

QUESTION

Should Robot-assisted radical prostatectomy vs. open radical prostatectomy be used for the treatment of localized prostate cancer?

POPULATION:	Men with diagnosis of localized prostate cancer
INTERVENTION:	Robot-assisted radical prostatectomy
COMPARISON:	Open radical prostatectomy
MAIN OUTCOMES:	
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<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	Problem has been identified as priority by Swiss Medical Board previously.	n/a

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input checked="" type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know	Based on evidence from one randomized controlled trial in 326 participants, RARP likely resulted in little to no difference in urinary tract function when compared to retropubic ORP (mean difference [MD] -1.30, 95%CI -4.65 to 2.05). The minimal difference perceived by patients as clinically important (MCID) was 6 points on a scale from 0 to 100. Furthermore, RARP did not appear to result in any significant difference in sexual function (MD 3.90, 95%CI -1.84 to 9.64 with MCID = 10 points). RARP reduced the length of hospital stay (LOS) by one or two days (MD -1.72 days, 95% CI -2.19 to -1.25 with MCID = 1 day). In addition, RARP did not appear to be associated with any difference in the need for blood transfusions (RR 0.16, 95% CI 0.02 to 1.32).	Observational studies that were not included in the assessment reported that both urinary tract and sexual functions were better in men who had RARP than in those who had ORP. A cohort study included all men diagnosed with prostate cancer in England between April and October 2014 who underwent prostatectomy in the National Health System (Nossiter <i>Br J Cancer</i> 2018). Eighteen months after diagnosis, RARP was associated with better sexual function (EPIC-26 sexual function scale). The difference to ORP was only 4 points (scale 0 - 100) while the established threshold for a clinically meaningful difference was 10 to 12 points. This suggests that most patients would not identify this improvement as important. There was no significant difference in other functional parameters, including continence or health-related quality of life. A cohort study of US Medicare patients reported comparable rates of complications and need for additional cancer therapies after RARP and ORP (Gandaglia <i>J Clin Oncol</i> 2014). Although RARP was associated with a lower risk of blood transfusions and slightly shorter LOS, these benefits did not translate into decreased expenditures and were mostly due to the laparoscopic approach. Generally, observational data need to be interpreted with caution given the increased risk of bias in these studies. The clinicians consulted for this Appraisal Report pointed out that RARP offers physical convenience to the surgeon, who can perform RARP in a more comfortable sitting position and without trembling of hands and instruments. However, this does not necessarily translate into a difference in desirable effects.

