

QUESTION

Should robot-assisted surgery vs. conventional laparoscopic surgery be used for hysterectomy?	
POPULATION:	Women with a benign or malignant health condition requiring simple or radical hysterectomy
INTERVENTION:	Robot-assisted laparoscopic hysterectomy (RAH)
COMPARISON:	Conventional laparoscopic hysterectomy (CLH)
MAIN OUTCOMES:	
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTEREST:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input checked="" type="radio"/> Don't know 	<p>The problem has been prioritized by Swiss Medical Board previously.</p>	n/a
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input checked="" type="radio"/> Trivial <input type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>The evidence of clinical effectiveness and harm of robot-assisted hysterectomy (RAH) was based on six randomized, controlled trials involving a total of 632 participants. In one trial, RAH showed no difference in post-operative pain when compared to conventional laparoscopic hysterectomy (CLH). The mean difference was -2.00 (95%CI -16.08 to 12.08), but the pain scale (range) was not reported. Moreover, data covered interventions for benign conditions only.</p> <p>In a single study in patients with endometrial cancer comparing RAH and CLH, no deaths in either treatment group occurred. Neither this nor any other study reported disease-free survival times. The evidence from two studies in benign conditions suggests small gains in quality of life in favor of RAH although data could not be pooled.</p> <p>RAH may have reduced LOS by less than one day (MD -0.30 day, 95% CI -0.53 to -0.07; MCID = 1 day). It remained uncertain whether RAH led to a reduction of total operating time; the mean difference between RAH and CLH was 41.18 min with 95% CI ranging from -6.17 to 88.53 min. Both these estimates were from two studies in benign conditions only.</p>	<p>Literature that was not formally included in this assessment documents potential advantages such as shorter operating times, decreased blood loss, fewer conversions to laparotomy, and shorter LOS for RAH compared to CLH in endometrial cancer. Surgeons practicing RAH argue that several steps of the surgery can be performed more easily with RAH than with CLH. This includes securing the uterine vessels and cardinal ligaments, performing accurate colpotomy, and oversewing the vaginal cuff. For endometrial cancer, uncontrolled studies describe more favorable results for RAH including better lymph node yield, reduced blood loss, lower complication rates and conversion rates, and shorter LOS, while the duration of surgery is comparable. Similarly, studies of robot-assisted laparoscopic radical hysterectomy in cervical cancer reported favorable results. Furthermore, case reports suggest that robot-assisted trachelectomy (i.e. removal of the cervix) may be an option for women seeking to preserve fertility because it allows better visualization of the vasculature and parametrial tissues. In the treatment of ovarian cancer, robot-assisted surgery still seems to be uncommon because of the difficulty to perform extensive exploration of the abdomen. There is limited evidence suggesting that robot-assisted surgery may be suitable in selected cases of early ovarian cancer.</p>
Undesirable Effects		
How substantial are the undesirable anticipated effects?		

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Moderate <input checked="" type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Intra- and post-operative complications after RAH and CLH were comparable; relative risk (RR) associated with RAH was 0.76 (95%CI 0.38 to 1.53) in benign conditions and 1.47 (95%CI 0.79 to 2.72) in endometrial cancer. When compared to CLH, RAH may have led to a higher risk of needing blood transfusions in benign conditions (RR 1.94; 95%CI 0.30 to 12.76) as well as in endometrial cancer (RR 2.94; 95%CI 0.62 to 13.87). None of the differences reached statistical significance.</p>	<p>Compared with the conventional approach, RAH might require more port incisions, and this may increase procedural risks. Mortality has been considered an important outcome but follow-up in trials including patients with endometrial cancer of International Federation of Gynecology and Obstetrics (FIGO) stage < II was not sufficiently long to show any difference (prognosis is good in general). RAH may increase the risk of complications from anesthesia due to the particular positioning of the patient. It has been reported that RAH increases the risk of damage to the ureter, especially in ovarian surgery. With RAH and robot-assisted surgery in general, there is a complete lack of haptic feedback for the surgeon, and this requires additional training.</p>

