Evidence report for surgical approaches to hysterectomy for benign conditions

Prepared by EBSCO Health Innovations and EBM Development Department:

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Scoping

Prepared by EBSCO Information Services

August 9, 2019

Amended August 20, 2019

Prepared by EBSCO Health Innovations and EBM Development Department:

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Methods

Using an established, structured template that delineates key elements for scoping (i.e., the population, interventions, and key outcomes to consider), we collaboratively agreed with UKSH on the scope of the present evidence report. Initial scoping was completed on August 12, 2019, and scoping was amended on August 20, 2019 based on feedback from UKSH.

Results – Criteria Selection for Critical Appraisal

Population:

Inclusion criteria

Adult females planning to undergo hysterectomy due to benign conditions such as abnormal uterine bleeding determined to be benign in nature, uterine fibroids, or endometriosis.

Exclusion criteria

Adult females with known or suspected malignant conditions.

We will not consider condition-specific effects (e.g., considering the effects of the different surgical approaches on hysterectomy pursued for fibroids), but rather the global indication of hysterectomy for benign reasons.

Interventions and comparators:

Vaginal hysterectomy

The intervention of interest is a traditional vaginal hysterectomy (i.e., it will not include laparoscopically-assisted vaginal hysterectomy).

The comparison of interest is a non-robot-assisted total laparoscopic hysterectomy .

Non-robot-assisted total laparoscopic hysterectomy

The intervention of interest is a non-robot-assisted total laparoscopic hysterectomy, meaning all of the surgical components of the procedure are performed laparoscopically. However, upon completion of the surgery, the uterus and cervix may be removed vaginally. If a woman desires to keep her cervix, the uterus is removed through the abdomen. The use of the word "total" in "total laparoscopic hysterectomy" does not convey anything about whether the woman's cervix is removed or left in place.

The comparison of interest is a traditional vaginal hysterectomy (i.e., it will not include laparoscopically-assisted vaginal hysterectomy).

Robot-assisted laparoscopic total hysterectomy

The intervention of interest is robot-assisted total laparoscopic hysterectomy, with the robotic assistance being the key difference from a non-robot-assisted total laparoscopic hysterectomy.

The comparison of interest is a non-robot-assisted total laparoscopic hysterectomy. Please see the details under "Non-robot-assisted total laparoscopic hysterectomy" for additional information.

<u>Notes about surgical approaches to hysterectomy (and reason for not including option of abdominal hysterectomy):</u>

-As noted in a recent Cochrane review comparing surgical approaches to hysterectomy[1] and the statement from the American College of Obstetricians and Gynecologists (ACOG),[2] abdominal hysterectomy is considered a "fallback option"[1] if the uterus cannot be removed via some less invasive approach.[2] As such, we do not include abdominal hysterectomy as an option for consideration, because it would only be applicable in situations that are not sensitive to patient preference (i.e., when abdominal hysterectomy is considered the only appropriate option).

-Gynecologic surgeons will have different thresholds and preferred approaches to hysterectomy based on their specific blend of clinical expertise and experience, and certain conditions may influence or preclude choice among the specified options. For instance, the options considered feasible for an enlarged myomatous uterus will depend on the surgeon's skillset, vaginal hysterectomy is often avoided or precluded in women with confirmed or suspected endometriosis or adnexal pathology, and some gynecologists may shy away from a vaginal hysterectomy after cesarean section while others may not (based on evidence that complications are not clearly worse among women receiving vaginal hysterectomy after cesarean section and an unequivocal statement from ACOG that vaginal hysterectomy is a safe and viable option after one or more cesarean sections).[1,2] We will include a statement about this at the beginning of Parts 4, 5, and 6 of this Evidence Report, with the understanding that surgeon utilizing this Evidence Report will also incorporate clinical judgment, only using the decision aid when appropriate, and only discussing/considering with the patient those options that are considered feasible based on his/her expertise and experience in light of the patient's specific circumstance.

Outcomes:

FAQ 1: What does the treatment involve?

We will include a description of the surgical approach.

Descriptive responses are acceptable, and this does not involve systematic evidence searches, critical appraisal, or evidence synthesis.

FAQ 2: Can I keep my cervix if I want to?

Although the details of this evidence report are intended to apply to women pursuing either total or subtotal (supracervical) hysterectomy, women opting to receive a subtotal hysterectomy are often preferentially treated with either abdominal or laparoscopic approaches. Although some note preservation of the cervix is possible in vaginal hysterectomies or laparoscopically-assisted vaginal hysterectomies,[1] they also note the operation is most easily performed via an abdominal or laparoscopic approach, and ACOG also recommends an abdominal or laparoscopic approach.[2] Although this consideration also pertains to the note about treatment options above, because the choice for total versus subtotal (supracervical) hysterectomy may itself be preference-sensitive (i.e., more about patient choice than clinical indication *per se*), we will include a descriptive response to this question as FAQ 2.

FAQ 3: How long is the surgery?

The outcome of interest is the duration of the surgery.

When possible, we will assess this outcome with data from randomized, controlled trials (or systematic reviews thereof). If sufficient data from randomized trials are lacking, we will adopt or supplement with descriptive responses, which do not involve systematic evidence searches, critical appraisal, or evidence synthesis.

FAQ 4: How long is the hospital stay?

The outcome of interest is the length of hospital stay.

When possible, we will assess this outcome with data from randomized, controlled trials (or systematic reviews thereof). If sufficient data from randomized trials are lacking, we will adopt or supplement with descriptive responses, which do not involve systematic evidence searches, critical appraisal, or evidence synthesis.

FAQ 5: How long does it take to recover?

The outcome of interest is time to return to normal activities. Across multiple systematic reviews of randomized, controlled trials[1,3,4,5,6] return to normal activity or recuperation as a holistic outcome is reported in two,[1,5] and none consider return to specific activities (eg, return to work, time to return to driving, time to return to sexual activity). Therefore, evidence from randomized trials will be reported only for the general measure of return to normal activities (when available for a given comparison). Otherwise, descriptive responses are acceptable for return to normal activity (when randomized trial data are not available for a given comparison) and for return to specific types of activities, which does not involve systematic evidence searches, critical appraisal, or evidence synthesis.

FAQ 6: What are the risks?

Risks of interest will be addressed first as broad-based considerations of complications, such as intraoperative and postoperative complications or major and minor complications, based on how the data are presented in the relevant evidence sources. As permitted by the available evidence, we may consider components of these outcomes as described below, but if broad-based risk outcomes are reasonably low and if there is no clear difference demonstrated for the components shown below, we may not quantify the risks below and instead adopt a descriptive response.

Types of intraoperative visceral injuries to be considered based on the available evidence include injuries to the bladder, ureter, urinary tract (bladder or ureter), bowel, and nerves.

Types of postoperative complications to be considered based on the available evidence include infections, febrile episodes postoperatively, postoperative pain, and need for transfusion.

The long-term complication to be considered based on the available evidence include urinary or bladder dysfunction.

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[1] Aarts JW, Nieboer TE, Johnson N, Tavender E, Garry R, Mol BW, Kluivers KB. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev. 2015 Aug 12;(8):CD003677. doi: 10.1002/14651858.CD003677.pub5.

[2] American College of Obstetricians and Gynecologists. Committee Opinion: Choosing the Route of Hysterectomy for Benign Disease. Published June 2017. Accessed August 9, 2019. Available at https://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co701.pdf.

[3] Lawrie TA, Liu H, Lu D, Dowswell T, Song H, Wang L, Shi G. Robot-assisted surgery in gynaecology. Cochrane Database Syst Rev. 2019 Apr 15;4:CD011422. doi: 10.1002/14651858.CD011422.pub2.

[4] Albright BB, Witte T, Tofte AN, Chou J, Black JD, Desai VB, Erekson EA. Robotic Versus Laparoscopic Hysterectomy for Benign Disease: A Systematic Review and Meta-Analysis of Randomized Trials. J Minim Invasive Gynecol. 2016 Jan;23(1):18-27. doi: 10.1016/j.jmig.2015.08.003.

[5] Lee SH, Oh SR, Cho YJ, Han M, Park JW, Kim SJ, Yun JH, Choe SY, Choi JS, Bae JW. Comparison of vaginal hysterectomy and laparoscopic hysterectomy: a systematic review and meta-analysis. BMC Womens Health. 2019 Jun 24;19(1):83. doi: 10.1186/s12905-019-0784-4.

[6] Sandberg EM, Twijnstra ARH, Driessen SRC, Jansen FW. Total Laparoscopic Hysterectomy Versus Vaginal Hysterectomy: A Systematic Review and Meta-Analysis. J Minim Invasive Gynecol. 2017 Feb;24(2):206-217.e22. doi: 10.1016/j.jmig.2016.10.020.

Evidence report for surgical approaches to hysterectomy for benign conditions

Evidence Summary

Prepared by EBSCO Information Services

August 26, 2019

Prepared by EBSCO Health Innovations and EBM Development Department:

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Martin Mayer, DMSc, MS, PA-C, Clinical Evidence Synthesizer

Eric Manheimer, PhD, EBM Editor

Search Summary

Number of articles screened and selected

	Screened	Selected*
1st-round (DynaMed Plus)	50	4
2nd-round (Systematic review searches)	45	4
3rd-round (Study tracing)	Not applicable	
4th-round (Original article searches)	77	2
Total	*172*	*10*

* Number shown is after deduplication

	Articles selected for evaluation (Author Year)
Systematic reviews	6 (Aarts 2015, Lawrie 2019, Lee 2019, Marra 2019, Sandberg 2017, Wong 2018)
Randomized, controlled trials	0
Other article types (e.g., observational studies, guidelines)	4 (Lim 2016, Luciano 2016, Rosero 2013, Wright 2013)

Results

Gynecologic surgeons will have different thresholds and preferred approaches to hysterectomy based on their specific blend of clinical expertise and experience, and certain conditions may influence or preclude choice among the specified options. It is expected that surgeons utilizing this Evidence Report will also incorporate clinical judgment, only using the decision aid when appropriate, and only discussing/considering with the patient those options that are considered feasible based on his/her expertise and experience in light of the patient's specific circumstance.

FAQ 1: What does the treatment involve?

Vaginal hysterectomy

Descriptive Summary

The surgery will take place through an incision made in the top of the vagina. No incisions will be made on the abdomen. The surgery can be done either with the area numbed (via local or spinal anesthesia) or with the patient asleep (via general anesthesia).

Non-robot-assisted total laparoscopic hysterectomy

Descriptive Summary

A total laparoscopic hysterectomy means the entire procedure is performed laparoscopically. It does not mean anything about whether a woman's cervix is removed or left in place. In other words, some women may have heard of "total hysterectomy" (meaning the uterus and cervix are removed) and "partial hysterectomy" (meaning the uterus is removed, but the cervix is left in place), but a woman can have either a total hysterectomy or partial hysterectomy with total laparoscopic hysterectomy. The surgery will take place through small incisions made in the lower abdomen. The laparoscope will be inserted through one of these incisions, allowing the surgeon to see inside the patient's abdominopelvic cavity. Other instruments are inserted through the other incisions to carry out the surgery. Upon completion of the surgery, the uterus and cervix may be removed vaginally. However, if a woman desires to keep her cervix, the uterus is often cut into small pieces (morcellation) and these pieces are then removed through the incisions already made, but in some cases, the uterus may need to be removed through a larger incision made in the lower abdomen specifically for removal of the uterus. This surgery is usually carried out with the patient asleep (via general anesthesia).

Robot-assisted total laparoscopic hysterectomy

Descriptive Summary

The description for total laparoscopic hysterectomy applies for robot-assisted hysterectomy. The key difference is – as the name implies – that the surgery is assisted by robotic technology (e.g., the da Vinci® surgical system). This allows the surgeon to do the surgery using mechanical arms that s/he controls remotely from a computer station that is situated away from the actual operating room table.

(Aarts 2015, ACOG 2017, ACOG 2018, Cleveland Clinic 2018, Healthwise 2018, Johns Hopkins nd, Lawrie 2019, Mayo Clinic 2019, NHS 2019, NIH 2018, Stanford Health Care nd)

FAQ 2: Can I keep my cervix if I want to?

Vaginal hysterectomy

Descriptive Summary

Although preservation of the cervix may be possible via a vaginal approach, preservation of the cervix is most easily accomplished via another surgical approach (Aarts 2015), and the American College of Obstetricians and Gynecologists also recommends using another approach if preservation of the cervix is desired (ACOG 2017).

The cervix is not usually kept when a woman has a vaginal hysterectomy. If a woman wants to keep her cervix, she should talk with her surgeon about other surgical options for the hysterectomy.

Non-robot-assisted total laparoscopic hysterectomy

Descriptive Summary

Yes, a woman has the option to keep her cervix with a total laparoscopic hysterectomy without robotic assistance.

Robot-assisted total laparoscopic hysterectomy

Descriptive Summary

Yes, a woman has the option to keep her cervix with a total laparoscopic hysterectomy with robotic assistance.

(Aarts 2015, ACOG 2017)

FAQ 3: How long is the surgery?

Non-robot-assisted total laparoscopic hysterectomy vs. vaginal hysterectomy

Articles Critically Appraised:*

Certainty	Systematic reviews	Randomized trials	Other article types
High			
Moderate	Sandberg 2017, Lee 2019		
Low			
Very low			
Unusable			
Not used	Aarts 2015†		

* Sources not shown are not relevant for the outcome and/or comparison of interest.
† Not used because more complete/current data were available in the other sources listed in this table

Quantitative Evidence Review and Evidence Synthesis Synopsis:

Effects of non-robot-assisted total laparoscopic hysterectomy (TLH) vs. vaginal hysterectomy (VH) on operating time (Sandberg 2017)

No of patients (studies)	Mean duration with TLH (range)	Mean duration with VH (range)	Mean difference (95% CI)	Certainty (reason for downgrade)
415 (6)	55 to 151 minutes	50 to 100.4 minutes	35.5 minutes longer (95% CI 5.9 longer to 65.1 longer)	Moderate (imprecision)

Data from Lee 2019 were not selected for synthesis because they are the same set of trials, and Sandberg's results are somewhat more conservative (ie, broader range of results). Synthesis method was a range of sufficiently-valid results from meta-analysis already done.

Evidence Summary:

In women having hysterectomy for benign conditions, the duration of surgery may be:

- **about 1 to 1.5 hours for vaginal hysterectomy**
- **about 1 to 2.5 hours for total laparoscopic hysterectomy without robotic assistance**

Surgery may last about a half-hour longer with total laparoscopic hysterectomy without robotic assistance compared to vaginal hysterectomy, but this difference may be as little as about 5 minutes longer or as much as about an hour longer. (Moderate certainty)

Robot-assisted vs. non-robot-assisted total laparoscopic hysterectomy

Articles Critically Appraised:*

Certainty	Systematic reviews	Randomized trials	Other article types
High			
Moderate			
Low	Lawrie 2019 (trial clearly limiting to total laparoscopic hysterectomy)		
Very low	Lawrie 2019 (analysis including trials that did and did not clearly limit to total laparoscopic hysterectomy)		
Unusable			
Not used	Aarts 2015†		

* Sources not shown are not relevant for the outcome and/or comparison of interest.
† Outcome of total operating room time did not match the desired outcome of duration of surgery

Quantitative Evidence Review, Descriptive Source Consultation, and Evidence Synthesis Synopsis:

Synthesis was based on the single trial clearly limiting to total laparoscopic surgery (rather than the analysis that included trials that did and did not clearly limit to total laparoscopic surgery).

Effects of robot-assisted total laparoscopic hysterectomy (RH) vs. non-robot-assisted total laparoscopic hysterectomy (nRH) on duration of surgery (Lawrie 2019)

No of patients (studies)	Mean duration in RH group	Mean duration in nRH group	Mean difference (95% CI)	Certainty (reason for downgrade)
53 (1)	172.8 minutes	102.7 minutes	70.1 minutes longer (95% CI 28.3 minutes to 111.9 minutes)	Low (risk of bias [unclear allocation concealment], inconsistency [single trial precludes assessing replicability of findings])

Descriptive information on duration of surgery for robot-assisted hysterectomy gave estimates that are generally consistent with the above estimate.

We also repeat the range of 55 to 151 minutes (about 1 to 2.5 hours) for non-robot-assisted total laparoscopic hysterectomy (from the comparison of non-robot-assisted total laparoscopic hysterectomy vs. vaginal hysterectomy) for ease of reference.

Evidence Summary:

In women having hysterectomy for benign conditions, the duration of surgery may be:

- **about 1 to 2.5 hours for total laparoscopic hysterectomy without robotic assistance**
- **about 3 hours for total laparoscopic hysterectomy with robotic assistance**

Surgery may last about an hour longer if using robotic assistance in a total laparoscopic hysterectomy, but this difference may be as little as about a half-hour longer or as much as about 2 hours longer. (Low certainty)

FAQ 4: How long is the hospital stay?

Non-robot-assisted total laparoscopic hysterectomy vs. vaginal hysterectomy

Articles Critically Appraised:*

Certainty	Systematic reviews	Randomized trials	Other article types
High			
Moderate			
Low			
Very low	Sandberg 2017		
Unusable			
Not used			

* Sources not shown are not relevant for the outcome and/or comparison of interest.

Quantitative Evidence Review and Evidence Synthesis Synopsis:

Effects of non-robot-assisted total laparoscopic hysterectomy (TLH) vs. vaginal hysterectomy (VH) on length of hospital stay (Sandberg 2017)

No of patients (studies)	Means with TLH (range)	Means with VH (range)	Mean difference (95% CI)	Certainty (reason for downgrade)
415 (6)	1 to 4.7	1.5 to 5.4	0.3 days lower (95% CI 0.9 lower to 0.2 higher)	Very low (risk of bias [no blinding], imprecision, heterogeneity [very serious concern])

Evidence Summary:

In women having hysterectomy for benign reasons, the length of stay may be:

- **1 to 5 days for vaginal hysterectomy**
- **1 to 5 days for total laparoscopic hysterectomy without robotic assistance**

There may be no meaningful difference in length of hospital stay between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance. (Very low certainty)

Robot-assisted vs. non-robot-assisted total laparoscopic hysterectomy

Articles Critically Appraised:*

Certainty	Systematic reviews	Randomized trials	Other article types
High			
Moderate			
Low			
Very low	Lawrie 2019		
Unusable			
Not used			

* Sources not shown are not relevant for the outcome and/or comparison of interest.