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 checked="" type="radio"/> Moderate <input type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Based on the evidence from one randomized controlled trial in 326 participants, RARP appeared to result in some reduction in postoperative pain as compared to ORP after one day (MD -1.15; 95%CI -1.68 to -0.62) and after one week (MD -1.13; 95%CI -1.65 to -0.61). However, there seemed to be little or no difference in postoperative pain after 12 weeks (MD 0.01, 95%CI -0.32 to 0.34). In addition, RARP appeared to result in little to no reduction of surgical (intra- and perioperative) complications of any severity (RR 0.41, 95%CI 0.16 to 1.04) and of serious postoperative complications (RR 0.16, 95% CI 0.02 to 1.32) although the point estimates suggested that RARP may have a potential to reduce these undesirable effects.</p>	<p>Given that RARP was only compared to ORP, any reduction in postoperative pain may be attributed to the laparoscopy itself, and it is unlikely that postoperative pain reduction is a specific effect of using the robot system. Furthermore, there might be some disadvantages with robot-assisted surgery that are not seen with conventional laparoscopy or with open surgery. For instance, patients need to be wrapped in plastic foil during the intervention, the positioning during the intervention differs, and there may be an additional need for perfusions. Additionally, conversion to open surgery might sometimes be necessary, which confers a considerable prolongation of total operating time.</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>For the included outcomes, the evidence of clinical effectiveness and harm was of moderate or low quality. For one of the <i>critically important</i> outcomes (i.e. serious postoperative complications), the quality of evidence was low. Consequently, the <i>overall</i> quality of the evidence of clinical effectiveness and harm was low.</p>	<p>The included outcome data originated from postoperative follow-up for the first 12 weeks. However, prostate cancer survivors deal with the potential adverse effects of the surgery, such as urinary incontinence or erectile dysfunction, for years. Consequently, the available research evidence appears to be insufficient to guide clinical decision-making. The data from mid-term to long-term follow-up in the included study were published only after completion of the Assessment Report. Urinary tract and sexual function did not differ between RARP and ORP after 6, 12, and 24 months (Coughlin <i>Lancet Oncol</i> 2018). The significant difference in cancer recurrence (RARP 3% vs. ORP 9%) was explained by the absence of standardization in postoperative management and the use of additional cancer treatments. The study authors concluded that the benefits of the robot-assisted approach are largely related to its minimally invasive nature.</p> <p>When assessing newly developed surgical techniques such as robot-assisted laparoscopy, appraisal of the ongoing evolution of the procedure and technology is a challenge. Available research evidence may originate from studies that have used a first-generation device, whereas the next (and possibly improved) generation may have already been introduced outside the trial setting. This hampers a fair comparison of interventions at one particular point in time.</p> <p>Furthermore, stakeholders pointed to the learning curve of surgeons performing the new technique in clinical trials and routine care. Certain outcomes of surgery depend on the surgeon's experience and the center's caseload. The design of the one trial included in this assessment did not account for differences in the performance of surgeons; RARP and ORP were performed by two different surgeons whose experience with their respective technique (number of interventions performed) varied. Any resulting difference in patient outcome might be explained by such factors rather than by the actual surgical approach.</p> <p>Presently, there are no clinical guidelines in Switzerland for the use of robot-assisted surgery in prostate cancer. The choice of surgical technique is a case-by-case decision based on local preferences, expertise, and availabilities, which also includes aspects of comorbidity.</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"> ○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ● 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 prostatectomy was not part of the formal assessment.</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 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 intervention) 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>

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>Based on the available evidence, there are no substantial differences between the two surgical approaches, especially in patient-relevant outcomes.</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 of radical prostatectomy, two scenarios were examined from a health insurance perspective. First, it was assumed that in any given hospital, a robot system would perform 50 RARP interventions and 25 other surgical interventions per year (base case #1). This scenario led to higher total costs per patient for RARP (CHF 24,495) compared to ORP (CHF 20,532). The cost difference between the interventions thus amounted to CHF 3,963, which was mainly driven by the higher costs of surgical equipment for RARP (excess of CHF 8,055). In contrast, estimated costs for the hospital stay after RARP were lower (by CHF 2,826) because of the shorter LOS. Costs for staff and operating room were CHF 891 less for RARP under the assumption that hourly rates for the operating room and operating surgeons were the same for both RARP and ORP. Costs due to complications in the perioperative period did barely differ (CHF 376 lower with RARP). Base case #2 assumed</p>	<p>Our <i>de novo</i> cost analysis did not take into account <u>all costs</u> for RARP and ORP but focused on cost items that were assumed to differ between the two interventions. During the appraisal, it was suggested that robot-assisted surgery requires more time for preparation in the operating room and that usually one or two additional staff are required. At the same time, it was argued that a robot-assisted surgical intervention may require only one surgeon, leading to lower estimates of staff costs. However, our cost analysis was based on limited information since many of the contacted centers did not respond. Currently, it seems difficult to obtain robust empirical data on the routine use of robot systems in RARP. According to stakeholders, Swiss hospitals are participating in the continued certification program for prostate cancer centers in Germany (www.dvpz.de). So far, no registry or other representative data collection to provide economic information has been established in Swiss hospitals.</p> <p>Our cost analysis assumed that the price of a new DaVinci® robot system is about CHF 1.8 million, and that annual maintenance costs account for approximately 10% of the purchase price (i.e. CHF 180,000). Currently, only one manufacturer (Intuitive Surgical, Inc., Sunnyvale, California, USA) offers robot systems for radical prostatectomy in Switzerland. With lacking competition,</p>