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>The quality of the evidence was moderate for the outcome 'intraoperative complications' but either low or very low for all others. In Switzerland, only the DaVinci® robot system (several versions) is used. However, the studies considered were conducted abroad, and they may have used systems from other manufacturers. It remains unclear whether these systems are comparable. It is conceivable that differences between systems would entail differences in the profile of desirable or undesirable effects if robot-assisted surgery was to be used more widely in Switzerland. Another shortcoming is that intensity and duration of training that surgeons received prior to the beginning of the trials was not reported. The surgeons' experience with a new technique is an important factor that influences the magnitude of the desirable and undesirable effects observed.</p> <p>The small number of studies included does not allow proper analysis of selective reporting (e.g. with funnel plots). Robot-assisted technology remains controversial because of the significant commercial interests. In the USA, hospitals promote the use of robot systems in gynecology without disclosing the inherent limitations and costs. For instance, hospital websites claim benefits such as reduced postoperative pain, shorter recovery time, and less blood loss with robot-assisted surgery. However, the few well-designed studies available to date provide insufficient evidence of the net benefit over the conventional laparoscopic technique. In addition, a considerable risk of bias was noted in a review of predominantly non-randomized studies of RAH versus other approaches (Kristensen <i>Acta Obstet Gynecol Scand</i> 2017).</p>	<p>None</p>

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability 	<p>A systematic search and assessment of the published research evidence of patient values with regard to robot-assisted laparoscopic</p>	<p>Patients may perceive robot-assisted surgery as more precise and reliable because it is a new and promising technology. However, the lack of high-quality evidence for patient-relevant outcomes may not be sufficiently well addressed in</p>

<ul style="list-style-type: none"> ● No important uncertainty or variability 	<p>hysterectomy was not part of the formal assessment.</p>	<p>conversations between health professionals and patients. Such information would be very important. For instance, concerns about potential complications may determine a patient's decision to undergo surgery.</p> <p>Another consideration was whether patients have a true choice between surgical interventions when being referred to a particular center. Depending on the expertise of surgeons and technical platform, the choice of center may determine which type of intervention will be proposed as first-line choice. Nevertheless, surgeon should inform patients about alternatives, even though these may not be offered by the particular center. In the context of this analysis, it could not be elucidated whether such information prior to obtaining the patient's consent is part of routine patient briefing. Additionally, other details (e.g. that the surgeon is not in the same room during the robot-assisted inter-vention) should be communicated in full. It was argued that, in the absence of any clear (contra-) indication for robot-assisted surgery, the technique might be preferred in some settings also because it will provide a training opportunity for surgeons.</p>
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Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Favors the comparison ○ Probably favors the comparison ● Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know 	<p>The low quality of evidence precluded a detailed appraisal of the balance between RAH and CLH regarding desirable and undesirable effects. Overall, this balance seems comparable for RAH and CLH. It appeared that RAH is rarely used in hysterectomies in Switzerland. Surgeons who were consulted stated that they almost exclusively perform CLH, despite the availability of a robot system at their center. This suggested that the level of experience with RAH in most Swiss hospitals is low, apart from very few centers.</p>	<p>None</p>

Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Large costs ● Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know 	<p>In the <i>de novo</i> cost analysis for simple or radical hysterectomy, two scenarios were examined from a health insurance perspective. First, it was assumed that in a given hospital, a robot system would be used to perform 10 RAH interventions and 65 other surgical interventions for both benign and malignant conditions in one year (base case #1). This scenario led to higher total costs per patient with RAH as compared to CLH. The costs estimated were CHF 18,514 versus CHF 12,950 for benign conditions (difference of CHF 5,564) and CHF 19,975 versus CHF 15,642 for malignant conditions (difference of CHF 4,333). The cost increase was mainly due to the more expensive surgery equipment use with RAH. The difference between interventions for benign and malignant conditions was mainly due to different durations of the intervention (i.e. time in the operating room). In benign conditions, surgery time and related costs were higher for RAH than for CLH while the opposite was true in malignant conditions. Furthermore, a small difference in costs was related to complications: patients undergoing RAH for benign conditions had a lower risk of</p>	<p>Realistic estimation of incurred costs would need to account for the number and qualification of staff needed to perform the surgical intervention. In one Swiss hospital, the surgery team for RAH currently comprises two senior surgeons, a surgeon in training, and two nurses. With increasing experience and routine, it may be possible to reduce the number of staff needed, and this would reduce the overall costs to be attributed to the intervention. In addition, the duration of surgery and time in the operating room can be reduced considerably (up to 70%) with increasing experience.</p>

