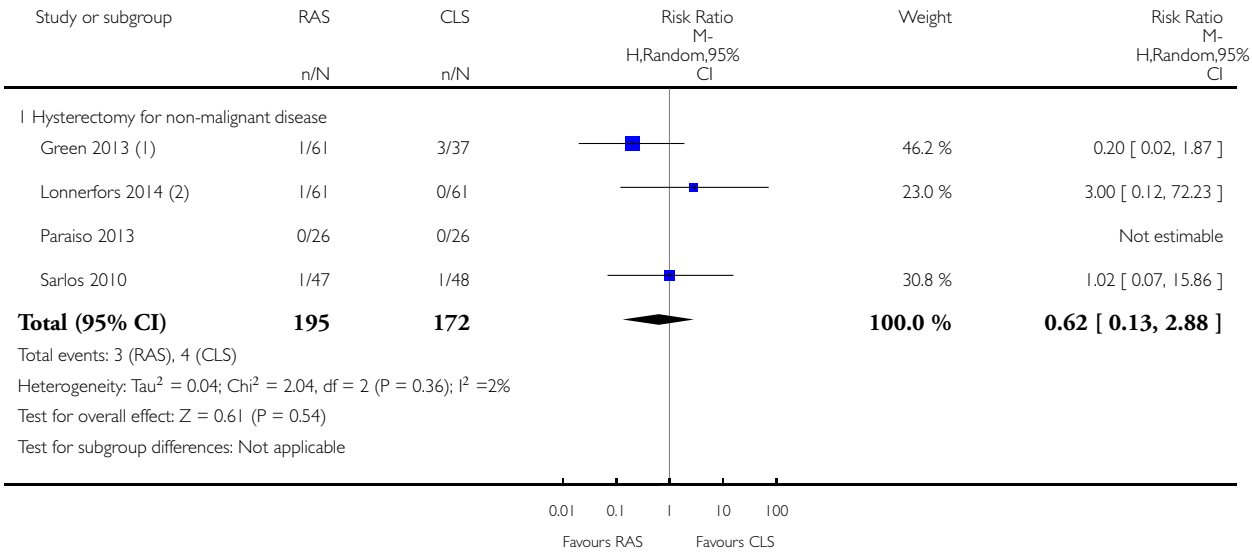
(2) Blood transfusion

Analysis 1.7. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 7 Complications: infection.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 7 Complications: infection



(1) per protocol data

(2) CLS arm included 25 women who underwent vaginal hysterectomy

Analysis 1.8. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 8 Total operating time.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 8 Total operating time

Study or subgroup	RAS N	Mean(SD)[min]	CLS N	Mean(SD)[min]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Hysterectomy for non-malignant disease							
Sarlos 2010	47	96 (28)	48	75 (21)		58.9 %	21.00 [11.03, 30.97]
Paraiso 2013	26	172.8 (89)	27	102.7 (63.7)		41.1 %	70.10 [28.30, 111.90]
Total (95% CI)	**73**		**75**			**100.0 %**	**41.18 [-6.17, 88.53]**

Heterogeneity: Tau^2 = 965.00; Chi^2 = 5.01, df = 1 (P = 0.03); I^2 =80%

Test for overall effect: Z = 1.70 (P = 0.088)

Test for subgroup differences: Not applicable

Analysis 1.9. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 9 Operating room time [min].

Review: Robot-assisted surgery in gynaecology

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

Outcome: 9 Operating room time [min]

Study or subgroup	RAS N	Mean(SD)	CLS N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Hysterectomy for non-malignant disease							
Sarlos 2010	47	106 (29)	48	75 (21)		69.1 %	31.00 [20.80, 41.20]
Paraiso 2013	26	245.8 (117.1)	27	171.6 (75.8)		30.9 %	74.20 [20.88, 127.52]
Total (95% CI)	**73**		**75**			**100.0 %**	**44.35 [5.22, 83.47]**

Heterogeneity: $Tau^2 = 549.48$; $Chi^2 = 2.43$, df = 1 (P = 0.12); $I^2 = 59\%$

Test for overall effect: Z = 2.22 (P = 0.026)

Test for subgroup differences: Not applicable

Analysis 1.10. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 10 Overall hospital stay.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 10 Overall hospital stay

Study or subgroup	RAS N	Mean(SD)[days]	CLS N	Mean(SD)[days]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Hysterectomy for non-malignant disease							
Sarlos 2010	47	3.3 (0.9)	48	3.6 (3.9)		4.1 %	-0.30 [-1.43, 0.83]
Lonnerfors 2014 (1)	61	1.1 (0.52)	36	1.4 (0.6)		95.9 %	-0.30 [-0.54, -0.06]
Total (95% CI)	**108**		**84**			**100.0 %**	**-0.30 [-0.53, -0.07]**

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.00$, df = 1 (P = 1.00); $I^2 = 0.0\%$

Test for overall effect: Z = 2.55 (P = 0.011)

Test for subgroup differences: Not applicable

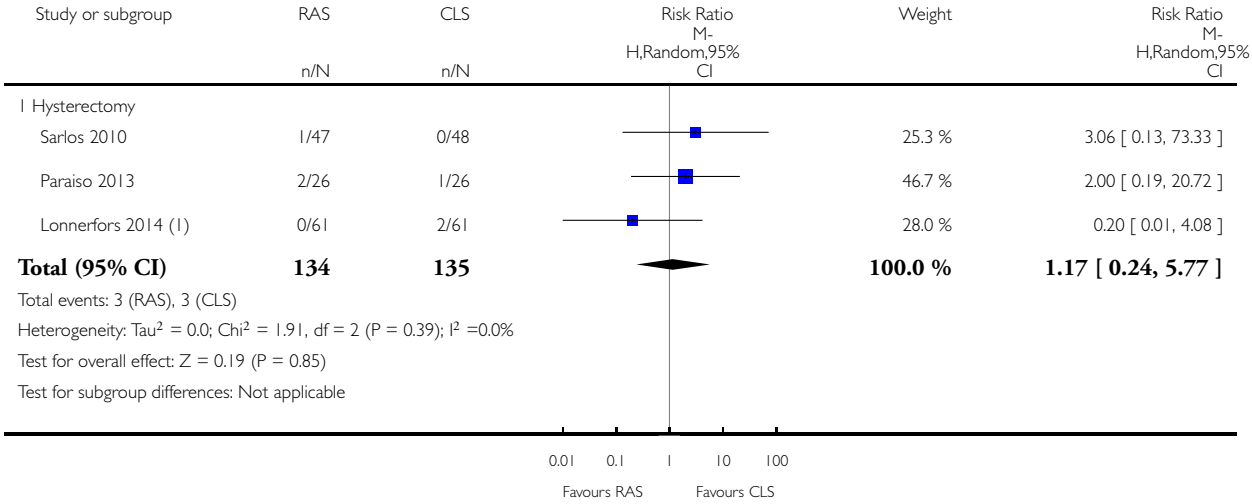
(1) Excluding 25 women who underwent a vaginal hysterectomy in the control arm

Analysis 1.11. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 11 Conversion to another approach.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 11 Conversion to another approach