	<p>that 100 RARP interventions and no other robot-assisted surgeries were performed per year. In this scenario, the excess cost per RARP patient (compared to ORP patients) decreased to CHF 2,417. When the number of robot-assisted interventions was increased to 209 in our model, a threshold was reached after which the costs per patient was lower with RARP than with ORP.</p> <p>A main factor that drove the cost difference between RARP and ORP in our cost analysis was the initial costs to purchase the robot system and its overall life span. If the costs for the robot system were excluded from the model, the cost difference between RARP and ORP in base case #1 decreased from CHF 3,963 to CHF 196. Additional factors were (i) hourly rate for use of the operating room for either intervention, (ii) total number of robot-assisted surgical interventions per year, and (iii) the costs for hospital stay (excluding surgery).</p>	<p>this manufacturer has no incentive to lower the price. The first generation of DaVinci® robots currently used in Swiss hospitals will need to be replaced in the coming years. Apparently, a second-hand market of robot systems is emerging, and this will potentially lower the purchase price. This aspect was not considered in the present economic analyses.</p> <p>Total costs of robot-assisted interventions include fix and variable costs and, thus, depend on the number of interventions per hospital. Swiss centers performing RARP differ substantially with respect to the number of interventions performed with the robot system. For hospitals with an annual caseload (for any robot-assisted intervention) of less than 25, the costs per intervention are even higher. The current German guideline for the treatment of prostate cancer recommends that a center should perform at least 50 RARP and an individual surgeon at least 25 RARP per year.³</p> <p>Our <i>de novo</i> cost analysis did not take into account <u>all costs</u> for RARP and ORP but focused on cost items that were assumed to differ between the two interventions. During the appraisal, it was suggested that robot-assisted surgery requires more time for preparation in the operating room and that usually one or two additional staff are required. At the same time, it was argued that a robot-assisted surgical intervention may require only one surgeon, leading to lower estimates of staff costs. However, our cost analysis was based on limited information since many of the contacted centers did not respond. Currently, it seems difficult to obtain robust empirical data on the routine use of robot systems in RARP. According to stakeholders, Swiss hospitals are participating in the continued certification program for prostate cancer centers in Germany (www.dvpz.de). So far, no registry or other representative data collection to provide economic information has been established in Swiss hospitals.</p> <p>Our cost analysis assumed that the price of a new DaVinci® robot system is about CHF 1.8 million, and that annual maintenance costs account for approximately 10% of the purchase price (i.e. CHF 180,000). Currently, only one manufacturer (Intuitive Surgical, Inc., Sunnyvale, California, USA) offers robot systems for radical prostatectomy in Switzerland. With lacking competition, this manufacturer has no incentive to lower the price. The first generation of DaVinci® robots currently used in Swiss hospitals will need to be replaced in the coming years. Apparently, a second-hand market of robot systems is emerging, and this will potentially lower the purchase price. This aspect was not considered in the present economic analyses.</p> <p>Total costs of robot-assisted interventions include fix and variable costs and, thus, depend on the number of interventions per hospital. Swiss centers performing RARP differ substantially with respect to the number of interventions performed with the robot system. For hospitals with an annual caseload (for any robot-assisted intervention) of less than 25, the costs per intervention are even higher. The current German guideline for the treatment of prostate cancer recommends that a center should perform at least 50 RARP and an individual surgeon at least 25 RARP per year.³</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
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<ul style="list-style-type: none"> ○ Very low ● Low ○ Moderate ○ High ○ No included studies 	<p>Available data on resource requirements and the resulting economic analysis were limited by several factors. It was difficult to obtain cost data from Swiss hospitals for the <i>de novo</i> cost analysis. Aggregated data for cost items such as daily rate for hospital stay, hourly rate for operating rooms, and costs for medical staff were made available by one university hospital only. It was assumed that staff costs (in particular for the surgeons) did not differ between RARP and ORP. Costs due to reusable and consumable materials needed for RARP seem to be highly variable and appear to depend, at least partly, on the surgeon's preference.</p> <p>Our cost-analysis did not assess the potential influence of learning curves of the surgeons and other staff in the operating room (e.g. in terms of shorter duration of interventions or additional costs due to perioperative complications). In addition, potential benefits due to improved working conditions for the surgeons when performing RARP could not be quantified as a monetary benefit.