Quantitative Evidence Review, Descriptive Source Consultation, and Evidence Synthesis Synopsis:

Effects of robot-assisted laparoscopic hysterectomy (RH) vs. non-robot-assisted laparoscopic hysterectomy (nRH) on length of hospital stay (Lawrie 2019)

No of patients (studies)	Mean duration of stay in RH group	Mean duration of stay in nRH group	Mean difference (95% CI)	Certainty (reason for downgrade)
95 (1)	3.3 days	3.6 days	0.30 days shorter (95% CI 1.4 days shorter to 0.8 days longer)	Very low (risk of bias [no blinding], imprecision, indirectness)

Descriptive information regarding duration of hospital stay for robot-assisted hysterectomy also indicated no difference in the duration of hospital stay between robot-assisted and non-robot-assisted hysterectomy.

The single trial informing this result failed to find a clear difference between the two surgical methods and is further limited by its indirectness for the comparison of interest (due to failure to specify whether the laparoscopic procedure was totally laparoscopic or partially laparoscopic). Consideration of this trial's results along with the results for the comparison of total laparoscopic hysterectomy versus vaginal hysterectomy suggest this trial's results are at least broadly compatible with the results for total laparoscopic hysterectomy in the comparison of total laparoscopic hysterectomy versus vaginal hysterectomy (Part 4 contains further detail). Therefore, in the bolded synthesis statement below, we include the range for total laparoscopic hysterectomy from the comparison of total laparoscopic hysterectomy versus vaginal hysterectomy (1 to 5 days) for ease of reference and also set robot-assisted total laparoscopic hysterectomy as equal to this range.

Evidence Summary:

In women having hysterectomy for benign reasons, the length of stay may be

- **1 to 5 days for total laparoscopic hysterectomy without robotic assistance**
- **1 to 5 days for total laparoscopic hysterectomy with robotic assistance**

There may be no meaningful difference in length of hospital stay when a total laparoscopic hysterectomy is done with or without robotic assistance. (Very low certainty)

FAQ 5: How long does it take to recover?

Vaginal, non-robot-assisted total laparoscopic, and robot-assisted total laparoscopic hysterectomy

Descriptive summary

Two systematic reviews report on recovery-related concepts: Aarts 2015 and Lee 2019. However, they do not present data for the comparisons of interest in this Evidence Report or present only limited data. Limited data reported does not suggest a meaningful difference in return to normal activities.

After having a hysterectomy, many women feel tired or get tired easily, and women will also have pain from the surgery. It is common for women to feel like their stomach is swollen or "puffy". It often takes 3 to 6 weeks to feel completely better, but for some women, it may take 8 weeks. Most of the pain from the surgery is usually in the first 2 weeks, and it is common to need pain medication during this time. It is common to have some mild vaginal bleeding for 2 to 6 weeks after the surgery. Beyond this initial period, ongoing vaginal bleeding can be influenced by whether the woman had a total or subtotal hysterectomy.

Women can slowly increase their activity levels each day, but they should avoid strenuous activity such as sports, jogging or running, or lifting (which may include lifting things like grocery bags or children) until cleared to do so by the health care team. This may take 3 weeks or more.

Women may need to take 2 to 4 weeks off from work, but depending on the nature of a woman's work, some women may need up to 8 weeks. Women may be able to return to driving once they can comfortably wear a seatbelt and respond to sudden traffic changes, such as needing to emergently apply the brake. The health care team will give an individualized timeframe for returning to work and driving.

Women who are sexually active are generally advised to avoid intercourse for 6 to 12 weeks after surgery. Similarly, women are generally advised to avoid putting anything like a tampon in the vagina for 4 to 12 weeks. Again, the health care team will give each patient an individualized timeframe.

(See FAQ 1 for references.)

FAQ 6: What are the risks?

Non-robot-assisted total laparoscopic hysterectomy vs. vaginal hysterectomy

Articles Critically Appraised:*

Certainty	Systematic reviews	Randomized trials	Other article types
High			
Moderate	Lee 2019†, Sandberg 2017‡		
Low	Sandberg 2017§		
Very low	Sandberg 2017¶		
Unusable			
Not used**	Aarts 2015, Lee 2019††		

* Sources not shown are not relevant for the outcome and/or comparison of interest
† For outcome Grade I complications
‡ For outcomes minor complications ('RCTs only' analysis) and postoperative pain at 24 hours (10-point VAS scale)
§ For outcome vaginal cuff dehiscence
¶ For all other outcomes from Sandberg 2017
** Parts 3 and 4 have additional detail regarding why these sources were not used at all or why they were not used for the outcomes specified
†† Overall complications and Grade II and Grade III complications

Quantitative Evidence Review and Evidence Synthesis Synopsis:

Effects of non-robot-assisted total laparoscopic hysterectomy (TLH) vs. vaginal hysterectomy (VH) on complications (Sandberg 2017)

Outcome and study designs pooled	No of patients (studies)	Odds ratio (95% CI)	TLH group event rate (%)	VH group event rate (%)	Certainty (reason for downgrade)
complications: major*					
RCTs only	433 (7)	0.85 (95% CI 0.16 to 4.56)	3.7% (8/216)	5.1% (11/217)	Very low (heterogeneity, imprecision [very serious concern])
RCTs plus cohort studies	6,423 (14)	1.49 (95% CI 0.78 to 2.85)	4.0% (104/2568)	2.3% (89/3855)	Very low (risk of bias [very serious concern - RCTs pooled with cohort studies], heterogeneity, imprecision)
complications: minor†					
RCTs only	433 (7)	0.59 (95% CI 0.30 to 1.15)	8.8% (19/216)	13.8% (30/217)	Moderate (imprecision)
RCTs plus cohort studies	2,384 (12)	0.83	4.0% (49/1228)	6.2% (72/1156)	Very low (risk of bias [very serious concern - RCTs pooled with

		(95% CI 0.53 to 1.28)			cohort studies], imprecision)
specific complications (RCTs plus cohort studies for all)					
infection‡					
local infection	1,017 (3)	0.77 (95% CI 0.19 to 3.15)	0.9% (4/449)	0.7% (4/568)	Very low (risk of bias, imprecision [very serious concern])
organ infection (all were urinary tract infection)	1,185 (5)	1.27 (95% CI 0.22 to 7.27)	1.5% (10/648)	1.5% (8/537)	Very low (risk of bias, imprecision [very serious concern])
fever (above 38 degrees Celsius)	1,538 (6)	0.91 (95% CI 0.44 to 1.87)	2.5% (21/847)	3.8% (26/691)	Very low (risk of bias, imprecision [very serious concern])
injuries§					
bowel injury	427 (1)	1.27 (95% CI 0.11 to 14.10)	0.8% (1/121)	0.7% (2/306)	Very low (risk of bias [very serious concern – based on single cohort study], imprecision [very serious concern])
urinary tract injury	2,293 (12)	0.81 (95% CI 0.34 to 1.92)	1.2% (14/1,149)	1.4% (16/1,144)	Very low (risk of bias, imprecision [very serious concern])
vaginal cuff dehiscence	4,702 (7)	**6.28 (95% CI 2.38 to 16.57)**	1.4% (24/1,740)	0.07% (2/2,962)	Low (risk of bias [very serious concern - pooled estimate driven by large cohort study])
blood transfusions	1,636 (7)	0.64 (95% CI 0.35 to 1.17)	2.4% (22/903)	4.9% (36/733)	Very low (risk of bias [very serious concern - pooled estimate driven by large cohort study], imprecision)

Statistically significant effects are bolded

* As defined by Dutch Society of Obstetrics and Gynecology. Major complications included major hemorrhage or hematoma requiring transfusion; urinary tract, bowel, or vascular injury; pulmonary embolism; major anesthesia problems; wound dehiscence (vaginal cuff dehiscence and port site hernia); and conversion to laparotomy.

† As defined by Dutch Society of Obstetrics and Gynecology. Minor complications included hemorrhage (not requiring transfusion) or hematoma (with spontaneous drainage); infection of the chest, urinary tract, wound, pelvis, other, or fever 38 degrees Celsius on any single occasion; deep vein thrombosis; and other minor complication requiring treatment (including voiding dysfunction and ileus).

‡ Infections were only reported separately per type of infection and not combined for all types of infections

§ Intraoperative visceral injuries were only reported separately per injury and not combined for all types of intraoperative injuries

Effects of non-robot-assisted total laparoscopic hysterectomy (TLH) vs. vaginal hysterectomy (VH) on postoperative pain (Sandberg 2017)

Outcome	No of patients (studies)	Mean difference (95% CI)	Certainty (reason for downgrade)
postoperative pain at 24 hours (10-point VAS scale) (RCTs only)	202 (3)	1.1 points lower (95% CI 1.7 lower to 0.4 lower)	Moderate (risk of bias [no blinding], imprecision)

Effects of vaginal hysterectomy (VH) vs. non-robot-assisted total laparoscopic hysterectomy (TLH) on Grade I complications* (Lee 2019)

Outcome	No of patients (studies)	Risk ratio (95% CI)	VH group event rate (%)	TLH group event rate (%)	Certainty (reason for downgrade)
Grade I complications*	455 (7)	1.26 (95% CI 0.84 to 1.88)	16.7% (38/227)	12.7% (29/228)	Moderate (imprecision)

* Grade I complications were fever, vault hematoma, urinary tract infection, vaginal bleeding, urinary retention, and unspecified infections.

For synthesis of complications outcomes, we sometimes pooled all the data for a given outcome when no clear difference was shown in order to make use of all available data. For instance, we did this for major and minor complications, which we explain briefly below to give examples.

For major complications, estimates come from Sandberg 2017, and because there was no clear difference demonstrated between the two surgical methods, we pooled the data together to make use of all available data. This yielded two estimates depending on whether one considered only the RCT data (19/433 = 4.4%) or the RCT and observational data (193/6,423 = 3.0%). We therefore conclude in the bolded statement below that up to 4.4% may have a major complication.

For minor complications, there were two sources that provided meaningful estimates (Sandberg 2017 and Lee 2019). Because in each source there was no clear difference demonstrated between the two surgical methods, we pooled the data together to make use of all available data. This yielded two estimates, one from Sandberg 2017 (49/433 = 11.3%) and one from Lee 2019 (67/455 = 14.7%). We therefore conclude in the bolded statement below that 11.3% to 14.7% may have a minor complication.

Evidence Summary:

Out of 1000 women having hysterectomy for benign conditions by vaginal hysterectomy or total laparoscopic hysterectomy without robotic assistance:

- **up to 44 (4.4%) may have major complications (such as an injury to an organ during the operation, needing blood, or a major problem with the anesthesia)**
    - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance for major complications.** (Very low certainty)
- **about 113 to 147 (11.3% to 14.7%) may have minor complications (such as bleeding that does not result in needing blood, a collection of blood near the surgery site, fever, temporary difficulty urinating that may require temporary placement of a catheter, or bladder infection)**

    - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance for minor complications.** (Very low certainty)
- **injuries to organs during operation**
    - **about 7 to 8 (0.7% to 0.8%) may have injury to bowel**
    - **about 13 (1.3%) may have injury to ureter and/or bladder**
        - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance for injuries to bowel, bladder, or ureter during the surgery.** (Very low certainty)
- **infections after surgery**
    - **about 8 (0.8%) may have an infection near the site of the surgery**
    - **about 15 (1.5%) may have a urinary tract infection**
        - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance for local infections or urinary tract infections.** (Very low certainty)
- **about 31 (3.1%) may have fever**
    - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance for fever.** (Very low certainty)
- **about 35 (3.5%) may need to get blood**
    - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance on need for transfusion.** (Very low certainty)

Out of 1000 women having total laparoscopic hysterectomy without robotic assistance for benign conditions, the area where the vagina was cut to do the surgery may separate in about 4 (0.4%). (Low certainty) **This risk does not apply if a woman chooses to keep her cervix, but the choice to remove or keep the cervix involves more than considering just this risk (see Evidence Report on total versus subtotal hysterectomy for benign reasons).**

Out of 1000 women having vaginal hysterectomy for benign conditions, the area where the vagina was cut to do the surgery may separate in less than 1 (<0.1%). (Low certainty)

Women having total laparoscopic hysterectomy without robotic assistance may have slightly less postoperative pain at 24 hours (about 1-point decrease in pain on 10-point scale) compared to women having vaginal hysterectomy. (Moderate certainty)

Robot-assisted vs. non-robot-assisted total laparoscopic hysterectomy

Articles Critically Appraised:*

Certainty	Systematic reviews	Randomized trials	Other article types
High			
Moderate			
Low			
Very low	Lawrie 2019†, Marra 2019		Luciano 2016‡, Rosero 2013§, Wright 2013¶
Unusable			
Not used**	Aarts 2015, Lawrie 2019††		Lim 2016, Luciano 2016‡‡, Rosero 2013§§, Wright 2013¶¶

* Sources not shown are not relevant for the outcome and/or comparison of interest.
† For outcomes infectious complication and blood transfusion
‡ For outcomes blood transfusion and wound complication
§ For outcomes blood transfusion, fever, urinary tract infection, and surgical complications
¶ For outcome blood transfusion, surgical site complications, and medical complications
** Parts 3 and 4 have additional detail regarding why these sources were not used at all or why they were not used for the outcomes specified
†† Outcomes intra- and post-operative complications, intraoperative injury, and pain at 1 to 2 weeks
‡‡ Outcomes infection and overall and major complications
§§ Outcomes any complication or postoperative medical complication
¶¶ Outcomes any complication and intraoperative complications

Quantitative Evidence Review and Evidence Synthesis Synopsis:

Effects of robot-assisted laparoscopic hysterectomy (RH) vs. non-robot-assisted laparoscopic hysterectomy (nRH) on need for transfusion*

Source	Relative risk (95% CI)	Certainty (reason for downgrade)
Lawrie 2019	1.94 (95% CI 0.30 to 12.76)	Very low (risk of bias [no blinding in all but 1 trial and unclear allocation concealment in 1 trial with blinding], imprecision [very serious concern], indirectness)
Luciano 2016	0.91 (95% CI 0.82 to 1.02)	Very low (risk of bias [very serious concern; observational data], imprecision, indirectness)
Rosero 2013	0.67 (95% CI 0.55 to 0.82)	Very low (risk of bias [very serious concern; observational data], indirectness)
Wright 2013	0.80 (95% CI 0.55 to 1.16)	Very low (risk of bias [observational data], imprecision, indirectness)

* Lawrie 2019's results are from 3 trials. The others are single observational studies.

Meta-analysis of the above results (with consideration of different meta-analytic models) gives an estimated relative risk of 0.80, with a lower and upper bound of the 95% CI of about 0.65 to 1.0, respectively (see Part 4 for details). Given the Very low certainty, we favor presenting the estimate for robot-assisted total laparoscopic hysterectomy as being similar to vaginal hysterectomy or non-robot-assisted total laparoscopic hysterectomy or possibly "somewhat lower" without explicit quantification of the degree by which it might be lower.

Effects of robot-assisted laparoscopic hysterectomy (RH) vs. non-robot-assisted laparoscopic hysterectomy (nRH) on infectious complications

Source (No studies and study type)	Relative risk (95% CI)	Certainty (reason for downgrade)
Marra 2019 (16 observational studies)	1.09 (95% CI 0.71 to 1.66)	Very low (risk of bias [very serious concern; observational data], imprecision, inconsistency, and indirectness)

Effects of robot-assisted laparoscopic hysterectomy (RH) vs. non-robot-assisted laparoscopic hysterectomy (nRH) on fever

Source	Risk in RH group	Risk in nRH group	Relative risk (95% CI)	Certainty (reason for downgrade)
Rosero 2013	20/7788 (0.2%)	14/7788 (0.2%)	1.4 (95% CI 0.72 to 2.82)	Very low (risk of bias [very serious concern; observational data], imprecision, indirectness)

Effects of robot-assisted laparoscopic hysterectomy (RH) vs. non-robot-assisted laparoscopic hysterectomy (nRH) on urinary tract infection

Source	Risk in RH group	Risk in nRH group	Relative risk (95% CI)	Certainty (reason for downgrade)
Rosero 2013	48/7788 (0.6%)	65/7788 (0.8%)	0.7 (95% CI 0.50 to 1.07)	Very low (risk of bias [very serious concern; observational data], imprecision, indirectness)

For the above 3 outcomes, we adopted a synthesis approach of qualitative description without quantitative description (see Part 4 for details).

Descriptive Evidence Review and Evidence Synthesis Synopsis:

Evidence is either too limited for other risks or does not demonstrate a clear difference between robot-assisted laparoscopic hysterectomy and non-robot-assisted laparoscopic hysterectomy. We adopt a qualitative approach to describe these findings but do not give any quantification for other risks.

Evidence Summary:

Women who have a total laparoscopic hysterectomy with robotic assistance may have the same chance or a slightly lower chance of needing blood compared to women who have a total laparoscopic hysterectomy without robotic assistance. (Very low certainty)

There may be no meaningful difference in the risk of getting a fever or infection when a total laparoscopic hysterectomy is done with or without robotic assistance. (Very low certainty)

Evidence for other risks is either too limited for us to know how total laparoscopic hysterectomy with robotic assistance compares to total laparoscopic hysterectomy without robot assistance or does not show any clear difference between the two. (Very low certainty)

Evidence report for surgical approaches to hysterectomy for benign conditions

Search and Selection

Prepared by EBSCO Information Services

August 15, 2019

Prepared by EBSCO Health Innovations and EBM Development Department:

Brian S. Alper, MD, MSPH, FAAFP, Vice President

Martin Mayer, DMSc, MS, PA-C, Clinical Evidence Synthesizer

Eric Manheimer, PhD, EBM Editor

Methods

First-round searching will consist of searching DynaMed Plus summaries pertinent to the topic. The search starts with DynaMed Plus because DynaMed Plus content is based on a thorough, systematic search and active literature surveillance system.

> Systematic literature surveillance (SLS) has been a cornerstone of creating DynaMed content since its inception. Currently, the SLS team works closely with members of McMaster University's Department of Health Research Methods, Evidence, and Impact to define and refine optimal search strategies, utilizing search terms for methodology and for clinical concepts (especially diagnosis and treatment) for each journal. These filters for PubMed searches are derived from PubMed Clinical Queries, McMaster University Hedges system, and DynaMed search filters and were found to capture >95% of relevant valid articles for use in DynaMed.[1]
> [1]Alper BS, Iorio A. Optimising search filters for active literature surveillance: a concordance study. Global Evidence Summit. Cape Town, South Africa; September 2017.
>
> The SLS team, in collaboration with McMaster University, continually evaluates and improves these filters to keep abreast of the ever-changing medical literature landscape. PubMed searches are performed daily. Each article is assessed by an external screener for clinical relevance, then reviewed by internal staff for both clinical relevance and validity. Any disagreements are settled by the Deputy Editor of the SLS team.
> In addition, the SLS team continually monitors the Journal source list against the list of journals catalogued in MEDLINE and existing DynaMed content to determine the set of journals that provide the highest yield for valid, clinically relevant content. As of November 2018, 507 Journals are systematically searched (see http://dynamed.com/home/content/content-sources). The journal selection threshold leads to routine adjustments to the number of journals selected.