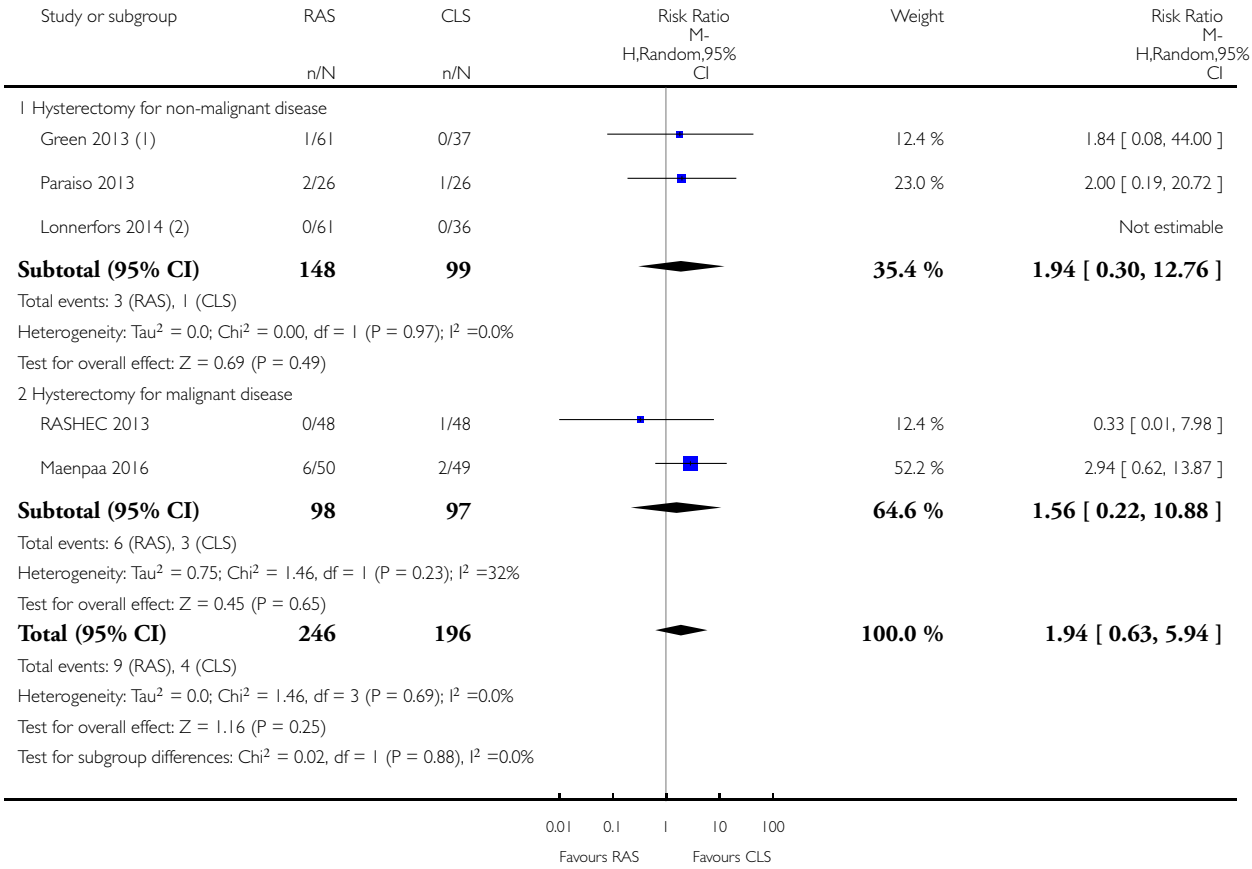
(1) Control arm included 25 women who underwent a vaginal hysterectomy

Analysis 1.12. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 12 Blood transfusions.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 12 Blood transfusions



(1) per protocol data

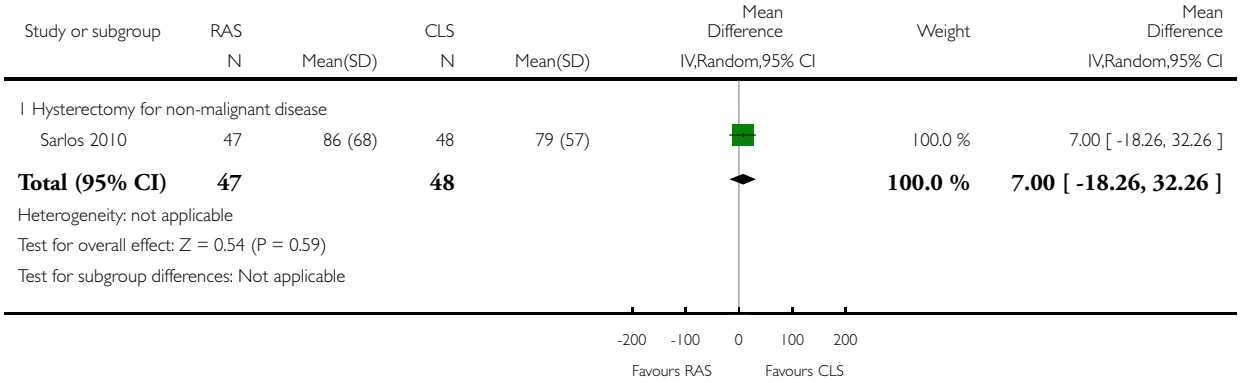
(2) Excluding 25 women who underwent a vaginal hysterectomy in the control arm

Analysis 1.13. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 13 Estimated blood loss.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 13 Estimated blood loss

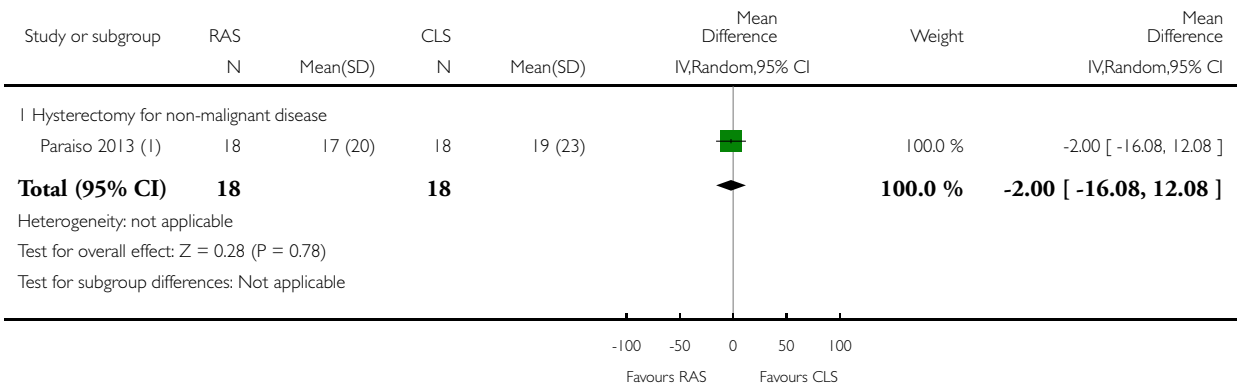


Analysis 1.14. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 14 Pain at 1 to 2 weeks.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 14 Pain at 1 to 2 weeks



(1) Pain at rest

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 15 Quality of life (6 weeks)

Study or subgroup	RAS N	Mean(SD)	CLS N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
2 Hysterectomy for non-malignant disease							
Sarlos 2010 (1)	47	13 (10)	48	5 (14)		100.0 %	8.00 [3.12, 12.88]
Total (95% CI)	**47**		**48**			**100.0 %**	**8.00 [3.12, 12.88]**
Heterogeneity: not applicable							
Test for overall effect: Z = 3.21 (P = 0.0013)							
Test for subgroup differences: Not applicable							

(1) EQ-5D mean change from baseline

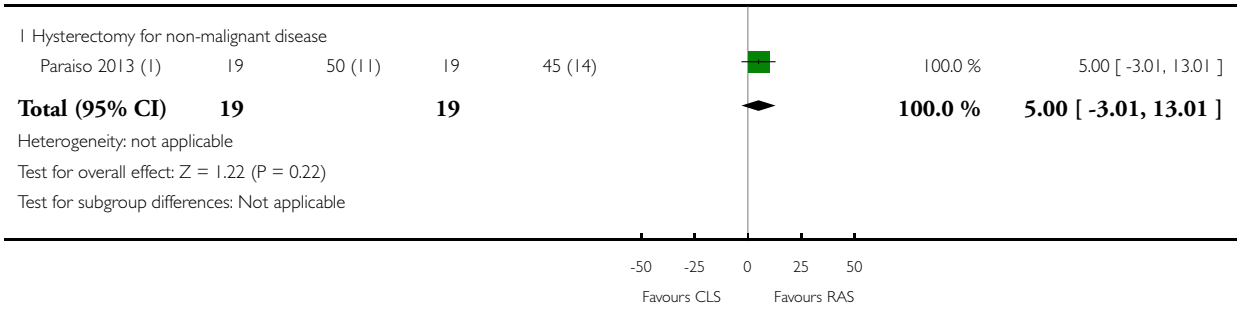
Analysis 1.16. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 16 Quality of life (6 months).