</p> <p>Our cost model was based on a 12-week follow-up after RARP in a single, randomized study in 326 patients. Consequently, any costs due to long-term effects (e.g. hospital readmission for cancer recurrence) were not considered. Other components for which no data were available included conversion to open surgery in the same patient, in-hospital medication costs (e.g. for anesthetics or antibiotics), and other costs during follow-up (e.g. outpatient visits or home-based care). For a valid budget impact analysis, reliable estimates of the total volume of robot-assisted interventions would be needed. This figure is identified by a specific Swiss classification code of surgical interventions (Schweizerische Operationsklassifikation [CHOP]) used in Swiss hospital statistics. However, it remained unclear whether this code is applied systematically thus providing a reliable estimate of the total number of robot-assisted operations performed. An additional assumption of the budget impact analysis was that the frequencies of RARP performed in Switzerland are evenly distributed among the Swiss hospitals.</p> <p>Stakeholders emphasized that the same diagnosis-related group (DRG) lump sums apply to open surgery, laparoscopic surgery, and robot-assisted surgery. They argued that the costs for purchase and maintenance of the robot system, specific disposable surgical equipment, etc. would need to be included when DRG lump sums are determined for robot-assisted interventions. However, it was also argued that this is not warranted in the absence of evidence of the clinical benefit of this technology. Furthermore, since an increased DRG lump sum would cover the full cost and exceed variable costs, incentives would arise to increase the volume of interventions.</p> <p>Taking into account the above-mentioned limitations, the Appraisal Committee concluded that the quality of evidence of resource requirements for RARP was low.</p>	<p>None</p>
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Does the cost-effectiveness of the intervention favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favors the comparison <input checked="" type="radio"/> Probably favors the comparison <input type="radio"/> Does not favor either the intervention or the comparison <input type="radio"/> Probably favors the intervention <input type="radio"/> Favors the intervention <input type="radio"/> Varies <input type="radio"/> No included studies 	<p>The results of the budget impact analysis suggest that the total direct costs for patients undergoing RARP or ORP in Switzerland were CHF 56.1 million in 2015. It was estimated that RARP accounted for about 59% of interventions and 63% of costs. If the current practice were changed to a scenario in which only ORP is performed, savings of CHF 5.7 million could be achieved. In turn, a scenario assuming exclusive use of RARP would also decrease the total costs for radical prostatectomy but only by CHF 500,000. This is mainly due to a scale effect resulting from better exploitation of the robot systems in place with higher caseload and better amortization of the initial investment. As a consequence, costs per intervention would decrease. The current approach of a mixture of RARP and ORP in centers of varying sizes incurs additional costs as long as the annual caseload per robot system remains at a low to moderate level. Notably, an increased use of the robot system would impact only modestly on the overall budget because higher numbers of interventions imply a substantial reduction of per-patient costs.</p>	<p>None</p>

Equity
What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Reduced <input type="radio"/> Probably reduced <input checked="" type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> 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 (open) prostatectomy is 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. 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"> <input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> 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. 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.</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
<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 radical prostatectomy 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>	None

SUMMARY OF JUDGEMENTS

PROBLEM	JUDGEMENT						
	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
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

JUDGEMENT

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 type="radio"/>	Conditional recommendation for either the intervention or the comparison <input checked="" 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 radical prostatectomy, the Appraisal Committee issues a conditional recommendation for either robot-assisted laparoscopic intervention or open surgical intervention. Use of the robot-assisted laparoscopic technique should be conditional on a minimum caseload per center.

Justification

There is some evidence indicating that patients undergoing radical prostatectomy may benefit from robot-assisted laparoscopy, at least in the short term after surgery.

Subgroup considerations

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.

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.