Second-round searching will involve PubMed/MEDLINE® searches for intervention-specific systematic reviews or guidelines that involve a systematic review that are more recent than those identified in first-round searching.

Third-round searching will involve original study tracing from systematic reviews, guidelines or other relevant sources. This may be done to identify additional evidence sources if the results from the first two rounds of searching are insufficient.

Fourth-round searching will involve searches for original evidence reports. Such searching will be limited to areas considered insufficiently addressed by earlier searches, such as focused concepts published after search dates in systematic reviews.

Additional selective searching, such as tracing citations from articles found or seeking related articles, may be done for additional concepts discovered.

Additional evidence updates may also be added continuously from feedback from any source.

FAQ Summary

Results

First-round searching – DynaMed Plus:

DynaMed Plus subsection	Number of article citations	Number of unique references included
Hysterectomy topic, Surgical Approaches section, Comparison of approaches subsection, Benign indications subsection	16	4 (Aarts 2015, Lawrie 2019, Rosero 2013, Wright 2013)
Hysterectomy topic, Surgical Approaches section, Complications and Management subsection, Infectious complications subsection	6	0
Hysterectomy topic, Surgical Approaches section, Complications and Management subsection, Bleeding complications subsection	5	0
Hysterectomy topic, Surgical Approaches section, Complications and Management subsection, Nerve injury subsection	1	0
Hysterectomy topic, Surgical Approaches section, Complications and Management subsection, Genitourinary and gastrointestinal tract injuries subsection	22	0

Second-round searching – searches for intervention-specific systematic reviews:

Database	Search string	Number of search results	Number of references included
PubMed August 15, 2019	robot-assisted[tiab] OR robotically-assisted[tiab] OR robotic-assisted[tiab] OR robot* assisted[tiab] OR da Vinci OR vaginal*[tiab] OR laparoscop*[tiab] OR keyhole[tiab] AND hysterectomy[tiab] AND benign AND (systematic[sb] OR meta-analysis[ti])	45	6 (Aarts 2015*, Lawrie 2019*, Lee 2019, Marra 2019, Sandberg 2017, Wong 2018)

* Already captured in first-round searching

Third-round searching – study tracing from systematic reviews:

Source	Tracing	Number of search results	Number of references included
Not applicable			

Fourth-round searching – searches for original evidence reports:

Database	Search string	Number of search results	Number of references included
PubMed August 16, 2019	robot-assisted[tiab] OR robotically-assisted[tiab] OR robotic-assisted[tiab] OR robot* assisted[tiab] OR da Vinci OR vaginal*[tiab] OR laparoscop*[tiab] OR keyhole[tiab] AND hysterectomy[tiab] AND benign AND (database[tiab] OR registry[tiab]) AND ("2015/01/01"[PDAT] : "3000/12/31"[PDAT])	77	2 (Lim 2016, Luciano 2016)

Search summary:

Number of articles screened and selected

	Screened	Selected*
1st-round (DynaMed Plus)	50	4
2nd-round (Systematic review searches)	45	4
3rd-round (Study tracing)	Not applicable	
4th-round (Original article searches)	77	2
Total	*172*	*10*

* Number shown is after deduplication

	Articles selected for evaluation (Author Year)
Systematic reviews	6 (Aarts 2015, Lawrie 2019, Lee 2019, Marra 2019, Sandberg 2017, Wong 2018)
Randomized, controlled trials	0
Other article types (e.g., observational studies, guidelines)	4 (Lim 2016, Luciano 2016, Rosero 2013, Wright 2013)

Evidence report for surgical approaches to hysterectomy for benign conditions

Critical Appraisal

Prepared by EBSCO Information Services

August 19, 2019

Prepared by EBSCO Health Innovations and EBM Development Department:

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Martin Mayer, DMSc, MS, PA-C, Clinical Evidence Synthesizer

Eric Manheimer, PhD, EBM Editor

Methods

For each study selected for critical appraisal, we assessed for criteria needed for Level 1 [likely reliable] evidence ratings in DynaMed's Levels of Evidence criteria in which evidence quality is labeled in 1 of 3 levels:

- **(level 1 [likely reliable] evidence)** for studies with clinical outcomes and minimal risk of bias;
- **(level 2 [mid-level] evidence)** for studies with clinical outcomes and significant methodological or statistical limitations; and
- **(level 3 [lacking direct] evidence)** for reports that do not include scientific analysis of clinical outcomes or for study types that do not include comparisons between groups.

The specific concepts we critically assessed are fully mapped to cover all the criteria used in GRADE. We summarized key concerns identified that reduce the certainty of evidence in categories used for GRADE methods (i.e., risks of bias, indirectness, imprecision, inconsistency, and other considerations if relevant). In the study-level summaries inconsistency assessment was applied to consistency of within-study results – this applies to consistency across related outcomes for both original studies and for systematic reviews, and also applies to consistency across studies when applied to systematic reviews.

FAQ Summary

FAQ 1: What does the treatment involve?

FAQ 2: Can I keep my cervix if I want to?

FAQ 3: How long is the surgery?

FAQ 4: How long is the hospital stay?

FAQ 5: How long does it take to recover?

FAQ6: What are the risks?

Results

Background and context

In our search, selection, and critical appraisal of the available evidence, we identified a common frame that helps contextualize the efforts of this Evidence Report. Reliable systematic reviews are available for the comparison of total laparoscopic hysterectomy vs. vaginal hysterectomy (eg, Aarts 2015, Lee 2019, Sandberg 2017). However, comparative data for robot-assisted total laparoscopic hysterectomy vs. non-robot-assisted total laparoscopic hysterectomy are much more limited, because it was uncommon for the evidence sources to clearly limit to total laparoscopic hysterectomy, even when considering individual studies aggregated by available systematic reviews. Additionally, even the 2019 Cochrane review by Lawrie and colleagues (which includes the comparison of robot-assisted laparoscopic hysterectomy vs. laparoscopic hysterectomy) has serious or very serious imprecision in all complication/risk outcomes, precluding meaningful comparison of these surgical approaches for these outcomes. We have reliable data for risks/complications with total laparoscopic hysterectomy from the comparative evidence for total laparoscopic hysterectomy vs. vaginal hysterectomy (eg, Sandberg 2017), so in many of the evidence sources, we focused efforts on obtaining the best-available univariate estimates of risks associated with robot-assisted hysterectomy (especially because no evidence source clearly limited to total laparoscopic hysterectomy). However, comparing univariate estimates for the robot-assisted hysterectomy group to the total laparoscopic hysterectomy group (from the comparative evidence for total laparoscopic hysterectomy vs. vaginal hysterectomy) ultimately amounts to an indirect comparison across groups (and the groups may be importantly different). Our reconciliation of this obstacle is addressed further in Part 4.

Characteristics and Results of Critically Appraised Studies/Sources

Below is a template for study summaries. At each major level, the intended content is a high-level statement (e.g., "Systematic review and meta-analysis of randomized controlled trials" for the item "Study design"). If there is a need to indicate additional relevant information, do so with a sub-bullet under the parent item. For instance, if downgrading once for "Risk of bias", one would comment "Serious concern" for the "Risk of bias" domain, and then using sub-bullets under the "Risk of bias" item, one would comment on the limitations that resulted in the serious concern. A template is included below, followed by an example summary.

AARTS 2015

Aarts JW, Nieboer TE, Johnson N, Tavender E, Garry R, Mol BW, Kluivers KB. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev. 2015 Aug 12;(8):CD003677.pub5 PubMed

Relevant to FAQ3, FAQ4, FAQ5, FAQ6

- **Study design:** systematic review of randomized trials
- **Population:** women having hysterectomy for benign gynecological conditions
- **Intervention:** traditional vaginal hysterectomy, non-robot-assisted laparoscopic modality, robot-assisted laparoscopic hysterectomy, abdominal hysterectomy
    - the relevant comparisons in this Cochrane review are the following:
        - non-robot-assisted total laparoscopic hysterectomy vs. traditional vaginal hysterectomy

        - robot-assisted laparoscopic hysterectomy vs. non-robot-assisted laparoscopic modality
- **Comparison:** different surgical approaches to hysterectomy were compared with one another and all interventions evaluated are listed above under 'Intervention'

- **Study inclusion criteria:** no additional relevant

- **Number of studies:** 47
    - There were 47 trials in total, but only 6 are of relevance for this Evidence Report:
        - 4 trials totaling 225 randomized patients comparing total laparoscopic hysterectomy to vaginal hysterectomy
        - 2 trials totaling 152 randomized patients comparing robot-assisted hysterectomy to laparoscopic hysterectomy
- **Number of participants:** 5,102
    - There were 5,102 patients in total, but only 377 patients contributed to comparisons of relevance for this Evidence Report (see details above)
- **Duration of follow-up:** > 2 years
    - the only relevant long-term complication reported appears to be long-term urinary dysfunction (Analysis 1.4.1); the analysis for this complication included only 1 trial (Ottosen 2000) with duration of 2 years and 5 months, and investigating a non-relevant comparison (vaginal vs. abdominal hysterectomy)
- **Results and certainty:**

This review has 2 key comparisons of interest, presented separately below:

TOTAL LAPAROSCOPIC HYSTERECTOMY VS. TRADITIONAL VAGINAL HYSTERECTOMY

Effects of total laparoscopic hysterectomy vs. traditional vaginal hysterectomy on duration of surgery, length of hospital stay, and return to normal activities

Outcome	No of patients (studies)	Mean difference (95% CI)	Certainty (reason for downgrade)
duration of surgery (minutes)*	60 (1)	17.3 higher (95% CI 3.3 higher to 31.3 higher)	Low (imprecision, inconsistency [single trial precludes assessment of replicability of findings])
length of hospital stay (days)†	60 (1)	0.5 days lower (95% CI 2.4 lower to 1.4 higher)	Very low (risk of bias [no blinding], imprecision, inconsistency [single trial precludes assessment of replicability of findings])

* 1 additional trial (Ribeiro 2003 [n = 40]) that compared TLH vs. VH and reported duration of surgery as an outcome was included in the Cochrane review, but the Cochrane reported this outcome with only descriptive results with no forest plot (Analysis 3.23). This trial reported a higher duration of surgery in TLH group (119 minutes vs. 78 minutes) although no measure of spread or p-value was reported. This is consistent with the results of the trial included in the forest plot (Analysis 3.9.3; Candiani 2009).

† 1 additional trial (Roy 2011 [n = 60]) that compared TLH vs. VH and reported length of hospital stay as an outcome was included in the Cochrane review, but the Cochrane reported this outcome with only descriptive results with no forest plot (Analysis 3.24). This trial reported a similar length of stay in TLH group (median 2 days in both groups) with no significant difference between groups (p = 0.15). This is consistent with the results of the trial included in the forest plot (Analysis 3.20.3; Candiani 2009).

Effects of total laparoscopic hysterectomy vs. traditional vaginal hysterectomy on complications

Outcome	No of patients (studies)	Odds ratio (95% CI)	Control group event rate (%)	Certainty (reason for downgrade)
intraoperative visceral injuries*				
ureter injury	45 (1)	not estimable (0 events in both groups)	0% (0/15)	Very low (imprecision [very serious concern], risk of bias [no blinding])
bladder injury	85 (2)	0.32 (95% CI 0.01 to 8.26)	2.9% (1/35)	Very low (imprecision [very serious concern], risk of bias [no blinding])
urinary tract (bladder or ureter) injury	85 (2)	0.32 (95% CI 0.01 to 8.26)	2.9% (1/35)	Very low (imprecision [very serious concern], risk of bias [no blinding])
bowel injury†	90 (1)	not estimable (0 events in both groups)	0% (0/30)	Very low (imprecision [very serious concern], risk of bias [no blinding])
postoperative complications				
infections‡				
wound/abdominal wall infection	45 (1)	not estimable (0 events in both groups)	0% (0/15)	Very low (imprecision [very serious concern], risk of bias [no blinding])
urinary tract infection	45 (1)	2.72 (95% CI 0.12 to 60.29)	0% (0/15)	Very low (imprecision [very serious concern], risk of bias [no blinding])
febrile episodes or unspecified infection	121 (2)	0.33 (95% CI 0.06 to 1.74)	7.5% (4/53)	Very low (imprecision [very serious concern], risk of bias [no blinding in either trial])
need for transfusion	45 (1)	1.58 (95% CI 0.06 to 41.03)	0% (0/15)	Very low (imprecision [very serious concern], risk of bias [no blinding])

* These outcomes were only reported separately per injury and not combined for all types of intraoperative injuries

† The only trial that reported this outcome (Roy 2011) is a three-armed trial with 90 patients comparing total laparoscopic hysterectomy (TLH) vs. laparoscopically-assisted vaginal hysterectomy vs. vaginal hysterectomy (VH). Other analyses that include this trial indicate 30 in TLH group and 15 in VH group, which suggests the VH group was split for comparing it as a control vs. each of the two types of laparoscopic hysterectomy. Therefore, it appears there may be a mistake and that 'No of patients (studies)' should be "45 (1)" and "Control group event rate %" should be "0/15" when considering the TLH vs. VH comparison specifically.

‡ Infections were only reported separately per type of infection and not combined for all types of infections.

ROBOT-ASSISTED LAPAROSCOPIC HYSTERECTOMY VS. NON-ROBOT-ASSISTED LAPAROSCOPIC MODALITY

Effects of robot-assisted laparoscopic hysterectomy vs. non-robot-assisted laparoscopic modality on total time in the operating room and return to normal activities

Outcome	No of patients (studies)	Range in robot-assisted group (unless stated otherwise)	Range in conventional laparoscopic surgery group (unless stated otherwise)	Mean difference (95% CI)	Certainty (reason for downgrade)
total time in the operating room (minutes); trials not limited to total laparoscopic surgery	152 (2)	106 to 246 minutes	75 to 172 minutes	44.1 minutes higher (95% CI 5.3 higher to 82.9 higher)	Very low ([unclear allocation concealment in 1 trial, which more strongly favored non-robot-assisted laparoscopic surgery and influenced pooled estimate], imprecision, indirectness [very serious concern; not limited to total laparoscopic surgery, and mismatch between outcome and duration of surgery])
total time in the operating room (minutes); single trial limited to total laparoscopic surgery*	52 (1)	246 minutes (range not applicable; SD 117 minutes)	172 minutes (range not applicable; SD 76 minutes)	74 minutes longer (95% CI 20.4 minutes to 127.6 minutes longer)	Very low (risk of bias [unclear allocation concealment], inconsistency [single trial precludes assessing replicability of findings], and indirectness [mismatch between outcome and duration of surgery])
return to normal activities (days)	100 (1)	28.8 (15.9) (mean [SD])	31.2 (15.4) (mean [SD])	2.4 days lower (95% CI 8.5 days lower to 3.7 days higher)†	Very low (imprecision [very serious concern], risk of bias [no blinding], indirectness)

* This analysis was not reported directly in the systematic review. It was extracted from the study results reported in the forest plot for total time in the operating room.
† One additional trial (Paraiso 2013 [n = 52]) reported only descriptive results (Analysis 4.5) and found a consistent result of no significant difference between groups (p = 0.25). It also found most returned to normal activities within 6 weeks.

Effects of robot-assisted laparoscopic hysterectomy vs. non-robot-assisted laparoscopic modality on intraoperative visceral injury and wound-related outcomes

Outcome	No of patients (studies)	Odds ratio (95% CI)	Control group event rate (%)	Certainty (reason for downgrade)
intraoperative visceral injuries				
ureter injury	100 (1)	0.33 (95% CI 0.01 to 8.21)	2% (1/50)	Very low (imprecision [very serious concern], risk of bias [no blinding], indirectness)
wound-related outcomes				
wound/abdominal wall infection	100 (1)	0.33 (95% CI 0.01 to 8.21)	2% (1/50)	Very low (imprecision [very serious concern], risk of bias [no blinding], indirectness)
wound dehiscence	100 (1)	0.33 (95% CI 0.01 to 8.21)	2% (1/50)	Very low (imprecision [very serious concern], risk of bias [no blinding], indirectness)

- **Other considerations:** The following outcomes were not carried forward to Part 4 (with reason[s] stated):
  - For comparison of total laparoscopic hysterectomy vs. vaginal hysterectomy
    - Duration of surgery and length of hospital stay were not progressed to Part 4 due to having less complete/current data compared to the Sandberg 2017 and Lee 2019 systematic reviews
    - None of the complications reported in Aarts 2015 for the comparison of total laparoscopic hysterectomy vs. vaginal hysterectomy were progressed to Part 4. Each was based on very limited and imprecise data (with 'very serious concern' about imprecision for each). These complications were all reported in Sandberg 2017 and with more complete (and current) data, with one exception. The only exception is wound/abdominal wall infection which was reported in Aarts 2015 (in 1 trial with 45 patients and 0 events) but not Sandberg 2017 (or Lee 2019). However, for our infection outcome, we used the Sandberg 2017 data, which grouped infection into local infection and organ infection (both of which were based on a much larger body of evidence). Because we do not report other types of specific infections and because the evidence base on wound/abdominal wall infection is so weak, we have not progressed this specific infection complication to Part 4.
    - We did not carry forward the outcome of total time in the operating room, because this does not match our desired outcome of duration of surgery, and Lawrie 2019 provides an outcome that matches duration of surgery
    - We also did not progress any of the complications reported in Aarts 2015 for the comparison of robot-assisted laparoscopic hysterectomy vs. non-robot-assisted laparoscopic hysterectomy to Part 4. These outcomes were all based on a single trial with 100 participants and very low event rates (1 event for each outcome in the non-robot-assisted arm and no events in the robot-assisted arm). These data are too limited to meaningfully contribute to this Evidence Report, so they were not progressed beyond Part 3.