Review: Robot-assisted surgery in gynaecology

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

Outcome: 16 Quality of life (6 months)

Study or subgroup	RAS N	Mean(SD)	CLS N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Hysterectomy for non-malignant disease							
Paraiso 2013 (1)	19	50 (11)	19	45 (14)		100.0 %	5.00 [-3.01, 13.01]
Total (95% CI)	**19**		**19**			**100.0 %**	**5.00 [-3.01, 13.01]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.22 (P = 0.22)							
Test for subgroup differences: Not applicable							



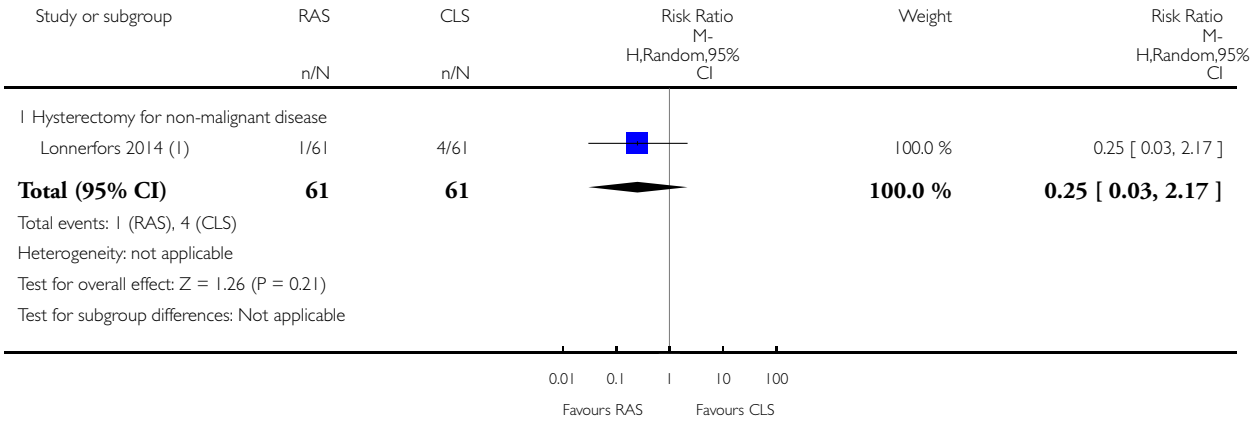
(1) 36 item short form health survey (mental component summary score). Physical summary scores were similar.

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 17 Re-intervention



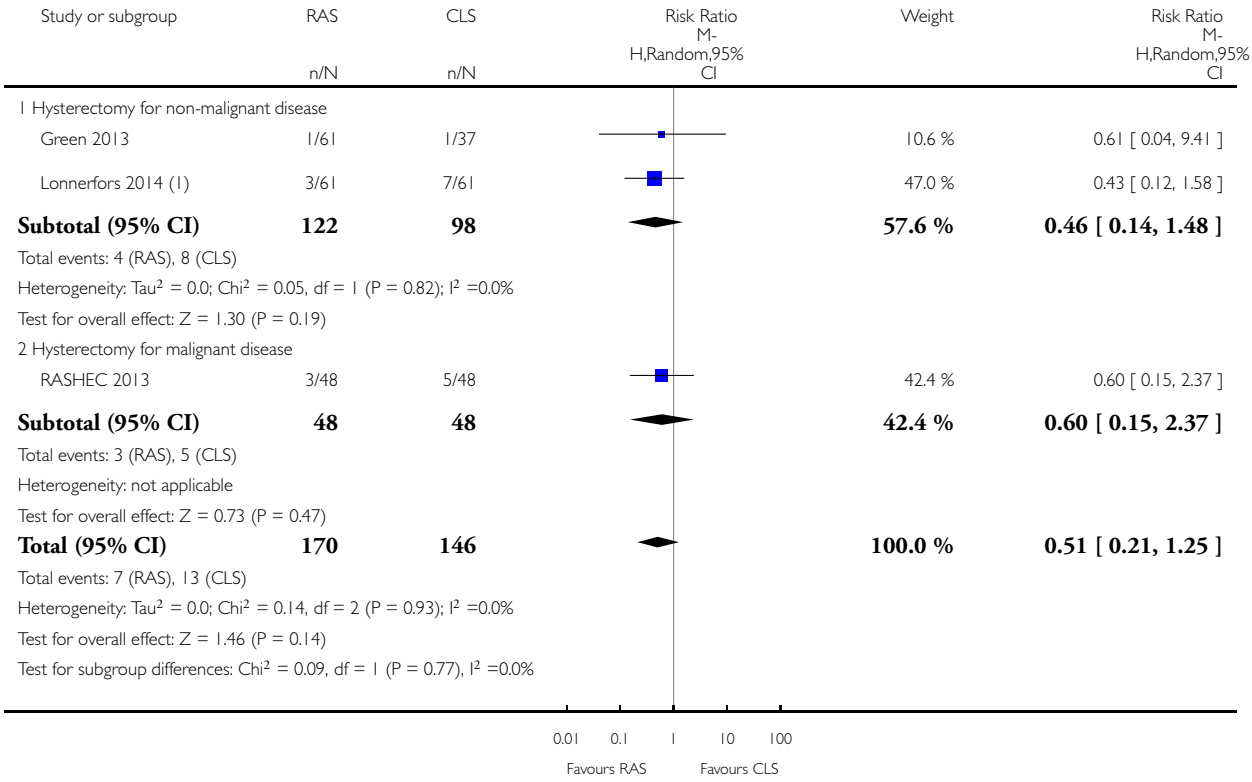
(1) Control arm included 25 women who underwent vaginal hysterectomy

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 18 Re-admission



(1) Control arm included 25 women who underwent vaginal hysterectomy

Analysis 1.19. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 19 Overall cost.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 19 Overall cost

Study or subgroup	RAS N	RAS Mean(SD)[US dollars]	CLS N	CLS Mean(SD)[US dollars]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Hysterectomy for non-malignant disease							
Lonnerfors 2014 (1)	61	8623 (1018)	36	7059 (1260)		100.0 %	1564.00 [1079.57, 2048.43]
Subtotal (95% CI)	**61**		**36**			**100.0 %**	**1564.00 [1079.57, 2048.43]**
Heterogeneity: not applicable							
Test for overall effect: Z = 6.33 (P < 0.00001)							
2 Hysterectomy for malignant disease							
RASHEC 2013 (2)	48	19937 (4248)	48	21505 (3363)		100.0 %	-1568.00 [-3100.75, -35.25]
Subtotal (95% CI)	**48**		**48**			**100.0 %**	**-1568.00 [-3100.75, -35.25]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.01 (P = 0.045)							
Test for subgroup differences: Chi^2 = 14.58, df = 1 (P = 0.00), I^2 =93%							

(1) Excluding 25 women who underwent a vaginal hysterectomy in the control arm

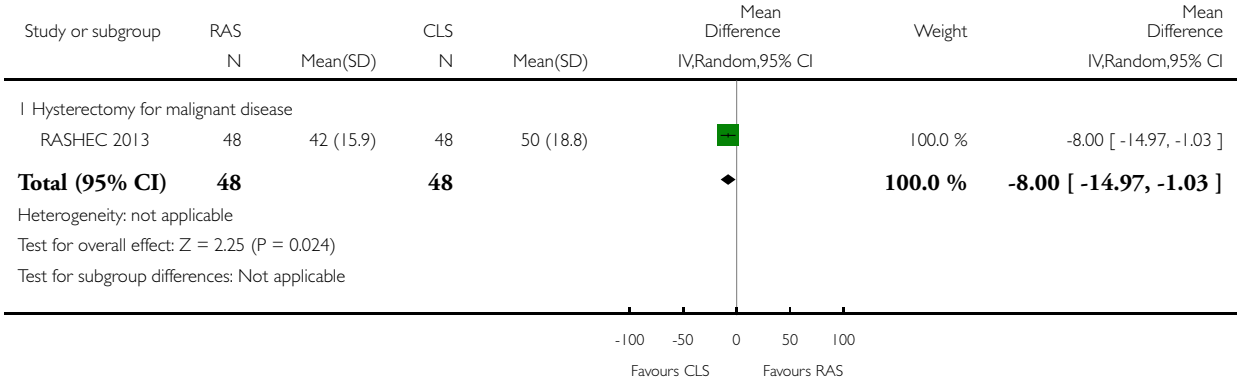
(2) Including investment cost of robot

Analysis 1.20. Comparison 1 Robot-assisted surgery versus conventional laparoscopic surgery (hysterectomy), Outcome 20 Lymph node yield.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 20 Lymph node yield