	<p>perioperative adverse events. In contrast, a higher risk of adverse events for RAH was estimated in malignant conditions. In both cases, the estimated differences did not reach statistical significance.</p> <p>Second, it was assumed that 100 RAH interventions and no other robot-assisted surgeries were performed in one year (base case #2). RAH incurred higher costs than CLH even in this scenario. The costs estimated were CHF 16,954 versus CHF 12,950 for benign conditions (difference of CHF 4,004) and CHF 18,415 versus CHF 15,642 for malignant conditions (difference of CHF 2,773). These differences were less pronounced than those calculated in base case #1, especially for malignant conditions. Again, the total number of interventions per year determined the costs for surgical equipment and the cost difference between RAH and CLH.</p>	
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Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Very low ● Low ○ Moderate ○ High ○ No included studies 	<p>Many assumptions had to be made for the <i>de novo</i> cost analysis and budget impact analysis. Some of these were based on the sparse evidence from the studies included. The number of studies included for benign and malignant conditions was small and estimates of desirable and undesirable effects were imprecise.</p> <p>Several aspects that may have influenced differences in costs between RAH and CLH could not be included in the model. For example, oncological outcomes (e.g. overall survival, cancer-specific survival, or recurrence), long-term undesirable effects (e.g. urinary incontinence) and resulting outpatient visits or hospital readmissions were not taken into account when considering resource requirements because there was no published evidence suggesting a significant difference between RAH and CLH.</p> <p>Many of the additional considerations by the Appraisal Committee in connection with the DaVinci® robot system for robot-assisted radical prostatectomy (see EtD document for this intervention) also apply to its use for RAH. This includes the lack of precise cost estimates from Swiss hospitals, information about staff learning curve, or costs occurring when a center changes from using the conventional technique routinely to robot-assisted or vice versa.</p> <p>Taking into account these limitations, the Appraisal Committee concluded that the quality of evidence about resource requirements for simple or radical hysterectomy was low.</p>	None

Cost effectiveness

Does the cost-effectiveness of the intervention favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
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<ul style="list-style-type: none"> ● Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ No included studies 	<p>The results of the budget impact analysis suggested that the total direct costs of patients undergoing RAH or CLH in Switzerland were CHF 79.9 million in 2015. It was estimated that RAH accounted for about 4% of interventions and about 6% of costs for simple or radical hysterectomy in both benign and malignant conditions. If the current practice were changed to a scenario in which CLH is performed exclusively, this would entail savings of CHF 1.3 million. In turn, a scenario assuming exclusive use of RARP would increase the total costs for hysterectomy by CHF 4.0 million. This model takes into account economies of scale as a consequence of the improved exploitation of the robot systems in place.</p> <p>In the short-term, increased use of RAH would cause additional direct costs as long as the caseload per robot remains low. The considerable costs for purchase and maintenance of the robot system as well as disposable equipment are only partially compensated by savings due to potentially shorter LOS. Increased use of the robot system for RAH would affect the overall costs only modestly because higher caseload substantially reduces per-patient costs.</p>	None
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Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Reduced ○ Probably reduced ● Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know 	<p>Systematic search and assessment of the published research evidence of health equity with a focus on access to robot-assisted surgery was not part of the formal assessment.</p>	<p>Robot-assisted and conventional (laparoscopic) hysterectomy are available for patients with basic statutory health insurance in Switzerland. The same policy for reimbursement applies for both approaches. It is unlikely that there are subgroups in the population that would be disadvantaged systematically, e.g. by withholding the robot-assisted intervention. Patients with private health plans are more likely to be offered new technologies with unproven benefit. However, the Appraisal Committee did not attempt to corroborate this assumption with evidence specific to robot-assisted surgery. In the absence of clear clinical guidance in which cases a robot-assisted intervention is clearly indicated (or not), the choice will heavily depend on the preferences of both patients and surgeons. For instance, in one Swiss hospital, patients with endometrial cancer (FIGO stage < II) who are eligible for robot-assisted surgery are very likely to actually receive this type of intervention while this may not be the case in other centers. Given that there is little support for the superiority of one approach over the other, the question of equitable access to the new technology may be of less importance than if one option was clearly superior.</p>

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know 	<p>Systematic search and assessment of the published research evidence of the acceptability of robot-assisted surgery for both patients and health professionals was not part of the formal assessment.</p>	<p>If robot-assisted technology is being promoted in the general public, a conventional approach such as open laparotomy might be perceived as an outdated technique. Patients' preference for or against the use of a robot system during surgery might not be pre-determined <i>per se</i> but may heavily depend on what information they receive.</p> <p>The Appraisal Committee discussed that, other than with drug interventions, a new technology is much more likely to enter the healthcare sector without the regulatory requirement to first demonstrate any net clinical or health economic benefit. Consequently, there are no hurdles for manufacturers to introduce such new technologies to the market. There is no</p>

