

Robot-assisted laparoscopic surgery versus open surgery  
for radical prostatectomy

Robot-assisted laparoscopic surgery versus conventional  
laparoscopic surgery for simple or radical hysterectomy



### **Executive Summary - Appraisal Report**

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## **Impressum**

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## Executive Summary

Cancer of the prostate and cancer of the female reproductive organs are common diseases and a frequent cause of cancer-related death in Switzerland. In men, radical prostatectomy (i.e. surgical removal of the prostate gland, both seminal vesicles, and a portion of both vas deferens) is a treatment option for patients with localized cancer and can be performed as an open or minimally invasive laparoscopic surgery, with or without support by a robot system. In women, removal of the uterus with or without its adnexa (i.e. radical or simple hysterectomy) is indicated for both benign and malignant conditions. Hysterectomy can be performed by an open abdominal, open vaginal, or minimally invasive laparoscopic approach. Laparoscopic interventions may be supported by a robot system, or not.

This Appraisal Report compares the effectiveness, safety, and cost-utility of the robot-assisted technique with those of the conventional techniques, i.e. open radical prostatectomy (ORP) and conventional laparoscopic hysterectomy (CLH). As of July 2018, a total of 33 robot systems existed in Swiss hospitals; all were DaVinci® robots with an approximate purchase price of CHF 1.8 million each.

In an Assessment Report (see Methods section and Supplementary Material) forming the basis of this appraisal, the evidence from randomized trials (as summarized in two Cochrane systematic reviews) was used to assess the effectiveness and safety of radical prostatectomy and simple or radical hysterectomy using robot-assisted laparoscopy. One review was updated for the purpose of this assessment in a Cochrane Targeted Update. The assessment of the two interventions was complemented by a comprehensive literature search of relevant health economic studies and a *de novo* cost analysis using estimates from Switzerland and data from the Swiss health insurer perspective. For the overall appraisal and formulation of recommendations, the Appraisal Committee then used the Evidence to Decision (EtD) framework. Stakeholder input was taken into account during the scoping and appraisal phases.

For RARP, the evidence of clinical effectiveness and harm was based on a single, randomized, controlled trial (326 participants) conducted in Australia. The differences in desirable effects (e.g. urinary tract and sexual function) between RARP and ORP were judged to be small, while the differences in undesirable effects (e.g. postoperative pain) were regarded as moderate. The overall quality of evidence was low. In the *de novo* cost analysis, patients with RARP incurred higher costs (approx. 4,000 CHF). However, reliable cost estimates for RARP in routine care from Swiss hospitals were scarce; this limited the validity of the economic analysis. The additional resource requirements for RARP as compared to ORP were considered moderate. Such additional requirements would become small if the use of RARP were centralized in fewer centers with higher caseloads for each robot system. The Appraisal Committee concluded that the evidence does not favor the current use of RARP in hospitals with low caseloads.

For robot-assisted hysterectomy (RAH), the evidence of clinical effectiveness and harm was based on six randomized trials (632 participants in total). The differences in desirable effects between RAH and conventional laparoscopic hysterectomy (CLH) were negligible, and undesirable effects were similar for the two approaches. Again, the overall quality of available evidence was low. The Appraisal Committee concluded that the available clinical evidence does not favor either RAH or CLH. In the *de novo* cost analysis, the costs per case of RAH for benign conditions exceeded those associated with CLH by approx. CHF 5,500. For malignant conditions such as cervical or ovarian cancer, the costs of RAH exceeded those of CLH by approx. CHF 4,300. These additional resource requirements were regarded as moderate, and the quality of the economic evidence was considered low. The Appraisal Committee concluded that the evidence of cost-utility favors the use of CLH for simple or radical hysterectomy.

The assessment did not include any analysis of published evidence on patient values, health equity, or acceptability of the robot-assisted technology by patients. The Appraisal Committee questioned whether the current practice of informing patients about the available treatment options is sufficient

to enable informed consent prior to the intervention. The patients' preference might depend on what information they receive about the surgical techniques. RARP is probably acceptable for many men because the alternative would be open surgery. In turn, RAH may or may not be acceptable for women; for many of them, the alternative would be CLH without the use of a robot system. Given that the technology is already in place in Switzerland and is covered by basic statutory health insurance, equitable access was not considered an issue *per se*.

## **Recommendations**

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.

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

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

### **2. Subgroup considerations**

For both radical prostatectomy and 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.

### **3. Implementation considerations**

Robot-assisted laparoscopic surgery should be restricted to hospitals with a minimal number of interventions per year for quality and economic reasons. 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.

### **4. 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.

### **5. 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.