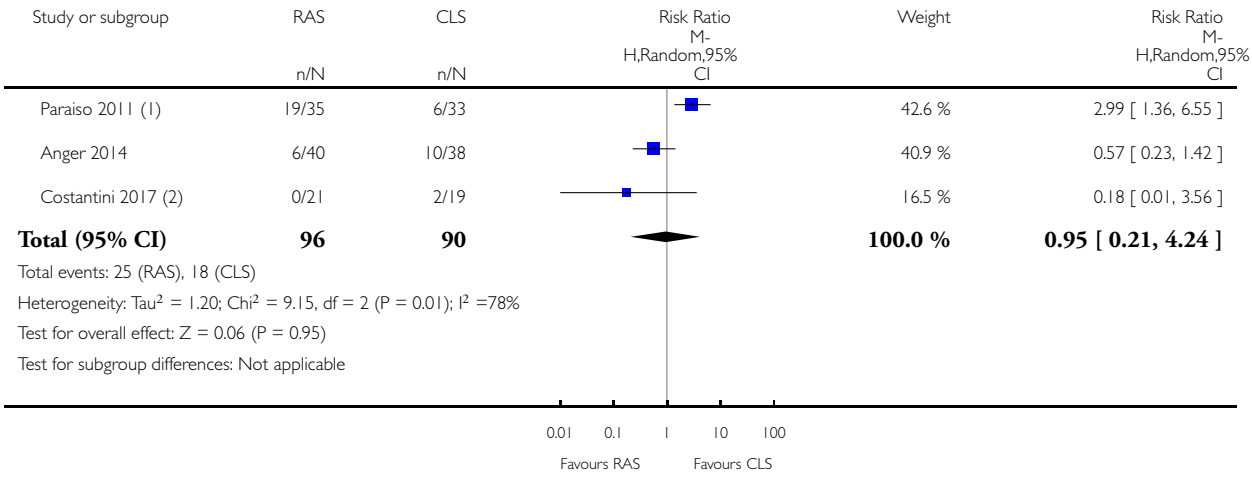


Analysis 2.1. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 1 Intraoperative and postoperative complications.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 1 Intraoperative and postoperative complications



(1) Is is unclear whether patients in this study experienced more than one complication

(2) No major complications but 2 intraoperative injuries in the CLS group

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 2 Intraoperative complications

Study or subgroup	RAS n/N	CLS n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Paraiso 2011 (1)	4/35	2/33		64.3 %	1.89 [0.37, 9.62]
Costantini 2017 (2)	0/21	2/19		35.7 %	0.18 [0.01, 3.56]
Total (95% CI)	**56**	**52**		**100.0 %**	**0.82 [0.09, 7.59]**

Total events: 4 (RAS), 4 (CLS)

Heterogeneity: $Tau^2 = 1.31$; $Chi^2 = 1.88$, df = 1 (P = 0.17); $I^2 = 47\%$

Test for overall effect: Z = 0.18 (P = 0.86)

Test for subgroup differences: Not applicable

(1) It is unclear from the report whether women experienced more than one complication

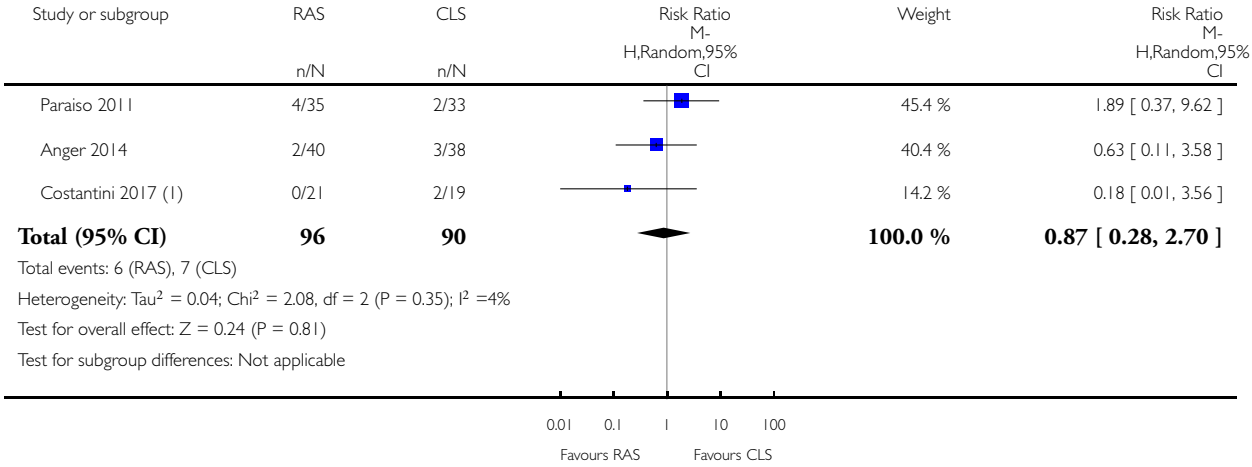
(2) 1 bladder injury and 1 mesh injury

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 3 Complications: intraoperative injury



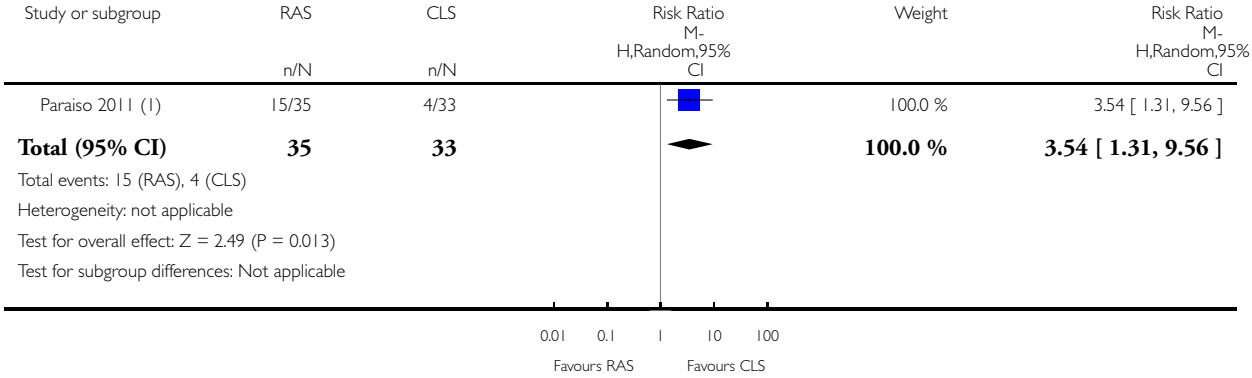
(1) 1 bladder injury and 1 mesh injury

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 4 Postoperative complications



