Robot-Assisted Surgery Compared with Open Surgery and Laparoscopic Surgery


Introduction

Robotic surgery for prostatectomy, hysterectomy, nephrectomy, and cardiac surgery are four procedures of interest to Canadian jurisdictions, based on clinical importance and the current and predicted use of robotic surgery.

Surgical robots were developed to facilitate minimally invasive surgery (laparoscopy) and to assist surgeons performing surgical procedures that would otherwise not be possible with traditional open or laparoscopic techniques. Eleven Canadian hospitals have robotic systems.

The most widely marketed and studied surgical robot is the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, California, USA), which is the only system available in Canada. The da Vinci Surgical System is a tele-manipulation system in which the operating surgeon directs three or four surgical arms from a computer video console using master handles, while seated close to the patient. Since 2000, this surgical system has been approved by the US Food and Drug Administration for urologic, general laparoscopic, gynecologic laparoscopic, general non-cardiovascular thoracoscopic, and thoracoscopically assisted cardiomyotomy surgical procedures in adults and children. The first-generation da Vinci Surgical System (the da Vinci Standard) was approved by Health Canada in March 2001. The second-generation da Vinci S Surgical System was approved in 2006, and the third-generation da Vinci Si was approved in January 2010.

Robot-assisted surgery with the da Vinci System may offer benefits to patients through the use of minimally invasive techniques, which may result in reduced blood loss, reduced blood transfusion, fewer complications, reduced postoperative pain, shorter hospital stays, and reduced recovery times. Surgeons may also benefit through improved ergonomics (for example, three-dimensional visualization and freedom, and intuitiveness of movement-enabled eye-hand coordination that may be lost in laparoscopic surgery), potentially resulting in better surgical performance. Robot-assisted surgery is, however, associated with high capital and operating costs.

Objective

The objective of the report was to answer four research questions.

The following research questions were asked:

1. Compared with open or laparoscopic approaches, what is the clinical effectiveness of robot-assisted surgery for:
   a. prostatectomy
   b. hysterectomy
   c. nephrectomy (because robot-assisted surgery plays a potential role in partial nephrectomy, not radical nephrectomy, the report will focus on partial nephrectomy)
   d. cardiac surgeries?

2. Compared with open or laparoscopic approaches, what is the cost-effectiveness of robot-assisted surgery for:
   a. prostatectomy
   b. hysterectomy
   c. nephrectomy
   d. cardiac surgeries?

3. What is the expected budget impact (including impact on staffing) on the Canadian provinces and territories for the adoption of robot-assisted surgery for:
   a. prostatectomy
   b. hysterectomy
c. nephrectomy
d. cardiac surgeries?

4. What are the expected planning and implementation issues (including maintenance of competence by staff) on the Canadian provinces and territories for the adoption of robot-assisted surgery for:
   a. prostatectomy
   b. hysterectomy
   c. nephrectomy
   d. cardiac surgeries?

**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 between-group 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.

**Results**

**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.

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 surgeon experience was associated with reductions in operative time, length of stay, incidence of complications, and risk of positive margin rates. Conclusions need to be drawn carefully from meta-analysis, 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. 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 regarding 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. 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 cost-saving 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.

Limitations

The limitation of the clinical review of this report is a lack of prospective RCTs of robot-assisted surgery compared with laparoscopic or open surgical approaches. This analysis is based on mostly single-institution observational studies, which means that the level of evidence is not as robust as that of RCT data. Many outcomes showed heterogeneity across trials, but no apparent potential causes of heterogeneity — including trial quality, trial design, sample size, definition of outcomes, and surgeon experience — adequately explained these differences.

For this HTA, the clinical data analyzed are not from Canadian centres and, as a result, potential sources of bias must be acknowledged (publication bias and patient selection bias). The systematic review for the economic assessment was conducted in a rigorous manner. Most of the data used in the economic evaluation and the health services impact analyses were obtained from Canadian sources.

Robotic surgery and laparoscopic surgery are associated with learning curves that require additional training and mentorship, and these costs are difficult to estimate and could not be captured in the analysis.

At the time of the analysis of the data for this report, the Canadian Institute for Health Information (CIHI) did not yet have reliable data on lengths of stay for the robotically performed procedures that are considered in this report. Hospitalization cost estimates derived from CIHI data would necessarily include the cost of disposable surgical equipment. Because the classification of robotic surgeries in CIHI’s Discharge Abstract Database is recent, identification and costing methods for robotic surgeries is incomplete, and it is unclear whether
the cost of robotic disposables has been included in the hospitalization costs.

In the population impact analysis, the number of hospital beds was used as a characteristic to identify institutions that are likely to adopt this technology. Surgical volume may have been a better indicator, but these data were unavailable.

Finally, there may be benefits of robotic surgery that are difficult to evaluate and that were not included in the economic assessment, such as the ergonomics of robotic surgery and the potential impact on surgeon fatigue and performance.

Conclusions

Based on the evidence included in this technology assessment, robot-assisted surgery may have an impact on many clinical outcomes in patients undergoing prostatectomy, partial nephrectomy, or hysterectomy; and benefits vary between indications. Findings on robot-assisted cardiac surgery were scarce but tended to favour robot-assisted surgery in length of hospital stay.

Comparisons between the methods of surgery on survival rates and time to return to work were inconclusive because of scarcity of evidence. However, given the limitations of the available evidence and uncertainty about the clinical relevance of the size of its benefits compared with the alternative approaches, decisions about the uptake of robot-assisted surgery are difficult and must be made carefully.

Robotically performed surgery is costly compared with laparoscopic and open approaches. The investment made in acquiring this technology is large, and institutions choosing to adopt it should monitor costs and outcomes to maximize cost-effective use in their centres. To decrease costs, centres could maximize caseloads, consider keeping the robot operational for longer durations, if possible, and use the technology for multiple indications, particularly those with greater potential impact on patient outcomes and institutional cost savings.

References