LAWRIE 2019
Lawrie TA, Liu H, Lu D, Dowswell T, Song H, Wang L, Shi G. Robot-assisted surgery in gynaecology. Cochrane Database Syst Rev. 2019 Apr 15;4:CD011422. doi: 10.1002/14651858.CD011422.pub2 PubMed

Relevant to FAQ3, FAQ4, FAQ6

- **Study design:** systematic review of randomized trials
- **Population:** women having hysterectomy for benign and malignant gynecological conditions
  - data was sub-grouped for hysterectomy according to type of disease (benign vs. malignant) and type of procedure (hysterectomy vs. sacrocolpopexy); we only extracted the data for hysterectomy for benign conditions
- **Intervention:** robot-assisted surgery
  - was not clearly limited to robot-assisted total laparoscopic surgery, resulting in indirectness downgrades for all outcomes
- **Comparison:** conventional laparoscopic surgery
  - above Issue for the intervention applies to the comparator as well

- **Study inclusion criteria:** no additional

- **Number of studies:** 12
  - hysterectomy was performed in 8 studies, 6 of which involved benign conditions
- **Number of participants:** 1,016
  - there were a total of 1,016 participants across the 12 trials included, but only 6 trials involved benign conditions; see results table below for number of participants contributing to each outcome
- **Duration of follow-up:** only intraoperative and short-term postoperative outcomes reported

- **Results and certainty:**

Effects of robot-assisted laparoscopic modality vs. conventional laparoscopic surgery on duration of surgery and length of hospital stay in women having hysterectomy for benign conditions

Outcome	No of patients (studies)	Range in robot-assisted group	Range in conventional laparoscopic surgery group	Mean difference (95% CI)	Certainty (reason for downgrade)
duration of surgery ("total operating time" outcome); trials not limited to total laparoscopic surgery	148 (2)	96 to 172.8 minutes	75 to 102.7 minutes	41.2 minutes higher (95% CI 6.2 minutes lower to 88.5 minutes higher)	Very low (risk of bias [unclear allocation concealment in 1 trial, which more strongly favored non-robot-assisted laparoscopic surgery and influenced pooled estimate], imprecision,

					indirectness)
duration of surgery ("total operating time" outcome); single trial limited to total laparoscopic surgery*	53 (1)	172.8 minutes (range not applicable; SD 89 minutes)	102.7 minutes (range not applicable; SD 63.7 minutes)	70.1 minutes longer (95% CI 28.3 minutes to 111.9 minutes)	Low (risk of bias [unclear allocation concealment], inconsistency [single trial precludes assessing replicability of findings])
length of hospital stay	192 (2)	1.1 to 3.3 days	1.4 to 3.6 days	0.3 days lower (95% CI 0.5 days lower to 0.07 days lower)	Very low (risk of bias [no blinding], imprecision, indirectness)

***** This analysis was not reported directly in the systematic review. It was extracted from the study results reported in the forest plot for duration of surgery ("total operating time").

Effects of robot-assisted laparoscopic modality vs. conventional laparoscopic surgery on complications in women having hysterectomy for benign conditions

Outcome	No of patients (studies)	Risk ratio (95% CI) (except where indicated otherwise)	Control group event rate (%)	Certainty (reason for downgrade)
intraoperative complications*	388 (4)	1.66 (95% CI 0.76 to 3.61)	4.4% (8/182)	Very low (risk of bias [no blinding in all but 1 trial and unclear allocation concealment in 1 trial with blinding], imprecision, indirectness)
complications: intraoperative injury	269 (3)	1.62 (95% CI 0.20 to 12.91)	0.7% (1/135)	Very low (risk of bias [no blinding in all but 1 trial and unclear allocation concealment in 1 trial with blinding], imprecision [very serious concern], indirectness)
postoperative complications†	434 (4)	0.61 (95% CI 0.34 to 1.09)	12.4% (24/193)	Very low (risk of bias [no blinding], imprecision, indirectness)
complications: infection	367 (4)	0.62 (95% CI 0.13 to 2.88)	2.3% (4/172)	Very low (risk of bias [no blinding in all but 1 trial and unclear allocation concealment in 1

				trial with blinding], imprecision [very serious concern], indirectness)
blood transfusion	247 (3)	1.94 (95% CI 0.30 to 12.76)	1.0% (1/99)	Very low (risk of bias [no blinding in all but 1 trial and unclear allocation concealment in 1 trial with blinding], imprecision [very serious concern], indirectness)
pain at 1 to 2 weeks	36 (1)	-2.0 (95% CI -16.1 to 12.1) (mean difference)		Very low (risk of bias [very serious concern because unclear allocation concealment and high loss to follow-up], imprecision [very serious concern], indirectness)

* Defined as "complications including injury to the bladder, ureters, bowel, blood vessels, and nerves". The word "including" suggests this outcome includes additional outcomes in addition to injuries, further suggested by the "complications: intraoperative injury" outcome below which is specific to injuries. The two forest plots (1.3 and 1.4) were compared and 1.3 ('intraoperative complications') includes additional events compared to 1.4 ('Complications: intraoperative injury') for 1 of the trials (Sarlos 2010).
† Defined as including vascular, wound (including infection and wound breakdown), gastrointestinal, incisional hernia, neurological, respiratory, and urinary complications.

- **Other considerations:** The following outcomes were not carried forward to Part 4 (with reason[s] stated):
    - intraoperative and postoperative complications: as was seen in multiple other evidence sources and as is discussed in the Descriptive Evidence Review for FAQ6 in Part 4, this lumping of outcomes was too broad to be helpful (and in some cases, is arguably inappropriate); additionally, a comparable outcome does not exist in the data for total laparoscopic hysterectomy vs. vaginal hysterectomy, thereby precluding meaningful comparison for these outcomes (even if we felt they were appropriately informative)
    - intraoperative injury: this outcome suffers from marked imprecision due to low event rates and cannot be considered as a reliable source for inference about this outcome
    - pain at 1 to 2 weeks: this is based on a single, small (n = 36) trial, and the resultant imprecision in the result precludes any meaningful inference about this outcome

LEE 2019

Lee SH, Oh SR, Cho YJ, Han M, Park JW, Kim SJ, Yun JH, Choe SY, Choi JS, Bae JW. Comparison of vaginal hysterectomy and laparoscopic hysterectomy: a systematic review and meta-analysis. BMC Womens Health. 2019 Jun 24;19(1):83. doi: 10.1186/s12905-019-0784-4. PubMed

Relevant to FAQ3, FAQ4, FAQ5, FAQ6

- **Study design:** systematic review of randomized trials
- **Population:** women having hysterectomy for benign gynecological conditions
- **Intervention:** vaginal hysterectomy
- **Comparison:** laparoscopic hysterectomy
    - trials were sub-grouped by type of laparoscopic hysterectomy and we extracted data for the subgroup of trials comparing vaginal hysterectomy vs. *total* laparoscopic hysterectomy; however, Lee 2019 does not present such data for all outcomes (ie, the outcomes below are those for which Lee 2019 provides subgroup data)
- **Study inclusion criteria:** included only trials published after January 2000
- **Number of studies:** 18
    - There were 18 trials total, but only 8 compared total laparoscopic hysterectomy to vaginal hysterectomy
- **Number of participants:** 1,618
    - There were 1,618 participants total, but only 652 were in trials contributing to the comparison of interest
- **Duration of follow-up:** only intraoperative and short-term postoperative outcomes reported

- **Results and Certainty:**

Effects of vaginal hysterectomy vs. total laparoscopic hysterectomy on operating time

Outcome	No of patients (studies)	Means with VH (range)	Means with TLH (range)	Mean difference (95% CI)	Certainty (reason for downgrade)
operating time (minutes)	415* (6)	56.3 to 100.4	66.3 to 151	35.6 minutes lower (63.3 lower to 8.0 lower)	Moderate (imprecision)

*Forest plot for this outcome in Lee 2019 forest plot for this outcome (Fig 5) includes in the 'total' columns the 20 patients in each group in the Ribeiro 2003 trial which reported means of 0 in both groups; the 40 patients in this trial were subtracted from the pooled totals columns to calculate the number of patients total.

Effects of vaginal hysterectomy vs. total laparoscopic hysterectomy on complications

Outcome	No of patients (studies)	Risk ratio (95% CI)	VH group event rate (%)	TLH group event rate (%)	Certainty (reason for downgrade)
Overall complications*	455 (7)	1.38 (95% CI 0.90 to 2.10)	21.6% (49/227)	14.0% (32/228)	Moderate (imprecision)
Grade I complications†	455 (7)	1.26 (95% CI 0.84 to 1.88)	16.7% (38/227)	12.7% (29/228)	Moderate (imprecision)
Grade II complications‡	455 (7)	4.39 (95% CI 0.97 to 19.98)	3.5% (8/227)	0.4% (1/228)	Low (imprecision [very serious concern])
Grade III complications§	455 (7)	1.30 (95% CI 0.26 to 6.60)	1.3% (3/227)	0.9% (2/228)	Low (imprecision [very serious concern])

* Classified by Dindo classification (grade I to V). No trial reported any grade IV or grade V complications after either vaginal or laparoscopic hysterectomy.
† Grade I complications were fever, vault hematoma, urinary tract infection, vaginal bleeding, urinary retention and unspecified infections.
‡ Grade II complications were mostly transfusions
§ Grade III complications included those that required surgical, endoscopic, or radiological intervention. These included 1 ureteral injury, 7 bladder injuries, and 2 reoperations in the vaginal group; and 8 bladder injuries, 1 vesicovaginal fistula, 1 ureterovaginal fistula, 1 reoperation, and 2 pulmonary embolisms in the laparoscopic group.

- **Other considerations:**
  - Overall complications [Grade I to V] was determined to be unhelpful for clinical decision- making because it combines very serious complications (eg, intraoperative visceral injuries) with minor complications (eg, fever) in a composite outcome. It was therefore not carried forward to Part 4.
  - Lee 2019 reported a postoperative pain outcome, but only for the comparison of VH vs. TH overall and not for the specific comparison of interest of VH vs. TLH.

LIM 2016
Lim PC, Crane JT, English EJ, Farnam RW, Garza DM, Winter ML, Rozeboom JL. Multicenter analysis comparing robotic, open, laparoscopic, and vaginal hysterectomies performed by high-volume surgeons for benign indications. Int J Gynaecol Obstet. 2016 Jun;133(3):359-64. PubMed

Relevant to FAQ6

- **Study design:** observational study
- **Population:** women having hysterectomy for benign conditions
- **Intervention:** robot-assisted laparoscopic hysterectomy
    - performed by physicians with prior experience of ≥ 60 robot-assisted benign hysterectomies (considered "high-volume" per article), at 9 US-based medical centers
    - was not clearly limited to robot-assisted total laparoscopic surgery, resulting in indirectness downgrades for all outcomes
- **Comparison:** non-robot-assisted laparoscopic hysterectomy
    - from high-volume cohorts in the Premier Database
    - report included analyses comparing robot-assisted laparoscopic hysterectomies with abdominal, vaginal, and non-robot-assisted laparoscopic hysterectomies from Premier Perspective database, but we only used this report to extract data for the robot-assisted and non-robot-assisted laparoscopic hysterectomy groups (see "Background and context" at beginning of Part 3)
    - above indirectness issue for the intervention applies to the comparator as well
- **Study inclusion criteria:** no additional relevant
- **Number of studies:** not applicable
- **Number of participants:** 14,252
    - 32,118 overall, but number above is for the number of women receiving either robot-assisted or non-robot-assisted laparoscopic hysterectomy at 9 centers (does not include women having other types of hysterectomy)
- **Duration of follow-up:** up to 30-days

- **Results and Certainty:**

Intraoperative complications in women who had robot-assisted vs. non-robot-assisted laparoscopic hysterectomy

Complications	Robot-assisted laparoscopic hysterectomy (n = 2,300)	Non-robot-assisted laparoscopic hysterectomy (n = 11,952)	Calculated relative risk (not provided)	Certainty (reason for downgrade)
≥ 1 intraoperative complication*	17 (0.7%)	142 (1.2%)	0.62 (95% CI, 0.38 to 1.03)	Very low (risk of bias [very serious concern; observational data, and data for robot-assisted surgeries were obtained via retrospective medical record review performed by 7 participating surgeons], indirectness, imprecision)
blood transfusion	2 (0.1%)	58 (0.5%)	0.18 (95% CI 0.04 to 0.73)	Very low (risk of bias [very serious concern; observational data, and data for robot-assisted surgeries were obtained via retrospective medical record review performed by 7 participating surgeons], indirectness)

*Categorized into hemorrhage, laceration/puncture accident during surgery, cautery/thermal injury, nerve injury, foreign body left in peritoneal cavity, mechanical failure, medical accident (not specified), surgical (not specified)

Post-operative complications (30-day follow-up) in women who had robot-assisted vs. non-robot-assisted laparoscopic hysterectomy

Complications	Robot-assisted laparoscopic hysterectomy (n = 2,059)	Non-robot-assisted laparoscopic hysterectomy (n = 11,952)	Calculated relative risk (not provided)	Certainty (reason for downgrade)
≥ 1 postoperative complication*	131 (6.3%)	1,953 (16.3%)	0.39 (95% CI 0.33 to 0.46)	Very low (risk of bias [very serious concern; observational data, and data for robot-assisted surgeries were obtained via retrospective medical record review performed by 7 participating surgeons], indirectness)
blood transfusion	5 (0.2%)	46 (0.4%)	0.63 (95% CI 0.25 to 1.59)	Very low (risk of bias [very serious concern; observational data, and data for robot-assisted surgeries were obtained via retrospective medical record review performed by 7 participating surgeons], indirectness, imprecision)

*Categorized into surgical, medical, genitourinary, gastrointestinal, respiratory, thromboembolic events, pain, cardiovascular, and central nervous system

- **Other considerations:** The following outcomes were not carried forward to Part 4 (with reason[s] stated):
  - intraoperative and postoperative complications: as was seen in multiple other evidence sources and as is discussed in the Descriptive Evidence Review for FAQ6 in Part 4, this lumping was too broad to be helpful (and in some cases, is arguably

inappropriate); additionally, a comparable outcome does not exist in the data for total laparoscopic hysterectomy vs. vaginal hysterectomy, which precludes meaningful comparison for these outcomes (even if we felt they were appropriately informative)
  - intraoperative and postoperative blood transfusion: we (and patients and clinicians) are most interested in the need for blood transfusion overall, not when that need arises, so this division is not helpful; combining the two time points would risk double-counting (because some who need intraoperative blood transfusion may also need another blood transfusion postoperatively)

LUCIANO 2016

Luciano AA, Luciano DE, Gabbert J, Seshadri-Kreaden U. The impact of robotics on the mode of benign hysterectomy and clinical outcomes. Int J Med Robot. 2016 Mar;12(1):114-24. PubMed

Relevant to FAQ6

- **Study design:** observational study
- **Population:** women having hysterectomy for benign gynecological conditions from January 2005 until December 2010
- **Intervention:** robot-assisted laparoscopic hysterectomies
  - was not clearly limited to robot-assisted total laparoscopic surgery, resulting in indirectness downgrades for all outcomes
- **Comparison:** non-robot-assisted laparoscopic hysterectomy
  - report included analyses comparing robot-assisted laparoscopic hysterectomy with abdominal, vaginal, and non-robot-assisted laparoscopic hysterectomies (all four procedures from Premier Perspective database), but we only used this report to extract data for the robot-assisted and non-robot-assisted laparoscopic hysterectomy groups (see “Background and context” at beginning of Part 3)
  - above indirectness issue for the intervention applies to the comparator as well

- **Study inclusion criteria:** no additional

- **Number of studies:** not applicable
- **Number of participants:** 98,929
  - 289,875 overall, but number above is total number receiving robot-assisted or non-robot-assisted laparoscopic hysterectomy
- **Duration of follow-up:** until discharge from hospital

- **Results and Certainty:**

Perioperative complications prior to discharge in women who underwent robot-assisted vs. non-robot-assisted laparoscopic hysterectomy

Complications	Robot-assisted laparoscopic hysterectomy (n = 20,781)	Non-robot-assisted laparoscopic hysterectomy (n = 78,148)	Calculated relative risk (not provided)	Certainty (reason for downgrade)
overall complications*	3,077 (14.8%)	14,501 (18.6%)	0.80 (95% CI 0.77 to 0.83)	Very low (risk of bias [very serious concern; observational data], indirectness)
major complications†	87 (0.4%)	414 (0.5%)	0.79 (95% CI 0.63 to 1.00)	Very low (risk of bias [very serious concern; observational data], indirectness, imprecision)
infection	1,099 (5.3%)	6,430 (8.2%)	0.64 (95% CI 0.60 to 0.68)	Very low (risk of bias [very serious concern; observational data], indirectness)
wound	54 (0.3%)	224 (0.3%)	0.91 (95% CI 0.67 to 1.22)	Very low (risk of bias [very serious concern; observational data], indirectness, imprecision)
transfusion	397 (1.9%)	1,638 (2.1%)	0.91 (95% CI 0.82 to 1.02)	Very low (risk of bias [very serious concern; observational data], indirectness, imprecision)

*Categorized into infection, gastrointestinal, genitourinary, respiratory, vascular, cardiac, wound, thromboembolic, neurologic, and mortality
† Defined as complication requiring re-intervention related to the hysterectomy

- **Other considerations:** The following outcomes were not carried forward to Part 4 (with reason[s] stated):
  - overall complications: as was seen in multiple other evidence sources and as is discussed in the Descriptive Evidence Review for FAQ6 in Part 4, this lumping of outcomes was too broad to be helpful (and in some cases, is arguably inappropriate); additionally, a comparable outcome does not exist in the data for total laparoscopic hysterectomy vs. vaginal hysterectomy, thereby precluding meaningful comparison for these outcomes (even if we felt they were appropriately informative)
  - major complications: Luciano 2016 used an overly-restrictive definition (only those complications that resulted in re-intervention related to the hysterectomy), resulting in substantial concern for underestimating the true rate of major complications
  - infection: this outcome is covered by the Marra 2019 systematic review (it includes Luciano 2016's data for this outcome)

MARRA 2019
Marra AR, Puig-Asensio M, Edmond MB, Schweizer ML, Bender D. Infectious complications of laparoscopic and robotic hysterectomy: a systematic literature review and meta-analysis. Int J Gynecol Cancer. 2019 Mar;29(3):518-530. PubMed

Relevant to FAQ6

- **Study design:** systematic review of randomized trials and observational studies
- **Population:** women having robot-assisted or non-robot-assisted laparoscopic hysterectomy for benign and malignant gynecological conditions
- **Intervention:** robot-assisted laparoscopic hysterectomy
    - was not clearly limited to robot-assisted total laparoscopic surgery, resulting in indirectness downgrades for all outcomes
- **Comparison:** non-robot-assisted laparoscopic hysterectomy
    - above issue for the intervention applies to the comparator as well

- **Study inclusion criteria:** study reported data on infectious complications

- **Number of studies:** 16
    - 50 studies in total, but number above represents the number of studies that evaluated treatment of women with benign gynecologic conditions (and 4 additional studies included both benign and malignant conditions in the same study)

- **Number of participants:** 166,961
    - 176,016 total participants, but number above is for the number of patients receiving robot-assisted or non-robot-assisted laparoscopic hysterectomy for benign reasons
- **Duration of follow-up:** short-term postoperative period

- **Results**: infectious complications in 3.1% (1,324/43,028) who received robot-assisted laparoscopic hysterectomy vs. 5.4% (6,706/123,933) in non-robot-assisted laparoscopic hysterectomy (odds ratio: 1.10 [95% CI 0.70 to 1.73]; calculated relative risk based on odds ratio and risk in non-robot-assisted laparoscopic hysterectomy group: 1.09 [95% CI 0.71 to 1.66])
- **Certainty: Very low**
    - Downgrades for risk of bias (very serious concern; observational data), imprecision, inconsistency, and indirectness