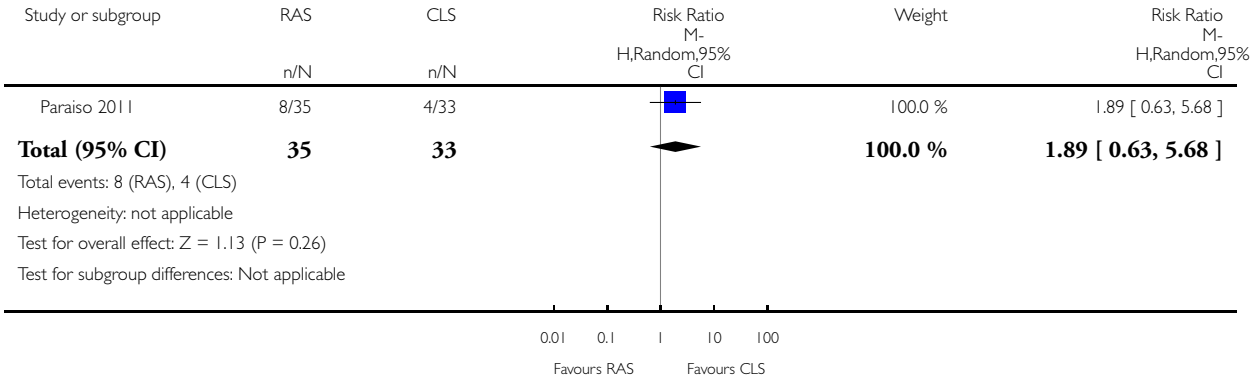
(1) UTI (5 vs 3), bowel obstruction (2 vs 0), wound infection (2 vs 0), erosion (2 vs 0), abdominal wall pain (3 vs 0) abscess (1 vs 1). Patients may have experienced more than one complication.

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

Review: Robot-assisted surgery in gynaecology

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.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 7 Total operating time

Study or subgroup	RAS N	Mean(SD)[min]	CLS N	Mean(SD)[min]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Paraiso 2011	35	265 (50)	33	199 (46)		35.7 %	66.00 [43.18, 88.82]
Anger 2014 (1)	40	202.8 (46.1)	38	178.4 (49.8)		36.8 %	24.40 [3.07, 45.73]
Costantini 2017 (2)	21	213 (55.9)	19	184 (55.9)		27.5 %	29.00 [-5.69, 63.69]
Total (95% CI)	**96**		**90**			**100.0 %**	**40.53 [12.06, 68.99]**

Heterogeneity: Tau^2 = 454.75; Chi^2 = 7.40, df = 2 (P = 0.02); I^2 =73%

Test for overall effect: Z = 2.79 (P = 0.0053)

Test for subgroup differences: Not applicable

(1) 58% of women had a concurrent hysterectomy

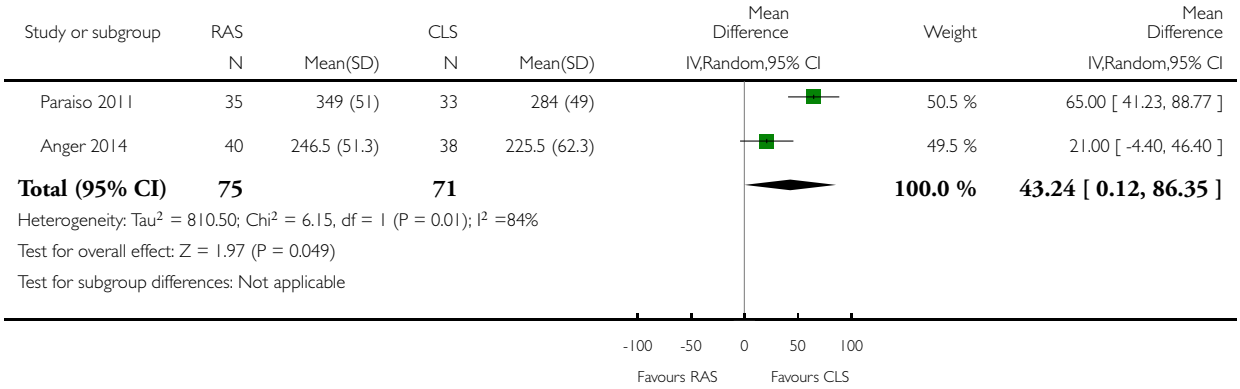
(2) SD not reported; estimated from p value

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 8 Operating room time [min]

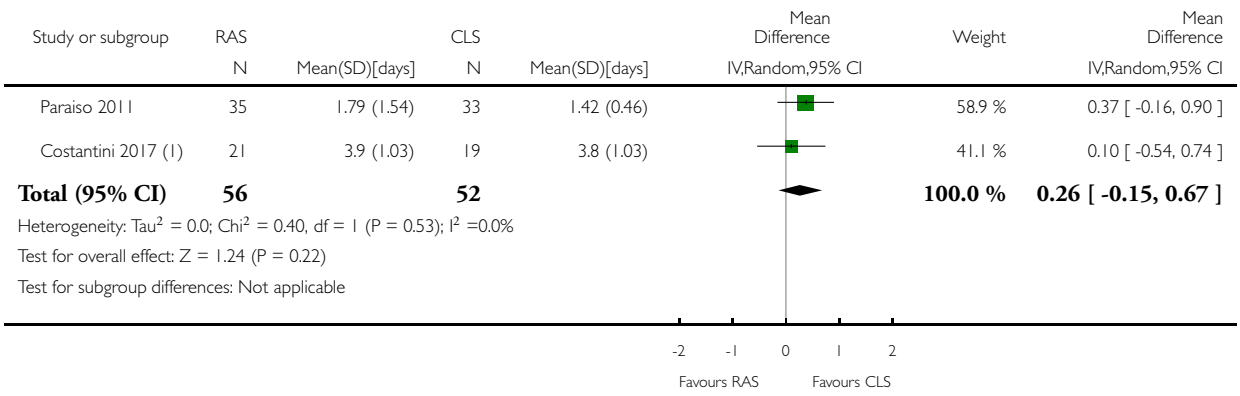


Analysis 2.9. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 9 Overall hospital stay.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 9 Overall hospital stay



(1) SD not reported; estimated from p value

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 10 Conversion to another approach

Study or subgroup	RAS n/N	CLS n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Paraiso 2011 (1)	3/35	2/33		100.0 %	1.41 [0.25, 7.94]
Total (95% CI)	**35**	**33**		**100.0 %**	**1.41 [0.25, 7.94]**
Total events: 3 (RAS), 2 (CLS)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.39 (P = 0.69)					
Test for subgroup differences: Not applicable					

(1) In RAS group, 3 conversions to laparotomy or vaginal approach, and 2 conversions to CLS due to robot malfunction

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 12 Estimated blood loss

Study or subgroup	RAS N	Mean(SD)	CLS N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Anger 2014	40	85.1 (51.9)	38	106.4 (206.9)		2.8 %	-21.30 [-89.02, 46.42]
Costantini 2017 (1)	21	32 (18.4)	19	47 (18.4)		97.2 %	-15.00 [-26.42, -3.58]
Total (95% CI)	**61**		**57**			**100.0 %**	**-15.17 [-26.43, -3.91]**

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.03$, df = 1 (P = 0.86); $I^2 = 0.0\%$

Test for overall effect: Z = 2.64 (P = 0.0083)

Test for subgroup differences: Not applicable

(1) SD not reported; estimated from p value

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 13 Pain at 1 to 2 weeks

Study or subgroup	RAS N	Mean(SD)	CLS N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Anger 2014 (1)	40	3.5 (2.1)	38	2.6 (2.2)		100.0 %	0.90 [-0.06, 1.86]
Total (95% CI)	**40**		**38**			**100.0 %**	**0.90 [-0.06, 1.86]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.85 (P = 0.065)

Test for subgroup differences: Not applicable

(1) Pain at normal activities

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

Review: Robot-assisted surgery in gynaecology

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

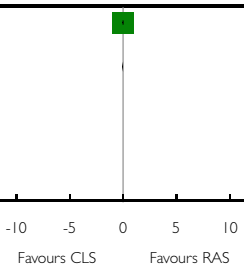
Outcome: 14 Quality of life (6 weeks)

Study or subgroup	RAS N	Mean(SD)	CLS N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Anger 2014	40	0.9 (0.1)	38	0.91 (0.11)		100.0 %	-0.01 [-0.06, 0.04]
Total (95% CI)	**40**		**38**			**100.0 %**	**-0.01 [-0.06, 0.04]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.42 (P = 0.67)

