Canadian Agency for Drugs and Technologies in Health

Robot-Assisted Surgery Compared with Open Surgery and Laparoscopic Surgery: Clinical Effectiveness and Economic Analyses

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EXECUTIVE SUMMARY

The Issue

Given the recent introduction and increasing diffusion of robotic surgery technology into the prostatectomy, nephrectomy, hysterectomy, and cardiac surgery fields, and its high capital and operating costs, a review of the clinical and economic impact is needed to inform decisions about its acquisition, and potential or expanded use.

Objectives

The primary objectives of this Health Technology Assessment (HTA) were to assess the clinical and cost-effectiveness of robotic surgery compared with open procedures and laparoscopic procedures. We conducted a systematic review to evaluate the clinical effectiveness of robotic surgery compared with open procedures and laparoscopic procedures, followed by a systematic review of economic evaluation studies. We also conducted a primary economic evaluation of robotic surgery in one indication from a Canadian perspective and assessed robotic surgery's potential impact on health services (population impact and budget impact) in Canada.

Methods

A systematic review with meta-analyses was conducted to compare clinical efficacy between robot-assisted, open, and laparoscopic surgeries. The measures of effect for dichotomous data, such as complication rates and positive margin rates, were expressed as risk ratios with 95% confidence intervals (CI). The measures of effect for continuous data, such as operative time and length of hospital stay, were expressed as weighted mean differences with 95% CI.

A systematic review of the economic literature was conducted with the aim of assessing the economic evidence on robotic surgery. The primary economic evaluation compared robotic surgery with open surgery and with laparoscopic surgery in the most frequently performed robotic procedure in Canada (radical prostatectomy). Because clinically important betweengroup differences in effects (as measured using outcomes such as mortality, morbidity, general quality of life, and potential disease recurrence) could not be demonstrated based on the data obtained from the clinical review, only the relative costs of the surgical alternatives were compared in a cost-minimization analysis. This analysis was conducted from the perspective of the publicly funded health care system, and costs were estimated for the length of hospitalization. The population impact analysis estimated the potential number of hospitals in Canada that would be eligible for a robotics program and the number of patients who might be treated. A budget impact analysis was used to estimate the net program costs from an institutional perspective.

Clinical Effectiveness

During the literature search, 2,031 citations were identified. After the exclusion of articles with irrelevant study designs, populations, interventions, or outcomes, 95 studies were selected for inclusion: 51 on prostatectomy, 26 on hysterectomy, 10 on nephrectomy, and eight on cardiac surgery. A review of the included trials revealed two findings. First, there were no data from randomized controlled trials, and data on nephrectomy and cardiac surgery were limited. Second, based on primary meta-analyses of the included observational studies, robot-assisted surgery was associated with a statistically significant benefit for several clinical outcomes.

- Length of hospital stay: robot-assisted surgery was shown to be associated with statistically significantly reduced lengths of hospital stay compared with open prostatectomy, laparoscopic prostatectomy, open hysterectomy, laparoscopic hysterectomy, and laparoscopic partial nephrectomy.
- Blood loss and transfusion rates: robot-assisted surgery was associated with a statistically significant reduction in blood loss and transfusion rates compared with open prostatectomy, laparoscopic prostatectomy, and open hysterectomy.
- Positive margin rates: robot-assisted surgery was associated with a statistically significant reduction of positive margin rates compared with open prostatectomy in pT2 patients (patients whose tumours are confined to the prostate).
- Incidence of complications: robot-assisted surgery was associated with statistically significant reductions in postoperative complication rates compared with open hysterectomy and laparoscopic hysterectomy.
- Operative time: robot-assisted surgery was associated with a statistically significantly increased operative time compared with open prostatectomy and open hysterectomy, and a reduced operative time compared with laparoscopic prostatectomy.

Findings on robot-assisted cardiac surgery were scarce, but seemed to favour robot-assisted surgery for length of hospital stay.