ROSERO 2013
Rosero EB, Kho KA, Joshi GP, Giesecke M, Schaffer JI. Comparison of robotic and laparoscopic hysterectomy for benign gynecologic disease. Obstet Gynecol. 2013 Oct;122(4):778-86. PubMed

Relevant to FAQ6

- **Study design:** observational study
- **Population:** women having hysterectomy for benign gynecological conditions
  - identified from US 2009 and 2010 Nationwide Inpatient Sample
- **Intervention:** robot-assisted laparoscopic hysterectomy
  - was not clearly limited to robot-assisted total laparoscopic surgery, resulting in indirectness downgrades for all outcomes
- **Comparison:** non-robot-assisted laparoscopic hysterectomy
  - above indirectness issue for the intervention applies to the comparator as well

- **Study inclusion criteria:** no additional relevant

- **Number of studies:** not applicable
- **Number of participants:** 15,576
  - number in overall cohort was 103,840 (86,253 receiving laparoscopic hysterectomy and 17,587 receiving robot-assisted laparoscopic hysterectomy), and total number in propensity-matched sample was 15,576
- **Duration of follow-up:** perioperative period

- **Results and Certainty:**

Complications in women who underwent robot-assisted vs. non-robot-assisted laparoscopic hysterectomy

Complications	**Robot-assisted laparoscopic hysterectomy (n = 7,788)**	**Non-robot-assisted laparoscopic hysterectomy (n = 7,788)**	**Relative risk (95% CI)**	**Certainty (reason for downgrade)**
any complication	685 (8.8%)	689 (8.9%)	0.99 (95% CI 0.89 to 1.09)	Very low (risk of bias [very serious concern; observational data],

				imprecision, indirectness)
surgical complications*	364 (4.7%)	415 (5.3%)	0.87 (95% CI 0.76 to 1.01)	Very low (risk of bias [very serious concern; observational data], imprecision, indirectness)
postoperative medical complications†	372 (4.8%)	339 (4.4%)	1.09 (95% CI 0.95 to 1.26)	Very low (risk of bias [very serious concern; observational data], imprecision, indirectness)
blood transfusion	165 (2.1%)	244 (3.1%)	0.67 (95% CI 0.55 to 0.82)	Very low (risk of bias [very serious concern; observational data], indirectness)
fever	20 (0.2%)	14 (0.2%)	1.4 (95% CI 0.72 to 2.82)	Very low (risk of bias [very serious concern; observational data], imprecision, indirectness)
urinary tract infection	48 (0.6%)	65 (0.8%)	0.7 (95% CI 0.50 to 1.07)	Very low (risk of bias [very serious concern; observational data], imprecision, indirectness)

*Included accidental puncture or laceration of pelvic or abdominal organs, foreign body left during procedure, iatrogenic pneumothorax, surgical wound disruption, postoperative hemorrhage or hematoma, and blood transfusion.
†Included postoperative stroke, respiratory failure, endotracheal intubation, pneumonia, atelectasis, pulmonary embolism or deep vein thrombosis, myocardial infarction, acute renal failure, ileus, urinary tract infection, urinary retention, fever, and sepsis.

- **Other considerations:** The following outcomes were not carried forward to Part 4 (with reason[s] stated):
  - any complication and postoperative complications: as was seen in multiple other evidence sources and as is discussed in the Descriptive Evidence Review for FAQ6 in Part 4, this lumping of outcomes was too broad to be helpful (and in some cases, is arguably inappropriate); additionally, a comparable outcome does not exist in the data for total laparoscopic hysterectomy vs. vaginal hysterectomy, thereby precluding meaningful comparison for these outcomes (even if we felt they were appropriately informative)

SANDBERG 2017

Sandberg EM, Twijnstra ARH, Driessen SRC, Jansen FW. Total Laparoscopic Hysterectomy Versus Vaginal Hysterectomy: A Systematic Review and Meta-Analysis. J Minim Invasive Gynecol. 2017 Feb;24(2):206-217.e22. PubMed

Relevant to FAQ3, FAQ4, FAQ6

- **Study design:** systematic review of randomized trials and observational studies
- **Population:** women having total laparoscopic hysterectomy or vaginal hysterectomy for benign indication or low-grade (pre)malignancy (cervical intraepithelial neoplasia or endometrial hyperplasia) without lymph node dissection
- **Intervention:** total laparoscopic hysterectomy
    - studies were only included if it was clear that the entire procedure was performed laparoscopically
- **Comparison:** vaginal hysterectomy

- **Study inclusion criteria:**
    - ≥ 10 patients
    - only studies published since year 2000

- **Number of studies:** 24
    - 7 randomized trials
    - 6 prospective cohort studies
    - 11 retrospective cohort studies
- **Number of participants:** 8,924
- **Duration of follow-up:** not reported for outcomes relevant for this Evidence Report, but limited to intraoperative and immediate postoperative for our outcomes of interest

- **Results and Certainty**

Effects of total laparoscopic hysterectomy (TLH) vs. vaginal hysterectomy (VH) on operative time, length of hospital stay, and postoperative pain in women having hysterectomy

Outcome and study designs pooled	No of patients (studies)	Means with TLH (range)	Rates with VH (range)	Mean difference (95% CI)	Certainty (reason for downgrade)
operative time (minutes)					
RCTs only	415 (6)*	55 to 151 minutes	50 to 100.4 minutes	35.5 minutes higher (95% CI 5.9 higher to 65.1 higher)	Moderate (imprecision)†*
RCTs plus cohort studies	4,074 (14)			42.6 minutes higher (95% CI 29.3 higher to 55.9 higher)	Low (risk of bias from cohort studies) but consistent with RCT-only estimate with greater precision

length of stay (days)					
RCTs only	415 (6)*	1 to 4.7	1.5 to 5.4	0.3 days lower (95% CI 0.9 lower to 0.2 higher)	Very low (risk of bias [no blinding], imprecision, inconsistency [very serious concern]**)
RCTs plus cohort studies	3,081 (12)			0.6 days lower (95% CI 1.2 lower to 0.01 higher)	Very low (risk of bias [very serious concern - RCTs pooled with cohort studies], imprecision, inconsistency [very serious concern]**)
postoperative pain at 24 hours (10-point VAS scale) (RCTs only)	202 (3)	1.8 to 4.0	3 to 4	1.1 points lower (95% CI 1.7 lower to 0.4 lower)	Moderate (risk of bias [no blinding], imprecision)

* This outcome is noted as including 7 trials, but one of the trials (Ribeiro 2003) did not contribute to either analysis (despite being included in the forest plots). Therefore, we report these outcomes as being based on 6 trials.
† This analysis includes the Sesti 2014 trial which had an unclear risk of bias for blinding domain in Sandberg 2017 but was blinded according to the Characteristics of included studies table in Aarts 2015 (and has no other risks of bias). All outcomes that include this trial and have pooled estimates that are consistent with this trial are not downgraded for risk of bias.
** Very serious inconsistency with high heterogeneity (I^2 90% or 98%) and at least one study favoring vaginal hysterectomy

Effects of total laparoscopic hysterectomy (TLH) vs. vaginal hysterectomy (VH) on complications in women having hysterectomy for benign conditions

Outcome and study designs pooled	No of patients (studies)	Odds ratio (95% CI)	TLH group event rate (%)	VH group event rate (%)	Certainty (reason for downgrade)
complications: major*					
RCTs only	433 (7)	0.85 (95% CI 0.16 to 4.56)	3.7% (8/216)	5.1% (11/217)	Very low (inconsistency, imprecision [very serious concern])
RCTs plus cohort studies	6,423 (14)	1.49 (95% CI 0.78 to 2.85)	4.0% (104/2568)	2.3% (89/3855)	Very low (risk of bias [very serious concern - RCTs pooled with cohort studies], inconsistency, imprecision)
complications: minor†					
RCTs only	433 (7)	0.59 (95% CI 0.30 to 1.15)	8.8% (19/216)	13.8% (30/217)	Moderate (imprecision)
RCTs plus cohort studies	2,384 (12)	0.83 (95% CI 0.53 to 1.28)	4.0% (49/1228)	6.2% (72/1156)	Very low (risk of bias [very serious concern - RCTs pooled with cohort studies], imprecision)
specific complications (RCTs plus cohort studies for all)					
infection‡					
local infection	1,017 (3)	0.77 (95% CI 0.19 to 3.15)	0.9% (4/449)	0.7% (4/568)	Very low (risk of bias, imprecision [very serious concern])

organ infection (all were urinary tract infection)	1,185 (5)	1.27 (95% CI 0.22 to 7.27)	1.5% (10/648)	1.5% (8/537)	Very low (risk of bias, imprecision [very serious concern])
fever (above 38 degrees Celsius)	1,538 (6)	0.91 (95% CI 0.44 to 1.87)	2.5% (21/847)	3.8% (26/691)	Very low (risk of bias, imprecision [very serious concern])
injuries§					
bowel injury	427 (1)	1.27 (95% CI 0.11 to 14.10)	0.8% (1/121)	0.7% (2/306)	Very low (risk of bias [very serious concern – based on single cohort study], imprecision [very serious concern])
urinary tract injury	2,293 (12)	0.81 (95% CI 0.34 to 1.92)	1.2% (14/1,149)	1.4% (16/1,144)	Very low (risk of bias, imprecision [very serious concern])
bladder injury	1,555 (9)	0.81 (95% CI 0.22 to 2.95)	1.2% (11/898)	1.2% (8/657)	Very low (risk of bias, imprecision [very serious concern])
ureter injury	795 (8)	1.31 (95% CI 0.26 to 6.58)	0.6% (2/351)	0.5% (2/444)	Very low (risk of bias, imprecision [very serious concern])
vaginal cuff dehiscence	4,702 (7)	**6.28 (95% CI 2.38 to 16.57)**	1.4% (24/1,740)	0.07% (2/2,962)	Low (risk of bias [very serious concern - pooled estimate driven by large cohort study])
blood transfusions	1,636 (7)	0.64 (95% CI 0.35 to 1.17)	2.4% (22/903)	4.9% (36/733)	Very low (risk of bias [very serious concern - pooled estimate driven by large cohort study], imprecision)

* As defined by Dutch Society of Obstetrics and Gynecology. Major complications included major hemorrhage or hematoma requiring transfusion; urinary tract, bowel, or vascular injury; pulmonary embolism; major anesthesia problems; wound dehiscence (vaginal cuff dehiscence and port site hernia); and conversion to laparotomy.
† As defined by Dutch Society of Obstetrics and Gynecology. Minor complications included hemorrhage (not requiring transfusion) or hematoma (with spontaneous drainage); infection of the chest, urinary tract, wound, pelvis, other, or fever 38 degrees Celsius on any single occasion; deep vein thrombosis; and other minor complication requiring treatment (including voiding dysfunction and ileus).
‡ Infections were only reported separately per type of infection and not combined for all types of infections
§ Intraoperative visceral injuries were only reported separately per injury and not combined for all types of intraoperative injuries

Additional consideration: To check whether any recent trials were not included in this Sandberg 2017 systematic review, we cross-checked the 7 trials included in Sandberg 2017 against the 8 trials with a TLH vs. VH comparison included in the Lee 2019 systematic review (7 trials included in Sandberg 2017 plus one additional trial [Sesti 2008]). We determined that Sandberg 2017's exclusion of the Sesti 2008 RCT seems appropriate because it does not actually have a TLH arm (it appears that Lee 2019 counted minilaparotomy as being TLH, but these are not the same procedure).

WONG 2018
Wong JMK, Bortoletto P, Tolentino J, Jung MJ, Milad MP. Urinary Tract Injury in Gynecologic Laparoscopy for Benign Indication: A Systematic Review. Obstet Gynecol. 2018 Jan;131(1):100-108. PubMed

Relevant to FAQ6

- **Study design:** systematic review of randomized trials and observational studies
- **Population:** women having gynecologic laparoscopy for benign conditions
- **Intervention:** gynecologic laparoscopy
    - incidence of urinary tract injury was reported separately per procedure type including for 4 different types of laparoscopic hysterectomy including total laparoscopic which we extracted and report below
- **Comparison:** not applicable

- **Study inclusion criteria:** reported incidence of urinary tract injury

- **Number of studies:** 37
    - 90 studies total and number above is for the number of studies that evaluated total laparoscopic hysterectomy
- **Number of participants:** 86,683
    - 140,444 surgeries total but number above is for the number of patients receiving total laparoscopic hysterectomy
- **Duration of follow-up:** perioperative period

- **Certainty**: Very low (risk of bias [possible underreporting with most studies being retrospective cohort studies and no clear assessment of systematic outcome ascertainment, a few very large studies with 0 events may skew any pooled event rates], inability to assess inconsistency)

- **Results**

Incidence of laparoscopic lower urinary tract injury in women having total laparoscopic hysterectomy

	No of surgeries (studies)	**Total lower urinary tract injury**		**Ureter injury**		**Bladder Injury**	
		n	**% (95% CI)**	**n**	**% (95% CI)**	**n**	**% (95% CI)**
total laparoscopic hysterectomy	86,683 (37)	122	0.1 (0.1 to 0.2)	31	0.04 (0.03 to 0.05)	91	0.1 (0.1 to 0.1)

WRIGHT 2013
Wright JD, Ananth CV, Lewin SN, Burke WM, Lu YS, Neugut AI, Herzog TJ, Hershman DL. Robotically assisted vs laparoscopic hysterectomy among women with benign gynecologic disease. JAMA. 2013 Feb 20;309(7):689-98. PubMed

Relevant to FAQ6

- **Study design:** observational study
- **Population:** women having hysterectomy for benign gynecological conditions
  - at 441 US hospitals from 2007 to 2010
- **Intervention:** robot-assisted laparoscopic hysterectomy
  - did not specify limiting to total laparoscopic hysterectomy; this resulted in indirectness downgrades for all outcomes
- **Comparison:** non-robot-assisted laparoscopic hysterectomy
  - above indirectness issue for the intervention applies to the comparison of non-robot-assisted laparoscopic hysterectomy as well
  - report also included analyses comparing robot-assisted laparoscopic hysterectomy with abdominal hysterectomy as well as other results (e.g., uptake over time and costs), but we limit our consideration to the outcomes pertaining to the noted intervention and comparator

- **Study inclusion criteria:** no additional relevant

- **Number of studies:** not applicable
- **Number of participants:** 9,942
  - 264,758 in overall cohort (123,288 had abdominal hysterectomy; 54,912 had vaginal hysterectomy; 75,761 had a laparoscopic procedure; and 10,797 had a robot-assisted
  - hysterectomy), and 9,942 in propensity-matched cohort
- **Duration of follow-up:** perioperative period

- **Results and Certainty:**

Complications in women who underwent robot-assisted vs. non-robot-assisted laparoscopic hysterectomy

Complications	Robot-assisted laparoscopic hysterectomy (n = 4,971)	Non-robot-assisted laparoscopic hysterectomy (n = 4,971)	Relative risk (95% CI)	Certainty (reason for downgrade)
any*	271 (5.5%)	264 (5.3%)	1.03 (95% CI 0.86 to 1.24)	Very low (risk of bias [observational data], imprecision, indirectness)
intraoperative†	126 (2.5%)	120 (2.4%)	1.05 (95% CI 0.75 to 1.47)	Very low (risk of bias [observational data], imprecision, indirectness)
surgical site‡	85 (1.7%)	100 (2.0%)	0.85 (95% CI 0.64 to 1.13)	Very low (risk of bias [observational data], imprecision, indirectness)
medical§	79 (1.6%)	59 (1.2%)	1.35 (95% CI 0.97 to 1.88)	Very low (risk of bias [observational data], imprecision, indirectness)
transfusion	68 (1.4%)	87 (1.8%)	0.80 (95% CI 0.55 to 1.16)	Very low (risk of bias [observational data], imprecision, indirectness)

* Composite of any of complications below

† Defined as bladder injury, ureteral injury, intestinal injury, vascular injury, and other operative injury

‡ Defined as wound complications, abscess, hemorrhage, bowel obstruction

§ Defined as venous thromboembolism, myocardial infarction, cardiopulmonary arrest, acute renal failure, respiratory failure, cerebrovascular accident, bacteremia/sepsis, shock, and pneumonia

- **Other considerations:** The following outcomes were not carried forward to Part 4 (with reason[s] stated):
    - any complication and intraoperative complications: as was seen in multiple other evidence sources and as is discussed in the Descriptive Evidence Review for FAQ6 in Part 4, this lumping of outcomes was too broad to be helpful (and in some cases, is arguably inappropriate); additionally, a comparable outcome does not exist in the data for total laparoscopic hysterectomy vs. vaginal hysterectomy, thereby precluding meaningful comparison for these outcomes (even if we felt they were appropriately informative)

Characteristics of studies identified in Part 2, but not included in Part 3:

Albright 2016 is a systematic review identified in second-round searching, but it was not progressed to Part 3. All the trials it includes are also included in the more comprehensive Lawrie 2019, and Albright 2016 also includes a quasi-randomized study, which we consider suboptimal.

Kiran 2016 and Louie 2018 are cohort studies identified in first- and fourth-round searching, but neither was progressed to Part 3. Neither includes consideration of robot-assisted laparoscopic hysterectomy and neither limits to total laparoscopic hysterectomy. Therefore, especially considering our identification of better evidence sources (eg, Sandberg 2017), we judged that neither of Kiran 2016 nor Louie 2018 would contribute meaningfully or reliably to this Evidence Report.

Sloth 2017 is a systematic review and guideline identified in second-round searching, but it was not progressed to Part 3. We judged Sloth 2017's data would not add meaningfully or reliably to this evidence report. It includes laparoscopic-assisted vaginal hysterectomy in the group of "conventional" laparoscopic hysterectomy and only presents subgroup analyses restricting to total laparoscopic hysterectomy for the outcome of operating time, which is already addressed by the more comprehensive Sandberg 2017 systematic review. Its consideration of robot-assisted laparoscopic hysterectomy is supplanted by the more comprehensive Lawrie 2019 Cochrane review.

Evidence report for report for surgical approaches to hysterectomy for benign conditions

Evidence Synthesis

Prepared by EBSCO Information Services

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Methods

For each FAQ, the key concepts (results and factors affecting certainty of the results) from the included studies that are most relevant to evidence synthesis will be summarized in Evidence Review Tables. Where evidence is very limited, or the FAQ is scoped as a descriptive response, summary text will be provided. Evidence Synthesis Process tables will come after the Evidence Review tables. An example Evidence Synthesis Process table is shown below, which also delineates the methods for evidence synthesis.