Test for subgroup differences: Not applicable



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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 16 Re-intervention

Study or subgroup	RAS n/N	CLS n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Sarlos 2010	0/47	2/48		45.2 %	0.20 [0.01, 4.14]
Anger 2014	1/40	1/38		54.8 %	0.95 [0.06, 14.65]
Total (95% CI)	**87**	**86**		**100.0 %**	**0.47 [0.06, 3.59]**

Total events: 1 (RAS), 3 (CLS)

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.56$, df = 1 (P = 0.45); $I^2 = 0.0\%$

Test for overall effect: Z = 0.72 (P = 0.47)

Test for subgroup differences: Not applicable

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 18 Overall cost

Study or subgroup	RAS N	Mean(SD)[US dollars]	CLS N	Mean(SD)[US dollars]	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Paraiso 2011	35	16278 (3326)	33	14342 (2941)			1936.00 [445.69, 3426.31]
Anger 2014	40	20898 (3386)	38	12170 (4129)			8728.00 [7047.37, 10408.63]

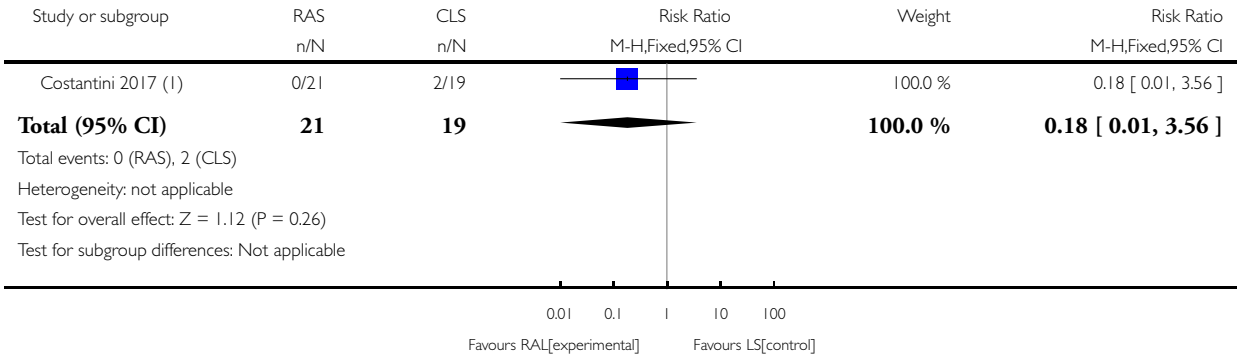
Test for subgroup differences: Not applicable

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 19 Complications: urinary incontinence



(1) 1 bladder injury and 1 mesh injury

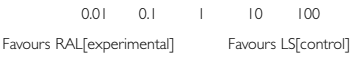
Analysis 2.20. Comparison 2 Robot-assisted surgery versus conventional laparoscopic surgery (sacrocolpopexy)), Outcome 20 Complications: sexual dysfunction.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 20 Complications: sexual dysfunction

Study or subgroup	RAS n/N	CLS n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Costantini 2017 (1)	1/21	1/19		100.0 %	0.90 [0.06, 13.48]
Total (95% CI)	**21**	**19**		**100.0 %**	**0.90 [0.06, 13.48]**
Total events: 1 (RAS), 1 (CLS)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.07 (P = 0.94)					
Test for subgroup differences: Not applicable					



(1) 1 bladder injury and 1 mesh injury

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 1 Intraoperative and postoperative complications

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
Wijk 2016	0/10	1/10		100.0 %	0.33 [0.02, 7.32]
Total (95% CI)	**10**	**10**		**100.0 %**	**0.33 [0.02, 7.32]**
Total events: 0 (RAS), 1 (Open surgery)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.70 (P = 0.49)					
Test for subgroup differences: Not applicable					

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

Review: Robot-assisted surgery in gynaecology

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

Outcome: 2 Intraoperative complications

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
Wijk 2016	0/10	0/10			Not estimable
Total (95% CI)	**10**	**10**			**Not estimable**
Total events: 0 (RAS), 0 (Open surgery)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Test for subgroup differences: Not applicable					

Analysis 3.4. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 4 Postoperative complications.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 4 Postoperative complications

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
Wijk 2016	0/10	1/10		100.0 %	0.33 [0.02, 7.32]
Total (95% CI)	**10**	**10**		**100.0 %**	**0.33 [0.02, 7.32]**

Total events: 0 (RAS), 1 (Open surgery)

Heterogeneity: not applicable

Test for overall effect: Z = 0.70 (P = 0.49)

Test for subgroup differences: Not applicable

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

Review: Robot-assisted surgery in gynaecology

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
Wijk 2016	0/10	1/10		100.0 %	0.33 [0.02, 7.32]
Total (95% CI)	**10**	**10**		**100.0 %**	**0.33 [0.02, 7.32]**

Total events: 0 (RAS), 1 (Open surgery)

Heterogeneity: not applicable

Test for overall effect: Z = 0.70 (P = 0.49)

Test for subgroup differences: Not applicable

Analysis 3.14. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 14 Quality of life (4 weeks).

Review: Robot-assisted surgery in gynaecology

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

Outcome: 14 Quality of life (4 weeks)

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
Wijk 2016 (1)	2/10	8/10		100.0 %	0.25 [0.07, 0.90]
Total (95% CI)	**10**	**10**		**100.0 %**	**0.25 [0.07, 0.90]**

Total events: 2 (RAS), 8 (Open surgery)

Heterogeneity: not applicable

Test for overall effect: Z = 2.13 (P = 0.033)

Test for subgroup differences: Not applicable

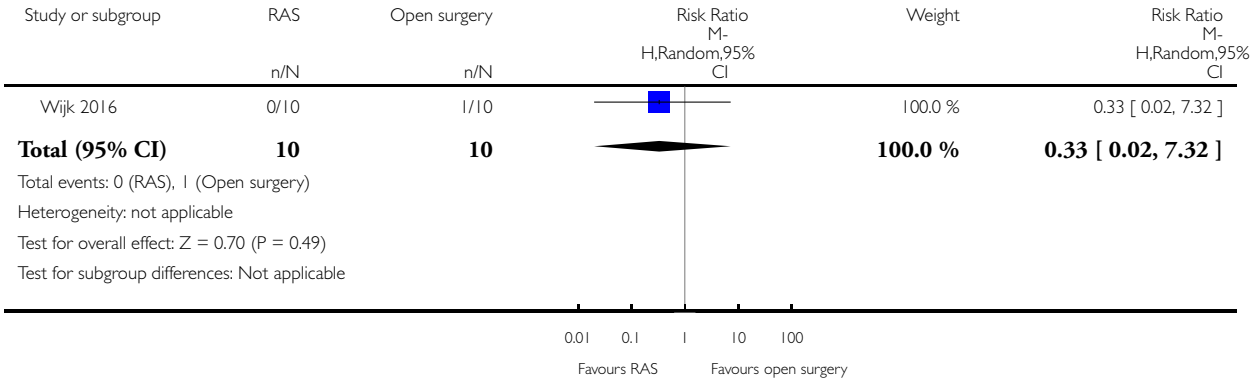
(1) Number with some restriction on WHO performance score at 4 weeks

Analysis 3.17. Comparison 3 Robot-assisted laparoscopic surgery versus open abdominal surgery (hysterectomy), Outcome 17 Re-admission.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 17 Re-admission