		<p>strong legal instrument to regulate the use of robot systems in Swiss hospitals.</p> <p>General feedback from practitioners who perform both robot-assisted and conventional surgery for either indication revealed that the robot system is associated with higher comfort for the operating surgeons and is thus more acceptable from their perspective. Robot-assisted surgery has some technical advantages such as three-dimensional vision, better and more precise visibility of the surgical site, better ergonomics, a higher degree of freedom of the robotic instruments, and a reduction of tremor interference.</p> <p>On the other hand, lack of direct access to the patient has been mentioned as a disadvantage (Sarlos <i>Eur J Obstet Gynecol Reprod Biol</i> 2010; Maenpaa <i>Am J Obstet Gynecol</i> 2016). Some surgeons seem to prefer open hysterectomy for malignant conditions when pelvic lymph node dissection (PLND) needs to be carried out as part of the intervention. It appears that they are more likely to achieve the intended result if PLND is performed by laparotomy. Gynecological surgeons emphasized that robot systems may be used less frequently if the expected time needed for preparation or the intervention itself is longer than with CLH, and explained that they might prefer CLH even though the robot system is available at their hospitals.</p> <p>An additional aspect mentioned was that it may be of less interest for surgical trainees to learn the open surgery technique if it is perceived as outdated. Opportunities to perform it regularly may even become rare in some hospitals. The Appraisal Committee considered that in the future, a patient's risk of undesirable effects might increase if open surgery is clearly indicated but attending surgeons will be less well trained and experienced with this approach.</p>
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Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Robot systems suitable for simple or radical hysterectomy are in place in many secondary and tertiary hospitals in all Swiss regions. Consequently, the technology has already been introduced and can be considered feasible from a technical and organizational point of view.</p>	<p>None</p>

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know

JUDGEMENT

RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention <input type="radio"/>	Conditional recommendation against the intervention <input checked="" type="radio"/>	Conditional recommendation for either the intervention or the comparison <input type="radio"/>	Conditional recommendation for the intervention <input type="radio"/>	Strong recommendation for the intervention <input type="radio"/>
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CONCLUSIONS

Recommendation

For simple or radical hysterectomy, the Appraisal Committee issues a conditional recommendation against the use of the robot-assisted laparoscopic technique.

Justification

There is no evidence for a net benefit of robot-assisted hysterectomy for patients with benign or malignant conditions.

Subgroup considerations

For simple or radical hysterectomy, it is important to consider that the balance of desirable and undesirable effects between surgical approaches may depend on patient criteria such as age or comorbidity. In addition, there are differences between robot-assisted hysterectomy for benign and malignant conditions that may be important for the individual choice of surgical technique.

Implementation considerations

Robot-assisted laparoscopic surgery should be restricted to hospitals with a minimal number of interventions per year because this is critical for quality assurance and economies of scale. The minimal caseload for Swiss hospitals should be determined based on an in-depth analysis of relevant data from the Swiss healthcare system, and, ideally, a structured consensus process with the participation of stakeholders.

The present Appraisal Report assessed the use of robot-assisted surgery for two selected indications but not for robot-assisted surgery in general. The information provided to patients, the general public, and decision makers (e.g. in hospitals) should reflect the current state of knowledge and avoid any extrapolation to future generations of the devices.

Monitoring and evaluation

Hospitals incur high costs at the time of purchase of the robot system. This entails the potential that the use of robot systems is promoted with the aim of better amortization and to provide training opportunities for surgical staff. To date, there is no systematic collection of data (e.g. a registry) on the use of robot-assisted technology in the centers, either within the specialties using the technique or across specialties. Given that the number of hospitals using such robot systems is still limited, efforts should be made to improve the monitoring of this technology and to systematically collect outcome data.

Research priorities

In the light of the large numbers of patients undergoing robot-assisted surgery in routine healthcare, the paucity of research evidence from comparative studies is striking. Targeted clinical research should include studies of adequate size and length of follow-up that measure critically important patient-relevant outcomes. This may include investigator-initiated trials or prospective cohort studies involving multiple centers. Such studies should allow estimating with greater confidence the desirable and undesirable effects of the technology, which is crucially needed for evidence-based decision making. Methods of implementation research, such as mixed quantitative and qualitative studies, may be employed to better understand contextual factors, e.g. whether robot-assisted technology is accepted by patients and health professionals.