Evidence Synthesis Process:

Outcome	**Appropriate to give a single synthesis result?**	**Suggested best approach**
Outcome name to be listed here, and may include timepoint of assessment if the outcome was assessed at different times	*Answer will be "Yes" or "No", and if "No", a justification will be given for why.* *The full question being answered is "Is it useful and appropriate to present the synthesis of evidence results as a single result as the best representation of the body of evidence?"*	*If "Yes", options include:* *(1) meta-analysis already done* *(2) meta-analysis created from the evidence results* *(3) median of all results* *(4) median of sufficiently-valid results, stating cutoff for validity* *If "No", options include:* *(1) range of all results* *(2) range of sufficiently valid results, stating cutoff for validity* *(3) descriptive summary without quantitative representation (e.g., consistency in direction, but inconsistency in magnitude)* *(4) statement of inconsistency too limiting for single synthesized conclusion* *If another option is considered more appropriate, the method will be stated and justification for not selecting one of the above methods will be given.*

Results

Gynecologic surgeons will have different thresholds and preferred approaches to hysterectomy based on their specific blend of clinical expertise and experience, and certain conditions may influence or preclude choice among the specified options. It is expected that surgeons utilizing this Evidence Report will also incorporate clinical judgment, only using the decision aid when appropriate, and only discussing/considering with the patient those options that are considered feasible based on his/her expertise and experience in light of the patient's specific circumstance.

FAQ 1: What does the treatment involve?

Vaginal hysterectomy

Descriptive Summary

The surgery will take place through an incision made in the top of the vagina. No incisions will be made on the abdomen. The surgery can be done either with the area numbed (via local or spinal anesthesia) or with the patient asleep (via general anesthesia).

Non-robot-assisted total laparoscopic hysterectomy

Descriptive Summary

A total laparoscopic hysterectomy means the entire procedure is performed laparoscopically. It does not mean anything about whether a woman's cervix is removed or left in place. In other words, some women may have heard of "total hysterectomy" (meaning the uterus and cervix are removed) and "partial hysterectomy" (meaning the uterus is removed, but the cervix is left in place), but a woman can have either a total hysterectomy or partial hysterectomy with total laparoscopic hysterectomy. The surgery will take place through small incisions made in the lower abdomen. The laparoscope will be inserted through one of these incisions, allowing the surgeon to see inside the patient's abdominopelvic cavity. Other instruments are inserted through the other incisions to carry out the surgery. Upon completion of the surgery, the uterus and cervix may be removed vaginally. However, if a woman desires to keep her cervix, the uterus is often cut into small pieces (morcellation) and these pieces are then removed through the incisions already made, but in some cases, the uterus may need to be removed through a larger incision made in the lower abdomen specifically for removal of the uterus. This surgery is usually carried out with the patient asleep (via general anesthesia).

Robot-assisted total laparoscopic hysterectomy

Descriptive Summary

The description for non-robot-assisted total laparoscopic hysterectomy applies for robot-assisted hysterectomy. The key difference is – as the name implies – that the surgery is assisted by robotic technology (e.g., the da Vinci® surgical system). This allows the surgeon to do the surgery using mechanical arms that s/he controls remotely from a computer station that is situated away from the actual operating room table.

(Aarts 2015, ACOG 2017, ACOG 2018, Cleveland Clinic 2018, Healthwise 2018, Johns Hopkins nd, Lawrie 2019, Mayo Clinic 2019, NHS 2019, NIH 2018, Stanford Health Care nd, University of Rochester Medical Center nd)

FAQ 2: Can I keep my cervix if I want to?

Vaginal hysterectomy

Descriptive Summary

Although preservation of the cervix may be possible via a vaginal approach, preservation of the cervix is most easily accomplished via another surgical approach (Aarts 2015), and the American College of Obstetricians and Gynecologists also recommends using another approach if preservation of the cervix is desired (ACOG 2017).

Non-robot-assisted total laparoscopic hysterectomy

Descriptive Summary

Yes, a woman has the option to keep her cervix with a total laparoscopic hysterectomy without robotic assistance.

Robot-assisted total laparoscopic hysterectomy

Descriptive Summary

Yes, a woman has the option to keep her cervix with a total laparoscopic hysterectomy with robotic assistance.

(Aarts 2015, ACOG 2017)

FAQ 3: How long is the surgery?

Non-robot-assisted total laparoscopic hysterectomy vs. vaginal hysterectomy

Evidence Review Tables for FAQ3:

Effects of non-robot-assisted total laparoscopic hysterectomy (TLH) vs. vaginal hysterectomy (VH) on operating time* (Sandberg 2017)

No of patients (studies)	Means with TLH (range)	Means with VH (range)	Mean difference (95% CI)	Certainty (reason for downgrade)
415 (6)	55 to 151 minutes	50 to 100.4 minutes	35.5 minutes longer (95% CI 5.9 longer to 65.1 longer)	Moderate (imprecision)

* Population was women having hysterectomy for benign indication or low-grade (pre)malignancy (cervical intraepithelial neoplasia or endometrial hyperplasia) without lymph node dissection

Effects of non-robot-assisted total laparoscopic hysterectomy (TLH) vs. vaginal hysterectomy (VH) on operating time* (Lee 2019)

No of patients (studies)	Means with TLH (range)	Means with VH (range)	Mean difference (95% CI)	Certainty (reason for downgrade)
415 (6)	66.3 to 151 minutes	56.3 to 100.4 minutes	35.6 minutes longer (95% CI 8.0 longer to 63.3 longer)	Moderate (imprecision)

* Population was women having hysterectomy for benign indication

Evidence Synthesis Process for FAQ3:

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
operating time (minutes)	Yes. Trials consistently find an increase in operating time with non-robot-assisted total laparoscopic hysterectomy compared to vaginal hysterectomy. The two recent systematic reviews comparing trials of non-robot-assisted total laparoscopic hysterectomy vs. vaginal hysterectomy have included the same 6 trials in their meta-analyses for this outcome and generated very similar pooled estimates.	Range of sufficiently-valid results from meta-analysis already done The pooled point estimate was a 36-minute mean increase in operating time with non-robot-assisted total laparoscopic hysterectomy compared to vaginal hysterectomy in both systematic reviews. The 95% CIs for the pooled mean difference and the within group range for means were slightly different between the two systematic reviews. For the 95% CIs of the mean difference, we used the lowest lower CI bound of the 2 systematic reviews for our lower estimate and the highest upper CI bound of the 2 systematic reviews for our higher estimate (which resulted in using the Sandberg 2017 estimate). For the ranges of operating times for each group, we used the lowest mean operating time reported in either of the 2 systematic reviews for the lower bound of our range and the highest mean reported in either of the 2 systematic reviews for the upper bound of our range (which resulted in using the Sandberg 2017 estimates).

In women having hysterectomy for benign conditions, the duration of surgery may be:

- **about 1 to 1.5 hours for vaginal hysterectomy**
- **about 1 to 2.5 hours for total laparoscopic hysterectomy without robotic assistance**

Surgery may last about a half-hour longer with total laparoscopic hysterectomy without robotic assistance compared to vaginal hysterectomy, but this difference may be as little as about 5 minutes longer or as much as about an hour longer. (Moderate certainty)

Robot-assisted vs. non-robot-assisted total laparoscopic hysterectomy

Evidence Review Tables for FAQ3:

Effects of robot-assisted laparoscopic hysterectomy (RH) vs. non-robot-assisted laparoscopic hysterectomy (nRH) on duration of surgery (Lawrie 2019)

Clearly limited to total laparoscopic surgery?	No of patients (studies)	Range in RH group	Range in nRH group	Mean difference (95% CI)	Certainty (reason for downgrade)
No	148 (2)	96 to 173 minutes	75 to 103 minutes	41.2 minutes longer (95% CI 6.2 minutes shorter to 88.5 minutes longer)	Very low (risk of bias [unclear allocation concealment in 1 trial, which more strongly favored non-robot-assisted laparoscopic surgery and influenced pooled estimate], imprecision, indirectness)
Yes	53 (1)	172.8 minutes (range not applicable; SD 89 minutes)	102.7 minutes (range not applicable; SD 63.7 minutes)	70.1 minutes longer (95% CI 28.3 minutes to 111.9 minutes)	Low (risk of bias [unclear allocation concealment], inconsistency [single trial precludes assessing replicability of findings])

We limit further consideration to the single trial limited to total laparoscopic surgery, as this is a direct match for this Evidence Report.

Because randomized, controlled trial data are lacking for this comparison and outcome, we also consulted descriptive sources as specified in Part 1 Scoping. Of the sources consulted (see FAQ1), the two sources commenting on surgery duration with robot-assisted methods gave consistent estimates for robot-assisted hysterectomy, each saying the surgery may last from 3 to 4 hours, which is generally consistent with the above estimate from the single trial explicitly limiting to total laparoscopic surgery in both arms. However, even these descriptive sources did not specify whether the robot-assisted hysterectomy was completed entirely laparoscopically (Johns Hopkins nd, University of Rochester Medical Center nd).

Evidence Synthesis Process for FAQ3:

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
operating time (minutes)	Yes.	Single study already done (using data from single trial in the Lawrie 2019 systematic review that reported on duration of surgery and explicitly limited to total laparoscopic procedures in both arms) From the comparative evidence for robot-assisted total laparoscopic hysterectomy vs. non-robot-assisted total laparoscopic hysterectomy, there is one estimate for duration of surgery for robot-assisted total laparoscopic hysterectomy (173 minutes) and one estimate for non-robot-assisted total laparoscopic hysterectomy (103 minutes). However, there are other estimates for non-robot-assisted total laparoscopic hysterectomy from the comparative evidence for vaginal vs. non-robot-assisted total laparoscopic hysterectomy (range of 55 to 151 minutes). The estimate of 103 minutes is consistent with the range of 55 to 151 minutes. Therefore, it seems reasonable to conclude that the range of 55 to 151 minutes is the overall best estimate of duration of surgery for non-robot-assisted total laparoscopic hysterectomy. However, one then needs to consider how this range compares to the estimate of 173 minutes for the robot-assisted total laparoscopic hysterectomy group, because despite the range being consistent, using the range of 55 to 151 minutes in an implicitly comparative framework with the estimate of 173 minutes for robot-assisted total laparoscopic hysterectomy still amounts to an indirect comparison. This indirect comparison implies a difference of 22 to 118 minutes longer in robot-assisted cases. This is notably consistent with the confidence interval for the direct comparison of robot-assisted total laparoscopic hysterectomy versus non-robot assisted total laparoscopic hysterectomy (28 to 112 minutes longer in robot-assisted cases). We therefore conclude that reporting the estimate of 173 minutes for robot-assisted total laparoscopic hysterectomy is appropriate (along with the mean difference and confidence interval). We also repeat the range of 55 to 151 minutes for non-robot-assisted total laparoscopic hysterectomy (from the comparison of non-robot-assisted total laparoscopic hysterectomy vs. vaginal hysterectomy) for ease of reference.

In women having hysterectomy for benign conditions, the duration of surgery may be:

- **about 1 to 2.5 hours for total laparoscopic hysterectomy without robotic assistance**
- **about 3 hours for total laparoscopic hysterectomy with robotic assistance**

Surgery may last about an hour longer if using robotic assistance in a total laparoscopic hysterectomy, but this difference may be as little as about a half-hour longer or as much as about 2 hours longer. (Low certainty)

FAQ 4: How long is the hospital stay?

Non-robot-assisted total laparoscopic hysterectomy vs. vaginal hysterectomy

Evidence Review Table for FAQ4:

Effects of non-robot-assisted total laparoscopic hysterectomy (TLH) vs. vaginal hysterectomy (VH) on length of hospital stay* (Sandberg 2017)

Study designs pooled	No of patients (studies)	Means with TLH (range)	Means with VH (range)	Mean difference (95% CI)	Certainty (reason for downgrade)
RCTs only	415 (6)	1 to 4.7	1.5 to 5.4	0.3 days lower (95% CI 0.9 lower to 0.2 higher)	Very low (risk of bias [no blinding], imprecision, heterogeneity [very serious concern])

* Population was women having hysterectomy for benign indication or low-grade (pre)malignancy (cervical intraepithelial neoplasia or endometrial hyperplasia) without lymph node dissection

Evidence Synthesis Process for FAQ4:

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
length of hospital stay	No. The point estimate of the comparative analysis favors non-robot-assisted total laparoscopic hysterectomy, but the confidence interval is compatible with no difference or a longer hospital stay with non-robot-assisted total laparoscopic hysterectomy; the point estimates in the contributing studies also vary considerably.	Range of all results Because there is no clear difference between the two groups, because the range for both groups is approximately 1 to 5 days, and to avoid overstating findings as an artifact of rounding (e.g., rounding 1.5 days to 2 days), we state the range for both groups as approximately 1 to 5 days

In women having hysterectomy for benign reasons, the length of stay may be:

- **1 to 5 days for vaginal hysterectomy**
- **1 to 5 days for total laparoscopic hysterectomy without robotic assistance**

There may be no meaningful difference in length of hospital stay between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance. (Very low certainty)

Robot-assisted vs. non-robot-assisted total laparoscopic hysterectomy

Evidence Review Table for FAQ4:

Effects of robot-assisted laparoscopic hysterectomy (RH) vs. non-robot-assisted laparoscopic hysterectomy (nRH) on length of hospital stay (Lawrie 2019)

Comparator arm	No of patients (studies)	Range in RH group	Range in nRH group	Mean difference (95% CI)	Certainty (reason for downgrade)
including trial with mixed comparator arm (vaginal or laparoscopic hysterectomy)	192 (2)	1.1 to 3.3 days	1.4 to 3.6 days	0.3 days shorter (95% CI 0.5 days shorter to 0.07 days shorter)	Very low (risk of bias [no blinding, possible imbalance in variables of prognostic importance], imprecision, indirectness*)
comparator arm of laparoscopic hysterectomy	95 (1)	3.3 days (range not applicable; SD 0.9 days)	3.6 days (range not applicable; SD 3.9 days)	0.3 days shorter (95% CI 1.4 days shorter to 0.8 days longer)	Very low (risk of bias [no blinding], imprecision, indirectness*)

* Laparoscopic surgeries were not clearly limited to total laparoscopic surgeries.

Although 2 trials contributed to the above outcome from the Lawrie 2019 systematic review, we note neither trial clearly limited to total laparoscopic hysterectomy. Additionally, this analysis includes the Lönnerfors 2014 trial, which randomized women to robot-assisted laparoscopic hysterectomy vs. another minimally-invasive procedure, which could include either vaginal or laparoscopic hysterectomy at the surgeon's discretion; however, there was a clear preference for vaginal hysterectomy: "The route of traditional minimally invasive surgery was chosen by the designated surgeon, with vaginal hysterectomy as the first choice, followed by laparoscopic hysterectomy." Although the Lawrie 2019 analysis notes it excluded 25 women who received vaginal hysterectomy in the comparison arm, this subverts the randomization process, and especially in light of the clearly-stated preference for vaginal hysterectomy as the first-choice procedure in the comparison arm, raises the question of whether the groups may have important prognostic imbalance. Therefore, we consider the other trial in this analysis (Sarlos 2010/2012) to be the more informative trial and limit our considerations hereafter to the Sarlos 2010/2012 trial.

Because randomized, controlled trial data are sparse for this comparison and outcome, we also consulted descriptive sources as specified in Part 1 Scoping. Of the sources consulted (see FAQ1), the one source commenting on length of stay with robot-assisted methods also indicated no difference in length of stay for robot-assisted hysterectomy vs. laparoscopic hysterectomy. However, even this descriptive source did not specify whether it was considering total vs. non-total laparoscopic hysterectomy (Stanford Health Care nd).

Evidence Synthesis Process for FAQ4:

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
length of hospital stay	No. See discussion in the next column.	Set duration of hospital stay in robot-assisted total laparoscopic hysterectomy as equal to the duration of stay for non-robot-assisted total laparoscopic hysterectomy The single trial informing this result failed to find a clear difference between the 2 surgical methods and is further limited by its indirectness for the comparison of interest. Even as such, if one considered the point estimate for this trial's mean difference, it is 0.3 days lower. However, this absolute value may be misleading due to the lack of explicit limitation to total laparoscopic hysterectomy. Re-calculating the data as a ratio of means (R version 3.6.1, meta package 4.9-6) gives 0.92 (95% CI 0.67 to 1.26). Again, these data fail to demonstrate a clear difference, and the point estimate also suggests even if there is a difference, it is likely modest (eg, if one uses the point estimate for the ratio of means with the estimated range of 1 to 5 days for duration of stay for total laparoscopic hysterectomy, the estimate for robot-assisted total laparoscopic hysterectomy would also be 1 to 5 days if rounding to a whole number). In the bolded synthesis statement, we include the range for total laparoscopic hysterectomy from the preceding comparison (total laparoscopic hysterectomy vs. vaginal hysterectomy) for ease of reference.

In women having hysterectomy for benign reasons, the length of stay may be:

- **1 to 5 days for total laparoscopic hysterectomy without robotic assistance**
- **1 to 5 days for total laparoscopic hysterectomy with robotic assistance**

There may be no meaningful difference in length of hospital stay when a total laparoscopic hysterectomy is done with or without robotic assistance. (Very low certainty)

FAQ 5: How long does it take to recover?

Vaginal, non-robot-assisted total laparoscopic, and robot-assisted total laparoscopic hysterectomy

Descriptive summary

Two systematic reviews report on recovery-related concepts: Aarts 2015 and Lee 2019. However, they do not present data for the comparisons of interest in this Evidence Report or present only limited data. The only relevant data from Aarts 2015 come from a single trial (n = 100) of robot-assisted laparoscopic hysterectomy vs. non-robot-assisted laparoscopic hysterectomy, and there was no clear difference in return to normal activities (mean [SD] in robot-assisted vs. non-robot-assisted groups was 28.8 [15.9] and 31.2 [15.4] for a mean difference [95% CI] of 2.4 days lower [8.5 days lower to 3.7 days higher]). Additionally, it was not clear that the surgeries performed were total laparoscopic hysterectomies (opposed to surgeries where the surgery is partially laparoscopic and partially vaginal). Lee 2019's recuperation outcome considers only laparoscopic hysterectomy (including laparoscopically-assisted vaginal hysterectomy, unspecified laparoscopic hysterectomy, and total laparoscopic hysterectomy) versus vaginal hysterectomy. As specified in Part 1 Scoping, we have therefore adopted descriptive responses for this FAQ, and because there does not appear to be a clear difference in recovery among the comparisons of interest, we present a single descriptive response.

After having a hysterectomy, many women feel tired or get tired easily, and women will also have pain from the surgery. It is common for women to feel like their stomach is swollen or "puffy". It often takes 3 to 6 weeks to feel completely better, but for some women, it may take 8 weeks. Most of the pain from the surgery is usually in the first 2 weeks, and it is common to need pain medication during this time. It is common to have some mild vaginal bleeding for 2 to 6 weeks after the surgery. Beyond this initial period, ongoing vaginal bleeding can be influenced by whether the woman had a total or subtotal hysterectomy.