Overall, many of the pooled estimates for comparisons of the selected indications were associated with statistically significant heterogeneity across studies. Subgroup analyses of study outcome data on study quality, study design, and removal of outliers did not show any systematic patterns. An increase in surgeons' experience was associated with reductions in operative time, length of stay, incidence of complications, and risk of positive margin rates. Given the lack of availability of randomized trials, the presence of unexplained heterogeneity in some pooled estimates, and the occasional identification of studies with conflicting findings, conclusions need to be drawn carefully from meta-analysis. In addition, statistically significant differences favouring robotic surgery were identified for several outcomes, but there is uncertainty about the clinical relevance of the size of these differences.

Economic Review and Analysis

A systematic review of the economic literature was conducted with the aim of assessing the economic evidence for robotic surgery in terms of study quality, methods, results, and relevance in a Canadian context, and a descriptive approach was used. Thirty economic analyses of the use of robotic surgery were reviewed: 15 on prostatectomy, four on cardiac surgery, two on radical nephrectomy, eight on hysterectomy, and one on multiple indications. The conclusions of the studies varied regarding the costs and cost-effectiveness of robotic surgery, as well as handling and inclusion of costs. Most studies were limited in the reporting of their methods, and one study in hysterectomy was relevant to a current Canadian setting.

In the cost-minimization analysis, shorter lengths of stay after robotic radical prostatectomy reduced hospitalization costs relative to open surgery and laparoscopic surgery. However, because of the costs of acquiring, operating, and maintaining the surgical robot, the estimated per-patient costs of the robotic technology were higher than the comparator (incremental costs compared with open surgery are $3,860 per patient and, compared with laparoscopic surgery, $4,625 per patient). By increasing the annual caseload, the incremental costs per patient for robotic surgery can be lowered−the mean incremental costs drop significantly during the first

200 procedures. A probabilistic sensitivity analysis suggests that robotic surgery is more expensive than open surgery and laparoscopic surgery in approximately 75% of cases, with costsaving situations for robotic surgery being largely attributed to variation in hospitalization costs.

Health Services Impact

The population impact analysis suggests that up to 31 Canadian centres could adopt the robotic technology, assuming the centres that do so have characteristics similar to the centres that already use it. Assuming that their caseloads are similar to those of operational centres, up to 4,030 robotic procedures may be performed in Canada annually. If the number of centres adopting this technology expands to include non-teaching hospitals of a similar bed capacity and hospitals with a smaller bed capacity, the number of patients being treated annually could rise to 11,050. Considering the average patient undergoing a robotic surgical procedure, and the utilization patterns in Canadian robotic centres, the net institutional costs for operating a robotics program with a new da Vinci Si Surgical System for seven years is estimated to be $2.9 million. Cardiac surgery was estimated to be the least costly indication-specific program, with net program costs of $0.9 million over seven years, and prostatectomy was estimated to be the most expensive, with net program costs of $3.5 million over seven years.

Conclusions

Based on the evidence that was included in this technology assessment, robot-assisted surgery may have an impact on several clinical outcomes in patients undergoing prostatectomy, partial nephrectomy, or hysterectomy. The benefits vary between indications. Findings regarding robotassisted cardiac surgery were scarce but tended to favour robot-assisted surgery in terms of length of hospital stay. Comparisons between the methods of surgery regarding survival rates and time to return to work were inconclusive due to the scarcity of evidence. Given the limitations of the available evidence and uncertainty about the clinical relevance of the size of benefits of robot-assisted surgery compared with alternative approaches, decisions about the uptake of robot-assisted surgery will be complex and need to be made carefully. Robotically performed surgery is expensive compared with open and laparoscopic approaches. The investment made in acquiring this technology is large, and institutions that choose to adopt this technology need to monitor their costs and outcomes so that they can maximize its cost-effective use in their centre. To decrease costs, centres could maximize caseloads, consider keeping the robot operational for longer, if possible, and use the technology for multiple indications, particularly those with greater potential impact on patient outcomes and institutional cost savings.