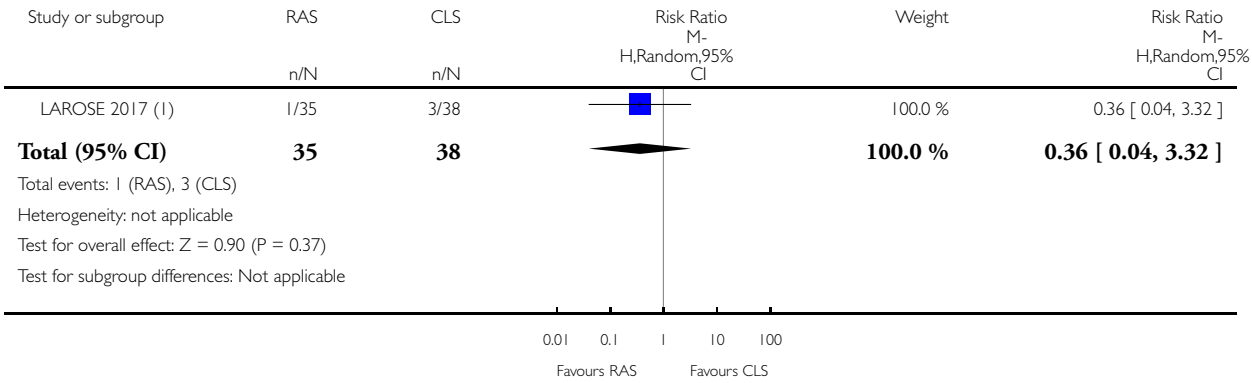


Analysis 4.2. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 2 Intraoperative complications.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 2 Intraoperative complications



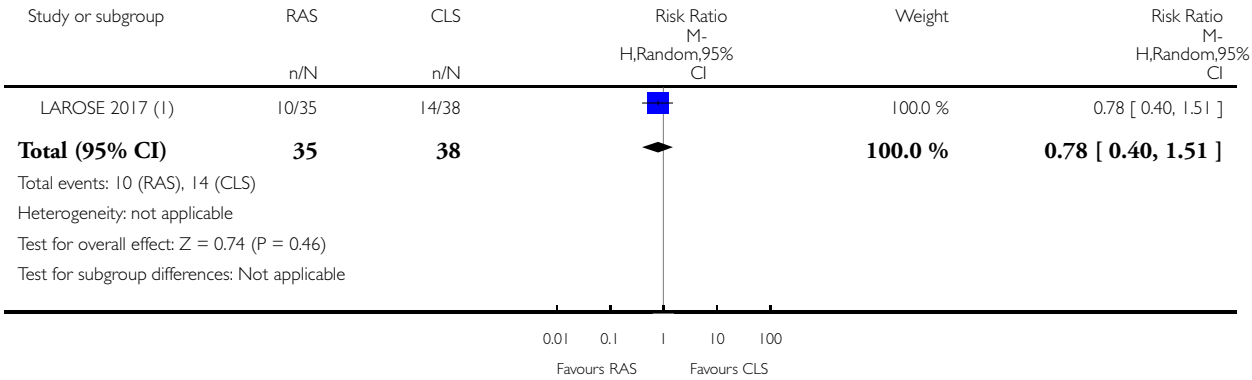
(1) Include urethral complications and bowel injury

Analysis 4.4. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 4 Postoperative complications.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 4 Postoperative complications



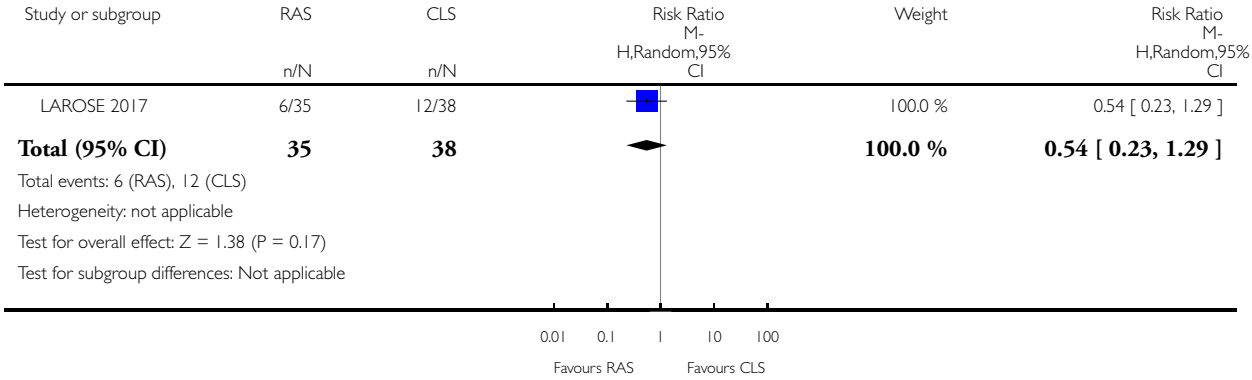
(1) It is unclear if women had more than one complication (wound infection, abscess, UTI or intractable pain)

Analysis 4.6. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 6 Complications: infection.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 6 Complications: infection

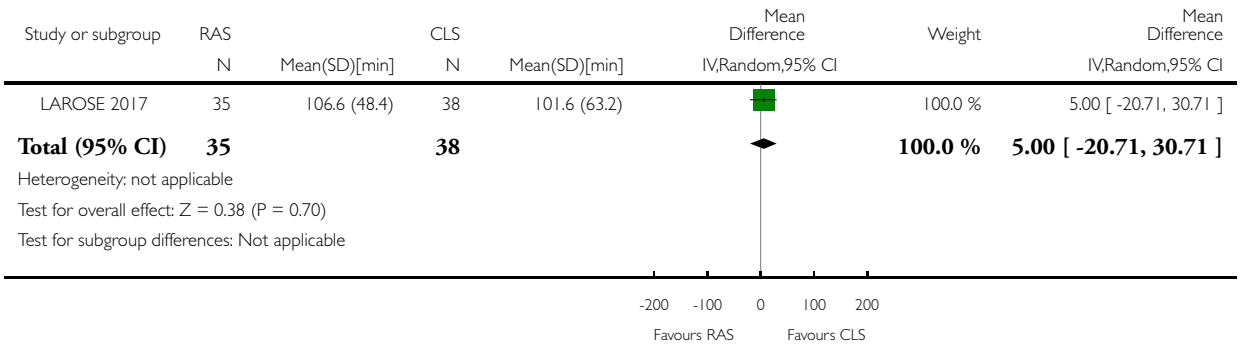


Analysis 4.7. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 7 Total operating time.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 7 Total operating time

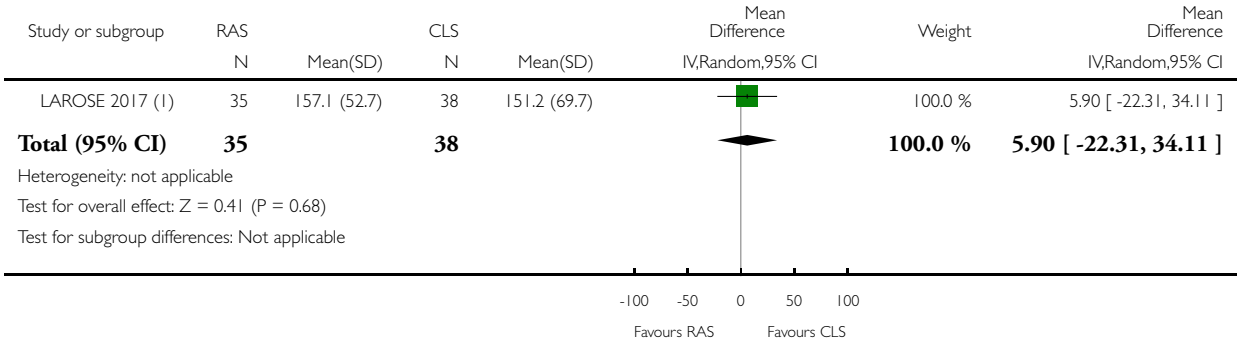


Analysis 4.8. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 8 Operating room time [min].