Women can slowly increase their activity levels each day, but they should avoid strenuous activity such as sports, jogging or running, or lifting (which may include lifting things like grocery bags or children) until cleared to do so by the health care team. This may take 3 weeks or more.

Women may need to take 2 to 4 weeks off from work, but depending on the nature of a woman's work, some women may need up to 8 weeks. Women may be able to return to driving once they can comfortably wear a seatbelt and respond to sudden traffic changes, such as needing to emergently apply the brake. The health care team will give an individualized timeframe for returning to work and driving.

Women who are sexually active are generally advised to avoid intercourse for 6 to 12 weeks after surgery. Similarly, women are generally advised to avoid putting anything like a tampon in the vagina for 4 to 12 weeks. Again, the health care team will give each patient an individualized timeframe.

(See FAQ 1 for references.)

FAQ 6: What are the risks?

Non-robot-assisted total laparoscopic hysterectomy vs. vaginal hysterectomy

Evidence Review Tables for FAQ6:

Effects of non-robot-assisted total laparoscopic hysterectomy (TLH) vs. vaginal hysterectomy (VH) on complications (Sandberg 2017)

Outcome and study designs pooled	**No of patients (studies)**	**Odds ratio (95% CI)**	**TLH group event rate (%)**	**VH group event rate (%)**	**Certainty (reason for downgrade)**
complications: major*					
RCTs only	433 (7)	0.85 (95% CI 0.16 to 4.56)	3.7% (8/216)	5.1% (11/217)	Very low (heterogeneity, imprecision [very serious concern])
RCTs plus cohort studies	6,423 (14)	1.49 (95% CI 0.78 to 2.85)	4.0% (104/2568)	2.3% (89/3855)	Very low (risk of bias [very serious concern - RCTs pooled with cohort studies], heterogeneity, imprecision)
complications: minor†					
RCTs only	433 (7)	0.59 (95% CI 0.30 to 1.15)	8.8% (19/216)	13.8% (30/217)	Moderate (imprecision)
RCTs plus cohort studies	2,384 (12)	0.83 (95% CI 0.53 to 1.28)	4.0% (49/1228)	6.2% (72/1156)	Very low (risk of bias [very serious concern - RCTs pooled with cohort studies], imprecision)
specific complications (RCTs plus cohort studies for all)					
infection‡					
local infection	1,017 (3)	0.77 (95% CI 0.19 to 3.15)	0.9% (4/449)	0.7% (4/568)	Very low (risk of bias, imprecision [very serious concern])
organ infection (all were urinary tract infection)	1,185 (5)	1.27 (95% CI 0.22 to 7.27)	1.5% (10/648)	1.5% (8/537)	Very low (risk of bias, imprecision [very serious concern])
fever (above 38 degrees Celsius)	1,538 (6)	0.91 (95% CI 0.44 to 1.87)	2.5% (21/847)	3.8% (26/691)	Very low (risk of bias, imprecision [very serious concern])

injuries§					
bowel injury	427 (1)	1.27 (95% CI 0.11 to 14.10)	0.8% (1/121)	0.7% (2/306)	Very low (risk of bias [very serious concern – based on single cohort study], imprecision [very serious concern])
urinary tract injury	2,293 (12)	0.81 (95% CI 0.34 to 1.92)	1.2% (14/1,149)	1.4% (16/1,144)	Very low (risk of bias, imprecision [very serious concern])
bladder injury	1,555 (9)	0.81 (95% CI 0.22 to 2.95)	1.2% (11/898)	1.2% (8/657)	Very low (risk of bias, imprecision [very serious concern])
ureter injury	795 (8)	1.31 (95% CI 0.26 to 6.58)	0.6% (2/351)	0.5% (2/444)	Very low (risk of bias, imprecision [very serious concern])
vaginal cuff dehiscence	4,702 (7)	**6.28 (95% CI 2.38 to 16.57)**	1.4% (24/1,740)	0.07% (2/2,962)	Low (risk of bias [very serious concern - pooled estimate driven by large cohort study])
blood transfusions	1,636 (7)	0.64 (95% CI 0.35 to 1.17)	2.4% (22/903)	4.9% (36/733)	Very low (risk of bias [very serious concern - pooled estimate driven by large cohort study], imprecision)

Statistically significant effects are bolded

* As defined by Dutch Society of Obstetrics and Gynecology. Major complications included major hemorrhage or hematoma requiring transfusion; urinary tract, bowel, or vascular injury; pulmonary embolism; major anesthesia problems; wound dehiscence (vaginal cuff dehiscence and port site hernia); and conversion to laparotomy.

† As defined by Dutch Society of Obstetrics and Gynecology. Minor complications included hemorrhage (not requiring transfusion) or hematoma (with spontaneous drainage); infection of the chest, urinary tract, wound, pelvis, other, or fever 38 degrees Celsius on any single occasion; deep vein thrombosis; and other minor complication requiring treatment (including voiding dysfunction and ileus).

‡ Infections were only reported separately per type of infection and not combined for all types of infections

§ Intraoperative visceral injuries were only reported separately per injury and not combined for all types of intraoperative injuries

Effects of non-robot-assisted total laparoscopic hysterectomy (TLH) vs. vaginal hysterectomy (VH) on postoperative pain (Sandberg 2017)

Outcome	No of patients (studies)	Means with TLH (range)	Rates with VH (range)	Mean difference (95% CI)	Certainty (reason for downgrade)
postoperative pain at 24 hours (10-point VAS scale) (RCTs only)	202 (3)	1.8 to 4.0	3 to 4	1.1 points lower (95% CI 1.7 lower to 0.4 lower)	Moderate (risk of bias [no blinding], imprecision)

Effects of vaginal hysterectomy (VH) vs. non-robot-assisted total laparoscopic hysterectomy (TLH) on complications (Lee 2019)*

Outcome	No of patients (studies)	Risk ratio (95% CI)	VH group event rate (%)	TLH group event rate (%)	Certainty (reason for downgrade)
Grade I complications†	455 (7)	1.26 (95% CI 0.84 to 1.88)	16.7% (38/227)	12.7% (29/228)	Moderate (imprecision)
Grade II complications‡	455 (7)	4.39 (95% CI 0.97 to 19.98)	3.5% (8/227)	0.4% (1/228)	Moderate (imprecision)
Grade III complications§	455 (7)	1.30 (95% CI 0.26 to 6.60)	1.3% (3/227)	0.9% (2/228)	Moderate (imprecision)

* Classified by Dindo classification (grade I to V). No trial reported any grade IV or grade V complications after either vaginal or laparoscopic hysterectomy. Note the order of the intervention and comparison is different in Lee 2019 than in many other sources (i.e., vaginal hysterectomy vs. non-robot-assisted total laparoscopic hysterectomy instead of non-robot-assisted total laparoscopic hysterectomy vs. vaginal hysterectomy).

† Grade I complications were fever, vault hematoma, urinary tract infection, vaginal bleeding, urinary retention, and unspecified infections.

‡ Grade II complications were mostly transfusions (in the overall comparison of vaginal hysterectomy vs. non-robot-assisted laparoscopic hysterectomy [which included laparoscopic-assisted vaginal hysterectomy, non-robot-assisted total laparoscopic hysterectomy, or unspecified laparoscopic hysterectomy], almost all of the grade II complications were transfusions [ie, 82 out of 84 total])

§ Grade III complications included those that required surgical, endoscopic, or radiological intervention. These included 1 ureteral injury, 7 bladder injuries, and 2 reoperations in the vaginal group; and 8 bladder injuries, 1 vesicovaginal fistula, 1 ureterovaginal fistula, 1 reoperation, and 2 pulmonary embolisms in the laparoscopic group.

Evidence Synthesis Process for FAQ6:

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
complications: major	No. In the Sandberg 2017 systematic review, the effects of TLH vs. VH on 'complications: major' were pooled separately for an 'RCTs only' analysis and an 'RCTs plus cohort studies' analysis. For both analyses, the confidence intervals are wide and compatible with either treatment being better than the other. Additionally, although the confidence intervals for the two analyses are largely overlapping, the point estimate of the 'RCTs only' analysis favored TLH whereas the point estimate of the 'RCTs plus cohort studies' analysis favored VH (which, in addition to the primary reason of wide confidence intervals, further argues against reporting any single synthesis result for a comparative analysis). Because no reliable data are available to report comparative effects, we report below only the univariate risk of major complications with hysterectomy (either TLH or VH). On looking at the distribution of the contributing data, we found no reason to consider any other approach more reasonable/better than pooling across both groups so that is the approach we used. For the 'RCTs only' analysis in Sandberg 2017, pooling the major complications data for each group separately yields risk estimates of 3.7% (8/216) for the TLH group and 5.1% (11/217) for the VH group. Pooling both groups together (given no clear difference demonstrated between the groups) yields an estimate of 4.4% (19/433). For the 'RCTs plus cohort studies' analysis in Sandberg 2017, pooling the data for each group separately yields risk estimates of 4.0% (104/2568) for the TLH group and 2.3% (89/3855) for the VH group. Pooling both groups together (given no clear difference demonstrated between the groups) yields a risk estimate of 3.0% (193/6,423). The Lee 2019 systematic review reports a 'Grade III complications' outcome (which had a very low event rate of 0.9% [2/228]) and which appears to have a definition fairly consistent with that of the 'complications: major' outcome in Sandberg 2017, at least in terms of the specific complications included under both broad definitions being serious enough to require additional surgical, endoscopic, or radiological intervention (which was the broad definition of a 'Grade III complication' in Lee 2019). However, one important difference is that the 'complications: major' outcome in Sandberg 2017 included transfusions, but the 'Grade III complication' in Lee 2019 did not include transfusions (which Lee 2019 classified as a 'Grade II complication'). We did not further consider the Lee 2019 'Grade III complication' outcome because of difference in how it was defined compared to the 'complications: major' outcome in Sandberg 2017 (which would prevent us from including both as a single outcome, and also we did not consider it useful to include both as separate outcomes in the final evidence synthesis statement). We preferentially used the Sandberg 2017 'complications: major' outcome primarily because it included both an analysis on 'RCTs only' and an analysis of 'RCTs plus cohort studies'.	Other: Given no clear difference demonstrated between the treatment groups in 'complications: major', we instead present this outcome as a risk of major complications regardless of whether a patient gets TLH or VH. Because we are presenting the same univariate estimate of risk for both groups, we found no clear reason to preferentially select the pooled risk estimates from 'RCTs only' subset vs. 'RCTs plus cohort studies' subset from Sandberg 2017; therefore, we give an estimate of "up to 4.4%" as a reasonable approximation of the risk of major complications for both groups and use this for concluding statements.

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
complications: minor	No. In the Sandberg 2017 systematic review, the results for the outcome 'complications: minor' were pooled separately for an 'RCTs only' analysis and an 'RCTs plus cohort studies analysis'. For both analyses, the confidence intervals are wide (and largely overlapping) and compatible with either treatment being better than the other. The Lee 2019 systematic review reports a 'Grade I complications' outcome which appears to have a definition fairly consistent with that of the 'complications: minor' outcome in Sandberg 2017. Consistent with Sandberg 2017, the pooled results were imprecise and compatible with either treatment being better than the other. Because no reliable data is available to report comparative effects, we report below only the univariate risk of major complications with hysterectomy (either TLH or VH). On looking at the distribution of the contributing data in the three analyses described above, we found no reason to consider any other approach more reasonable/better than pooling across both groups so that is the approach we used. We rated the 'RCTs only' analysis in Sandberg 2017 as having Moderate certainty for this outcome. Pooling the minor complications data for each group separately yields risk estimates of 8.8% (19/216) for the TLH group and 13.8% (30/217) for the VH group. Pooling both groups together (given no clear difference demonstrated between the groups) yields a risk estimate of 11.3% (49/433). We rated Lee 2019 (which was restricted to RCTs) as having Moderate certainty for this outcome. Pooling the data for each group separately yields risk estimates of 12.7% (29/228) for the TLH group and 16.7% (38/227) for the VH group. Pooling both groups together (given no clear difference demonstrated between the groups) yields a risk estimate of 14.7% (67/455). We rated the 'RCTs plus cohort studies' analysis in Sandberg 2017 as having Very low certainty for this outcome. Pooling the data for each group separately yields risk estimates of 4.0% (49/1228) for the TLH group and 6.2% (72/1156) for the VH group. Pooling both groups together (given no clear difference demonstrated between the groups) yields a risk estimate of 5.1% (121/2,384). However, these data are of Very low certainty, so we did not consider it appropriate to include them along with the above Moderate certainty estimates.	Other: Given no clear difference demonstrated between the treatment groups in minor complications in the 'RCTs only' analysis in Sandberg 2017 and in the analyses of RCTs on 'Grade I complications' in Lee 2017 (which was defined similarly to minor complications in Sandberg 2017), we instead present this outcome as a risk of major complications regardless of whether a patient gets TLH or VH. We found no clear reason to preferentially select from the 2 outcomes with Moderate certainty, so we have included both pooled estimates as a range (ie, 11.3% from Sandberg 2017 and 14.7% from Lee 2019).
intraoperative	No. Neither of our systematic review sources reported risk of intraoperative visceral	Risk for specific intraoperative visceral

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
visceral injuries (as a class)	injuries overall. In the Sandberg 2017 systematic review, intraoperative visceral injuries were reported only separately per injury and not combined for all types of intraoperative injuries. In the Lee 2019 systematic review, intraoperative visceral injuries were classed as a Grade III complication, but because this Grade III category also includes other non-injury related complications (eg, pulmonary embolism), it cannot be used as a reliable surrogate for intraoperative visceral injury.	injuries will be reported instead of intraoperative visceral injuries overall.
bowel injury	No. The confidence interval is too wide to be meaningful for the comparative estimate.	Because only a single study contributes to this outcome, we calculated the point estimate and 95% confidence interval for the univariate estimate from each group: non-robot-assisted total laparoscopic hysterectomy, 0.8% (95% CI 0.1% to 4.5%); vaginal hysterectomy, 0.7% (95% CI 0.2% to 2.4%). The confidence interval is very wide, and therefore, presenting the bounds of the confidence interval (particularly the upper bound of the confidence interval) may give a misleading impression of bowel injury being more common than other injury types. However, the available evidence does not permit such an inference, and rather, it may simply be a consequence of the limited data for bowel injury. As such, we consider reporting a range of the point estimates to the most reasonable evidence synthesis, giving a range of 0.7% to 0.8%.
urinary tract injury	Yes. The point estimate of the comparative analysis suggests possibly little difference between the two treatment options, and the confidence interval is compatible with either treatment being better than the other. The individual studies contributing to the analysis show a consistent pattern of low overall event rates, including about half of the studies having a 0% event rate for either group. Pooling the data for each group separately yields estimates of 1.2% (14/1149) for the non-robot-assisted total laparoscopic hysterectomy group to 1.4% (16/1144) for the	Other: Pool data across groups to yield a single estimate of risk to be used for both groups

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
	vaginal hysterectomy group. Pooling all the data together (given no clear difference demonstrated between the groups) yields an estimate of 1.3% (30/2,293). We consider 1.3% to be a reasonable approximation of the rate of urinary tract injury for both groups and use this for evidence synthesis.	
bladder injury	Yes. The point estimate of the comparative analysis suggests possibly little difference between the two treatment options, and the confidence interval is compatible with either treatment being better than the other. The individual studies contributing to the analysis show a consistent pattern of low overall event rates, including about half of the studies having a 0% event rate for either group. Pooling the data for each group separately yields estimates of 1.2% (11/898) for the non-robot-assisted total laparoscopic hysterectomy group to 1.2% (8/657) for the vaginal hysterectomy group. Pooling all the data together (given no clear difference demonstrated between the groups) yields an estimate of 1.2% (19/1,555). We consider 1.2% to be a reasonable approximation of the rate of bladder injury for both groups and use this for evidence synthesis.	Other: Pool data across groups to yield a single estimate of risk to be used for both groups
ureter injury	Yes. The point estimate of the comparative analysis suggests possibly little difference between the two treatment options, and the confidence interval is compatible with either treatment being better than the other. The individual studies contributing to the analysis show a consistent pattern of low overall event rates, with three-quarters of the studies having a 0% event rate for either group. Pooling the data for each group separately yields estimates of 0.6% (2/351) for the non-robot-assisted total laparoscopic hysterectomy group and 0.5% (2/444) for the vaginal hysterectomy group. Pooling all the data together (given no clear difference demonstrated between the groups) yields an estimate of 0.5% (4/795). We consider 0.5% to be a reasonable approximation of the rate of ureter injury for both groups and use this for evidence synthesis.	Other: Pool data across groups to yield a single estimate of risk to be used for both groups
infection (as a class)	No. Neither of our systematic review sources reported risk of infection overall. In the Sandberg 2017 systematic review, infections were reported only separately for local infection and organ infection and not combined. In the Lee 2019 systematic review, infections were classed as a Grade I complication (which included urinary tract infection and unspecified infections), but because this Grade I category also includes other non-infection related complications (eg, urinary retention), it cannot be used as a reliable surrogate for infections.	Risk for local and organ infections will be reported instead of infections overall.
local infection	Yes. The pooled effects of TLH vs. VH on local infections from Sandberg 2017 had very	Other: Pool data across groups to yield a

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
	wide CIs compatible with either treatment being better than the other. Because no informative data is available on comparative effects, we report below only the univariate risk of major complications with hysterectomy (either TLH or VH). The three cohort studies contributing to the pooled analysis show a pattern of low overall event rates, although higher in 1 of the 3 studies which appeared to be an outlier (Morton 2008: 2.7% in TLH group; 4.7% in VH group). We considered that reporting a range would give too much emphasis to the higher rates in this one study and reporting a pooled estimate would more accurately reflect the results from all 3 studies. Pooling the data for each group separately yields estimates of 0.9% (4/449) for the TLH group and 0.7% (4/568) for the VH group. Pooling all the data together (given no clear difference demonstrated between the groups) yields an estimate of 0.8% (8/1,017). We consider 0.8% to be a reasonable approximation of the rate of local infection for both groups and use this for evidence synthesis.	single estimate of risk to be used for both groups
organ infection (all were urinary tract infection)	Yes. The pooled effects of TLH vs. VH on organ infections (all urinary tract infections) from Sandberg 2017 had very wide CIs compatible with either treatment being better than the other. Because no informative data is available on comparative effects, we report below only the univariate risk of organ infection with hysterectomy (either TLH or VH). The five cohort studies contributing to the pooled analysis show a pattern of low overall event rates, although somewhat higher in 2 of the 5 studies (Drahonovsky 2010 had outlier event rate for TLH group and Muller 2010 had outlier event rate for VH group. Both had low rates for the other group.) We considered that reporting a range (especially if done separately per group) would give too much emphasis to the outlying rates in Drahonovsky 2010 (TLH group) and Muller 2010 (VH) whereas reporting a pooled estimate would more accurately reflect the results from all 5 studies. Pooling the data for each group separately yields estimates of 1.5% (10/648) for the TLH group and 1.5% (8/537) for the VH group. Pooling all the data together (given no clear difference demonstrated between the groups) yields an estimate of 1.5% (18/1,185). We consider 1.5% to be a reasonable approximation of the rate of organ infection for both groups and use this for evidence synthesis.	Other: Pool data across groups to yield a single estimate of risk to be used for both groups
fever above 38 degrees Celsius	Yes. The pooled effects of TLH vs. VH on fever from Sandberg 2017 had wide CIs compatible with either treatment being better than the other. Because no informative data is available on comparative effects, we report below only the univariate risk of	Other: Pool data across groups to yield a single estimate of risk to be used for both groups

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
	fever with hysterectomy (either TLH or VH). The six studies contributing to the pooled analysis show a pattern of mostly low overall event rates, although higher in 2 of the 5 studies (Drahonovsky 2010 and Kim 2010 both had higher rates in both arms than the other studies). We considered that reporting a range would give too much emphasis to the higher rates in Drahonovsky 2010 and Kim 2010 whereas reporting a pooled estimate would more accurately reflect the results from all six studies. Pooling the data for each group separately yields estimates of 2.5% (21/847) for the TLH group and 3.8% (26/691) for the VH group. Pooling all the data together (given no clear difference demonstrated between the groups) yields an estimate of 3.1% (47/1,538). We consider 3.1% to be a reasonable approximation of the rate of fever for both groups and use this for evidence synthesis.	
postoperative pain at 24 hours (10-point VAS scale) (RCTs only)	Yes. Pooled analysis of 3 randomized trials finds a decrease in postoperative pain with TLH compared to VH. This outcome is included in only the Sandberg 2017 systematic review.	Results from meta-analysis already done The pooled point estimate was a 1.1-point decrease (on 10-point scale) in mean postoperative pain with TLH compared to VH. The mean differences were about 0, 1, and 2 points in the 3 trials. For synthesis, we describe this as slightly less pain in the TLH group.
need for transfusion	Yes. Although the point estimate from Sandberg 2017 favors non-robot-assisted total laparoscopic hysterectomy, the confidence interval is wide and compatible with no difference between treatments or vaginal hysterectomy being better. In the forest plot of the contributing studies, there was little statistical heterogeneity, but this is likely due to wide confidence intervals in most studies, with the pooled estimate being heavily influenced by a single, large cohort study. Reporting the ranges of the individual studies or the mean or median of the individual studies would lead to a situation of potentially-misleading synthesis. Therefore, the two remaining options are either reporting the pooled estimate from each group as a range (for both treatment options) or pooling the data for both groups (which would increase power of the estimate) given there was no clear difference demonstrated between the two groups. We favored the latter approach, as we saw no reason to report the range instead of a single result. Pooling across both groups gives us 3.5% (58/1636). Lee 2019 also reported Grade II complications, which were predominantly (but not	Other: Pool data across groups to yield a single estimate of risk to be used for both groups

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
	entirely) comprised of needing a blood transfusion; however, in the subset of trials limited to non-robot-assisted total laparoscopic hysterectomy vs. vaginal hysterectomy, this outcome suffered from low event rates (total of 9 events among the 455 participants). We therefore did not feel this outcome added meaningfully to the explicitly-defined transfusion outcome in Sandberg 2017.	
vaginal cuff dehiscence	Yes. Pooled analysis of 7 studies finds an increase in vaginal cuff dehiscence with TLH compared to VH. This outcome is included in only the Sandberg 2017 systematic review. Although 42% of the weight in the meta-analysis was from a cohort study which showed a greatly increased risk with TLH (Hur 2011), the other 6 studies contributing to the pooled analysis all also showed an increased risk with TLH although none were statistically significant.	Results from meta-analysis already done The pooled point estimate found an increased risk with TLH compared to VH (odds ratio 6.28, 95% CI 2.38 to 16.57). With this odds ratio and an estimate of 0.07% (2/2,962) in the VH group, the estimated absolute risk in the TLH group is 0.4% (95% CI 0.2% to 1.1%). Of note, vaginal hysterectomies are typically total hysterectomies. A total hysterectomy leaves a woman with a vaginal cuff after surgery. However, total laparoscopic hysterectomy permits either total hysterectomy or subtotal/partial hysterectomy. If a woman elects to have a subtotal/partial hysterectomy, she will still have a cervix after surgery and the outcome of vaginal cuff dehiscence will not apply. However, the choice of whether to have a total or subtotal/partial hysterectomy involves more than this consideration (see Evidence Report on total versus subtotal hysterectomy for benign reasons).

Out of 1000 women having hysterectomy for benign conditions by vaginal hysterectomy or total laparoscopic hysterectomy without robotic assistance:

- **up to 44 (4.4%) may have major complications (such as an injury to an organ during the operation, needing blood, or a major problem with the anesthesia)**
    - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance for major complications.** (Very low certainty)
- **about 113 to 147 (11.3% to 14.7%) may have minor complications (such as bleeding that does not result in needing blood, a collection of blood near the surgery site, fever, temporary difficulty urinating that may require temporary placement of a catheter, or bladder infection)**
    - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance for minor complications.** (Very low certainty)
- **injuries to organs during operation**
    - **about 7 to 8 (0.7% to 0.8%) may have injury to bowel**
    - **about 13 (1.3%) may have injury to ureter and/or bladder**
        - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance for injuries to bowel, bladder, or ureter during the surgery.** (Very low certainty)
- **infections after surgery**
    - **about 8 (0.8%) may have an infection near the site of the surgery**
    - **about 15 (1.5%) may have a urinary tract infection**
        - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance for local infections or urinary tract infections.** (Very low certainty)
- **about 31 (3.1%) may have fever**
    - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance for fever.** (Very low certainty)
- **about 35 (3.5%) may need to get blood**
    - **There may be no meaningful difference between vaginal hysterectomy and total laparoscopic hysterectomy without robotic assistance on need for transfusion.** (Very low certainty)

Out of 1000 women having total laparoscopic hysterectomy without robotic assistance for benign conditions, the area where the vagina was cut to do the surgery may separate in about 4 (0.4%). (Low certainty) **This risk does not apply if a woman chooses to keep her cervix, but the choice to remove or keep the cervix involves more than considering just this risk (see Evidence Report on total versus subtotal hysterectomy for benign reasons).**

Out of 1000 women having vaginal hysterectomy for benign conditions, the area where the vagina was cut to do the surgery may separate in less than 1 (<0.1%). (Low certainty)

Women having total laparoscopic hysterectomy without robotic assistance may have slightly less postoperative pain at 24 hours (about 1-point decrease in pain on 10-point scale) compared to women having vaginal hysterectomy. (Moderate certainty)

Robot-assisted vs. non-robot-assisted total laparoscopic hysterectomy

Evidence Review Tables for FAQ6:

Effects of robot-assisted laparoscopic hysterectomy (RH) vs. non-robot-assisted laparoscopic hysterectomy (nRH) on need for blood transfusion*

Source	Risk in RH group	Risk in nRH group	Relative risk (95% CI)	Certainty (reason for downgrade)
Lawrie 2019	2% (3/148)	1.0% (1/99)	1.94 (95% CI 0.30 to 12.76)	Very low (risk of bias [no blinding in all but 1 trial and unclear allocation concealment in 1 trial with blinding], imprecision [very serious concern], indirectness)
Luciano 2016	397/20781 (1.9%)	1638/78148 (2.1%)	0.91 (95% CI 0.82 to 1.02)	Very low (risk of bias [very serious concern; observational data], imprecision, indirectness)
Rosero 2013	165/7788 (2.1%)	244/7788 (3.1%)	0.67 (95% CI 0.55 to 0.82)	Very low (risk of bias [very serious concern; observational data], indirectness)
Wright 2013	68/4971 (1.4%)	87/4971 (1.8%)	0.80 (95% CI 0.55 to 1.16)	Very low (risk of bias [observational data], imprecision, indirectness)

* Lawrie 2019's results are from 3 trials. The others are single observational studies.

Effects of robot-assisted laparoscopic hysterectomy (RH) vs. non-robot-assisted laparoscopic hysterectomy (nRH) on infectious complications

Source (No studies and study type)	Risk in RH group	Risk in nRH group	Relative risk (95% CI)	Certainty (reason for downgrade)
Lawrie 2019 (4 trials)	1.5% (3/195)	2.3% (4/172)	0.62 (95% CI 0.13 to 2.88)	Very low (risk of bias [no blinding in all but 1 trial and unclear allocation concealment in 1 trial with blinding], imprecision [very serious concern], indirectness)
Marra 2019 (16 observational studies)	3.1% (1324/43028)	5.4% (6706/123933)	1.09 (95% CI 0.71 to 1.66)	Very low (risk of bias [very serious concern; observational data], imprecision, inconsistency, indirectness)

Effects of robot-assisted laparoscopic hysterectomy (RH) vs. non-robot-assisted laparoscopic hysterectomy (nRH) on fever

Source	Risk in RH group	Risk in nRH group	Relative risk (95% CI)	Certainty (reason for downgrade)
Rosero 2013	20/7788 (0.2%)	14/7788 (0.2%)	1.4 (95% CI 0.72 to 2.82)	Very low (risk of bias [very serious concern; observational data], imprecision, indirectness)

Effects of robot-assisted laparoscopic hysterectomy (RH) vs. non-robot-assisted laparoscopic hysterectomy (nRH) on urinary tract infection

Source	Risk in RH group	Risk in nRH group	Relative risk (95% CI)	Certainty (reason for downgrade)
Rosero 2013	48/7788 (0.6%)	65/7788 (0.8%)	0.7 (95% CI 0.50 to 1.07)	Very low (risk of bias [very serious concern; observational data], imprecision, indirectness)

Descriptive Evidence Review for FAQ6:

Other than the outcomes shown in the above Evidence Review Tables, evidence for this comparison and FAQ is very limited for the following key reasons:

- many sources have low or very low event rates for various outcomes, thus precluding reliable inference (eg, Aarts 2015, Lawrie 2019)
- the only source reporting on "major complications" (Luciano 2016) used an overly-restrictive definition (only those complications that resulted in re-intervention related to the hysterectomy), resulting in substantial concern for underestimating the true rate of major complications, and
- many sources reported composite risk outcomes (eg, any complication, postoperative complications) that:
    - did not correspond to any composite risk outcomes reported for the comparison of total laparoscopic hysterectomy (thus precluding meaningful comparison of the 3 treatment options being considered in this Evidence Report), and
    - are inappropriately broad and therefore of limited or no clinical utility; for instance, 3 evidence sources (Luciano 2016, Rosero 2013, and Wright 2013) considered "any" complication or "overall" complications, which either explicitly included very serious events (eg, death, stroke, cardiac arrest) with less serious (eg, needing a transfusion) and/or rather minor issues (eg, fever) or only gave vague categorical descriptors of included events that still suggested of a broad array of possibilities that patients would be unlikely to consider equally important.

Because of these issues, we did not progress these outcomes to Evidence Review Tables in Part 4, but we still provide the brief review above to highlight the issues in the existing evidence.

Outcomes remaining for the comparison of robot-assisted vs. non-robot-assisted laparoscopic hysterectomy after the above considerations are shown below:

Source	Outcome	Risk in robot-assisted group	Risk in non-robot-assisted group	Relative risk (95% CI)
Luciano 2016	wound complications	0.3%	0.3%	0.91 (95% CI 0.67 to 1.22)
Wright 2013	surgical site complications	1.7%	2.0%	0.85 (95% CI 0.64 to 1.13)
Rosero 2013	surgical complications	4.7%	5.3%	0.87 (95% CI 0.76 to 1.01)
Wright 2013	medical complications	1.6%	1.2%	1.35 (95% CI 0.97 to 1.88)

Certainty for all the above outcomes is Very low (risk of bias [very serious; observational data], imprecision, and indirectness [did not clearly limit to total laparoscopic hysterectomy or explicitly included laparoscopically-assisted vaginal hysterectomy]).

However, a general pattern may seem to emerge from the above outcomes: There is no clear difference or possibly no meaningful difference between robot-assisted laparoscopic hysterectomy vs. non-robot-assisted laparoscopic hysterectomy. We acknowledge that 2 outcomes are of borderline statistical significance (surgical complications in Rosero 2013 and medical complications in Wright 2013), and one might reasonably contend that disregarding those outcomes based solely on the failure to pass the (ultimately arbitrary) threshold of $p < 0.05$ would be overly simplistic. We would agree with this contention, but our inference is not limited to this threshold. Rather, we emphasize: (1) even if the "truth" is that there is a difference, the absolute difference was small in both studies (0.6% and 0.4%, respectively); (2) one outcome would "favor" robot-assisted laparoscopic hysterectomy, whereas the other would "favor" non-robot-assisted laparoscopic hysterectomy; (3) because of how the outcome was defined, no meaningful comparison can be made against the data for non-robot-assisted total laparoscopic hysterectomy (obtained from the comparison of non-robot-assisted total laparoscopic vs. vaginal hysterectomy); and (4) particularly given the Very low certainty of these results, we feel strongly that a more reasonable conclusion would highlight the issues with the existing evidence and suggest the presently-available evidence does not convincingly demonstrate a meaningful difference for this comparison.

Evidence Synthesis Process for FAQ6:

Outcome	Appropriate to give a single synthesis result?	Suggested best approach
transfusion	No. The above data table shows results from several evidence sources, but all are of Very low certainty. We conducted a meta-analysis of all available data (functionally a meta-analysis of observational data). However, this meta-analysis has Very low certainty and a result consistent with both lower risk with robot-assisted hysterectomy and no difference.	Meta-analysis created from results, presented qualitatively We combined the data from the 4 difference data sources, yielding 6 studies being meta-analyzed for a pooled result (the data from Lawrie 2019 are based on 3 trials, and the most appropriate approach is to enter the data from those 3 trials separately). We used a random-effects model throughout, and although the results appear to display a trivial degree of sensitivity to model parameters, we discuss this briefly below to prevent any confusion. For instance, if using the Sidik-Jonkman, Paule-Mandel, or restricted maximum likelihood estimators (along with the methods of Hartung-Knapp in each case, and with all analyses carried out with R version 3.6.1 and meta package 4.9-6), the meta-analytic relative risk is 0.80 (95% CI 0.63 to 1.03), 0.81 (95% CI 0.66 to 0.999), and 0.80 (95% CI 0.64 to 1.00), respectively. If using the DerSimonian-Laird estimator (analysis carried out with same software and package, with this method being mentioned because it is the only random-effects estimator available in RevMan despite having noteworthy limitations compared to other methods), the meta-analytic relative risk is 0.80 (95% CI 0.67 to 0.97). Some may make different inferences based on whether the upper bound of the confidence interval crosses 1 (the line of no effect). However, this would be an overly-simplistic interpretation of rather consistent results. The point estimate is approximately 0.80, the lower bound approximately 0.65, and the upper bound approximately 1. Given the Very low certainty, we favor presenting the estimate for robot-assisted total laparoscopic hysterectomy as being similar to vaginal hysterectomy or non-robot-assisted total laparoscopic hysterectomy or possibly “somewhat lower” without explicit quantification of the degree by which it might be lower.
infectious complications	No. Both evidence sources suggest there may be no difference in infectious complications. However, Lawrie 2019 suffers from greater imprecision than Marra 2019, and although Marra 2019 uses observational data, it ultimately represents a more robust source of evidence in this case (and also has results that are broadly consistent with Lawrie	Qualitative description without quantitative representation: Given the considerations in the column to the left and because there is no comparable outcome for non-robot-assisted total laparoscopic hysterectomy (ie, no overall infectious complications outcome), we provide a qualitative description of these results, namely: “There may be no difference in the risk of getting an infection with robot-assisted total laparoscopic hysterectomy compared to total laparoscopic

	2019, though again, the imprecision in Lawrie 2019's results impedes this analysis). The point estimate for Marra 2019 suggests no meaningful difference between the two groups, but the confidence interval is consistent with either method being better than the other.	hysterectomy without robotic assistance."
fever	No. Although only one evidence source reports on this outcome, it fails to demonstrate any clear difference between the two options. The risk of fever was very low in both groups, and although the point estimate of the relative risk favors non-robot-assisted surgery, the confidence interval is compatible with either option being better than the other.	Qualitative description without quantitative representation. Given the considerations in the column to the left, we provide a qualitative description of these results, namely: "There may be no difference in the risk of developing a fever after surgery with robot-assisted total laparoscopic hysterectomy compared to total laparoscopic hysterectomy without robotic assistance."
urinary tract infection	No. Although only one evidence source reports on this outcome, it fails to demonstrate any clear difference between the two options. Although the point estimate and majority of the confidence interval suggests a possible benefit with robot-assisted surgery, we are reluctant to conclude this suggests a "real" benefit given the Very low certainty of the evidence. Additionally, both groups had a very low risk for urinary tract infection, and this is generally consistent with the low risk for urinary tract infection in the total hysterectomy group in the evidence for the comparison of total laparoscopic hysterectomy vs. vaginal hysterectomy (so any difference is likely to be of questionable clinical importance anyway).	Qualitative description without quantitative representation. Given the considerations in the column to the left, we provide a qualitative description of these results, namely: "There may be no difference in the risk of developing a urinary tract infection with robot-assisted total laparoscopic hysterectomy compared to total laparoscopic hysterectomy without robotic assistance." However, because urinary tract infection is ultimately an infectious complication and because the evidence synthesis ultimately reaches the same conclusion, in our bolded evidence synthesis statements, we do not mention urinary tract infection separately.
other complications data (see Descriptive Evidence Review)	No. Reasons are stated in the Descriptive Evidence Review.	Given the considerations in the Descriptive Evidence Review, we feel the following is a reasonable evidence synthesis statement following the above-noted descriptive statements: "Evidence for other risks is either too limited for us to know how robot-assisted total laparoscopic hysterectomy compares to total laparoscopic hysterectomy without robotic assistance or does not show any clear difference between the two."

Women who have a total laparoscopic hysterectomy with robotic assistance may have the same chance or a slightly lower chance of needing blood compared to women who have a total laparoscopic hysterectomy without robotic assistance. (Very low certainty)

There may be no meaningful difference in the risk of getting a fever or infection when a total laparoscopic hysterectomy is done with or without robotic assistance. (Very low certainty)

Evidence for other risks is either too limited for us to know how total laparoscopic hysterectomy with robotic assistance compares to total laparoscopic hysterectomy without robotic assistance or does not show any clear difference between the two. (Very low certainty)

Evidence report for report for surgical approaches to hysterectomy for benign conditions

Reference list

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