Review: Robot-assisted surgery in gynaecology

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

Outcome: 8 Operating room time [min]



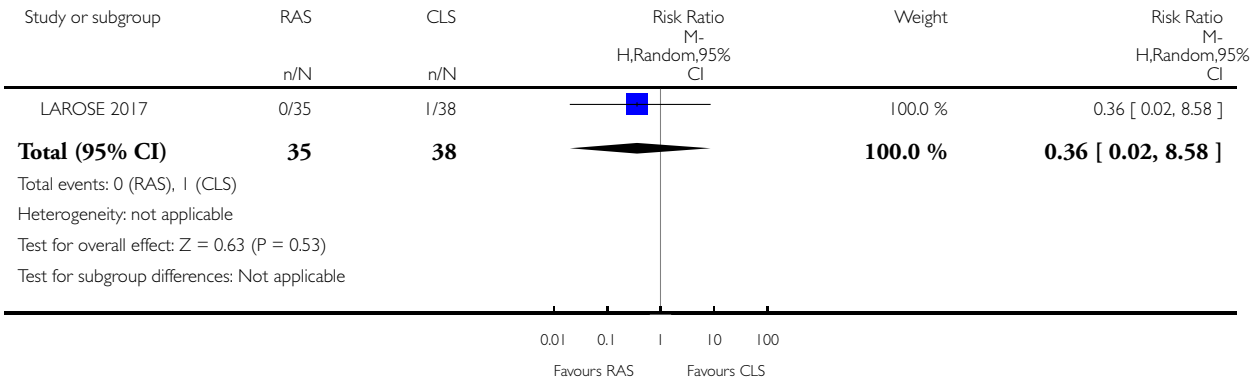
(1) Reported mean anaesthesia time

Analysis 4.11. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 11 Conversion to another approach.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 11 Conversion to another approach

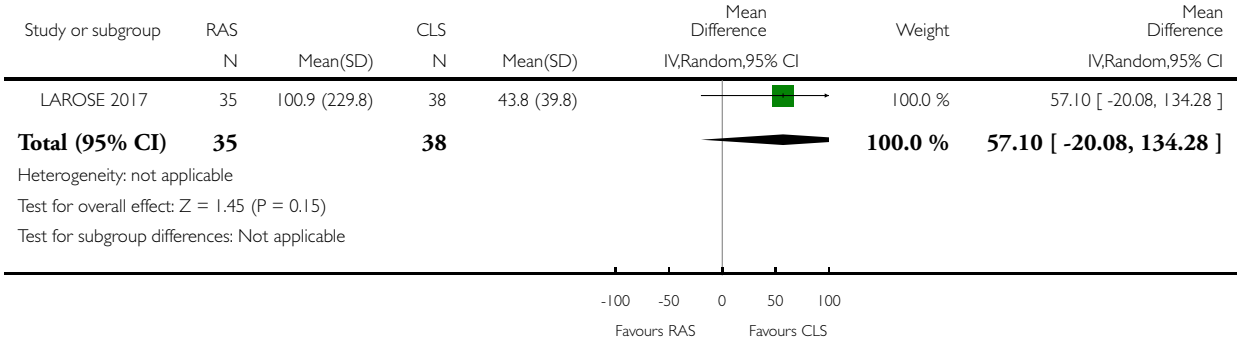


Analysis 4.12. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 12 Estimated blood loss.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 12 Estimated blood loss

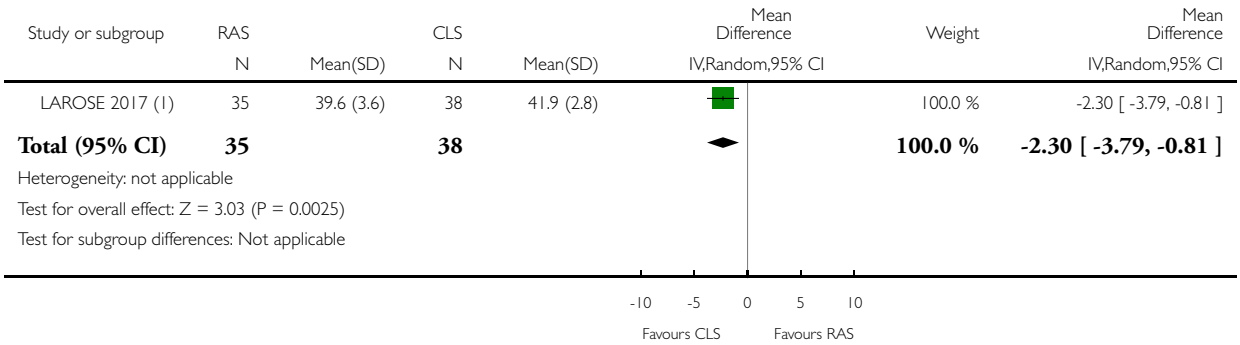


Analysis 4.14. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 14 Quality of life (6 weeks).

Review: Robot-assisted surgery in gynaecology

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

Outcome: 14 Quality of life (6 weeks)



(1) Physical Health Score at 6 weeks (CLS higher at baseline)

Analysis 4.15. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 15 Quality of life (6 months).

Review: Robot-assisted surgery in gynaecology

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

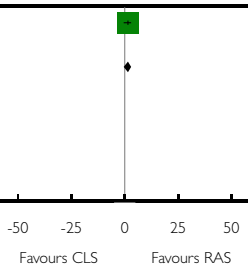
Outcome: 15 Quality of life (6 months)

Study or subgroup	RAS N	Mean(SD)	CLS N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
LAROSE 2017 (1)	35	42.4 (3.9)	38	41.1 (4.3)		100.0 %	1.30 [-0.58, 3.18]
Total (95% CI)	**35**		**38**			**100.0 %**	**1.30 [-0.58, 3.18]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.35 (P = 0.18)

Test for subgroup differences: Not applicable



(1) Physical Health Score at 6 months

Analysis 4.17. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 17 Re-admission.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 17 Re-admission

Study or subgroup	RAS n/N	CLS n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
LAROSE 2017	2/35	3/38		100.0 %	0.72 [0.13, 4.08]
Total (95% CI)	**35**	**38**		**100.0 %**	**0.72 [0.13, 4.08]**

Total events: 2 (RAS), 3 (CLS)

Heterogeneity: not applicable

Test for overall effect: Z = 0.37 (P = 0.71)

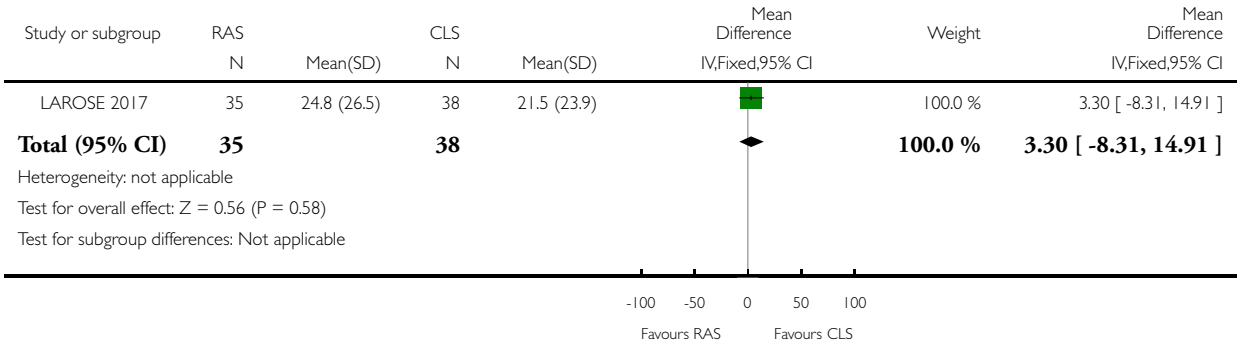
Test for subgroup differences: Not applicable

Analysis 4.19. Comparison 4 Robot-assisted surgery for endometriosis versus conventional laparoscopic surgery, Outcome 19 Pain at 6 months.

Review: Robot-assisted surgery in gynaecology

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

Outcome: 19 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 sterili?ation 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
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

HISTORY

Review first published: Issue 12, 2014

Date	Event	Description
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.

SOURCES OF SUPPORT

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]; Gynecologic Surgical Procedures [methods]; Hysterectomy [methods]; Laparoscopy; Randomized Controlled Trials as Topic; Robotic Surgical Procedures [*methods]

MeSH check words

Female; Humans