TITLE: The da Vinci® Surgical Robotic System: A Review Of The Clinical And Cost-Effectiveness

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CONTEXT AND POLICY ISSUES:

The da Vinci® Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA)1 is a telemanipulation system in which the operating surgeon directs three or four robotic surgical arms from a computer video console using master handles.2 Robotic surgical instruments have an elbow and wrist joint, enabling movements which mimic the natural motions of open surgery. Surgery with this technology may offer benefits to patients through the use minimally invasive techniques, as well as to surgeons through improved ergonomics (e.g. three-dimensional visualization and freedom and intuitiveness of movement enable eye-hand coordination that may be lost in laparoscopic surgery), potentially resulting in better surgical performance, and possibly to society because of shorter hospital length of stay and recovery times.2

The da Vinci® surgical robotic system was first licensed for laparoscopic and thoracoscopic procedures by Health Canada in March 2001, with various components of the surgical system being thereafter approved from June 2005 to September 2006.3,4 Since 2000, this surgical system has been approved by the U.S. Food and Drug Administration (FDA) for urologic, general laparoscopic, gynecologic laparoscopic, general non-cardiovascular thoracoscopic, and thoracoscopically-assisted cardiotomy surgical procedures in adults and pediatrics.1 Although most widely used in prostatectomy procedures5, studies reported in the literature (case reports and observational studies included) indicate that this technology is being used in numerous indications.

This technology is associated with significant capital and operating costs. Recently reported estimates3 indicate that list price of the da Vinci® robot is between US$1.5 and US$1.65 million. Annual maintenance costs are between US$140,000 and US$150,000, depending on the model. In addition, the average instrument cost per procedure is approximately US$1,200.
Manufacturer-provided training programs cost between US$3,000 and US$3,500 per surgeon for a 1 or 2-day session.\textsuperscript{6}

There is a learning curve associated with effective use of the da Vinci\textsuperscript{®} surgical system, and factors affecting this learning curve include over-riding second-nature surgical approaches that are not applicable to robotic surgery, the learning of new and complex techniques, and application of prior surgical experience.\textsuperscript{6}

Given the relatively recent introduction of this technology, the numerous indications in which it may be used, and its high capital and operating costs, a review of its clinical and cost-effectiveness would be useful for informing decisions regarding its acquisition and potential use. The present report aims to review the current evidence for the clinical effectiveness and cost-effectiveness of the da Vinci\textsuperscript{®} surgical robotic system in various indications.

**RESEARCH QUESTIONS:**

1. What is the clinical effectiveness of the da Vinci\textsuperscript{®} surgical robotics system for various indications?
2. What is the cost-effectiveness of the da Vinci\textsuperscript{®} surgical robotics system for various indications?

**METHODS:**

A limited literature search was conducted on key health technology assessment resources, including PubMed, OVID’s Medline and Embase, The Cochrane Library (Issue 4, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2003 and November 2008, and are limited to English language publications only. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, economic, and quality of life studies. Internet links are provided, where available.

A total of 429 abstracts and 40 grey-literature documents were retrieved for screening. From this initial screening, 42 articles were selected for further evaluation. The final review yielded 19 reports: one meta-analysis, one systematic review, three randomized trials, four randomized trials that had also done an economic assessment of the comparators, and ten economic studies based on observational data. Reasons for exclusion of studies in the second screening were: not a systematic review, not a comparative economic study, not a randomized trial, not a randomized trial in a medical condition, study not specific to the da Vinci\textsuperscript{®} Surgical System, and duplicate report.

**SUMMARY OF FINDINGS:**

**Systematic reviews and meta-analyses**

The indication in both the systematic review and the meta-analysis was prostatectomy.

Ficarra et al.\textsuperscript{5} published a systematic review of the clinical evidence for robot-assisted laparoscopic radical prostatectomy (RALP) using the da Vinci\textsuperscript{®} surgical system in 2007. Abstracts, meeting reports, and papers in journals not available in Italy were excluded. Papers
included in the review were graded for level of evidence according to the criteria described by Phillips and Sackett (Centre for Evidence Based Medicine, accessed on-line). A total of 33 studies published from 2000 to 2006 were included in the review, seven of which were case series of less than ten patients. Five of the included studies compared RALP to open retropubic radical prostatectomy (RRP) and three compared RALP to laparoscopic radical prostatectomy (LRP). Most of the studies were case series or poor-quality case-control (Level 4), with the exception of a few comparative studies (Level 3b). The authors addressed learning curve and initial experience with RALP, post-operative outcomes in mature clinical series, oncologic outcomes, and functional outcomes. With regards to the learning curve in RALP, it was noted that operative time in RALP is significantly reduced as the surgeon becomes more experienced with using this technology. Comparative studies of the first 40 RALPs performed at the Vattikuti Urology Institute in Michigan (United States) showed that operative times during their structured training program were similar to those for LRP procedures performed by two expert laparoscopists. This study also showed a significant blood loss reduction with the da Vinci system. A comparison of the 30 first RALPS performed by a single surgeon and 30 RRP s performed at the Vattikuti Institute demonstrated longer operating times in the RALP group, but lower rates of blood loss, blood transfusion, post-operative pain, and shorter length of stay. In mature clinical series, mean operating times with RALP have been shown to be as low as 180 minutes (range: 81 to 365 minutes), with low transfusion rates (range: 0% to 12% of cases) and complication rates ranging between 1.5% and 16%. A comparison of the first 200 RALPs performed by one surgeon with 100 consecutive RRRPs showed similar operating times once the learning curve was completed and showed an advantage with RALP with regards to blood loss, transfusion rates, post-operative pain, and length of stay. At the same time, a non-randomized study of 159 RALPs and 154 RRP s showed no difference in post-operative pain, and yet another study showed no difference in transfusion rates. Two studies of RALP versus LRP found no differences in operative times, transfusions, and complication rates. With respect to oncologic outcome, the authors note that rates of positive surgical margin (cancer not completely removed) are extremely variable (range: 2% to 59%) and are highly dependent on the pathologic stage of the primary tumor. They also noted that a surgeon’s increasing expertise and improvement in surgical technique showed a progressive reduction in positive surgical margins in a few studies. Two comparative studies of RALP versus RRP showed higher positive surgical margin rates in the RRP group, while a comparative study of RALP versus LRP showed higher surgical margin rates with RALP. No differences were reported with regards to nerve-sparing techniques. At a mean follow-up of less than six months, between 82% and 100% of patients undergoing RALP had a prostate-specific antigen lower than 0.1-0.2 ng/ml (based on eleven studies). Finally the authors note that data on long-term functional outcomes such as urinary incontinence and erectile function recovery are limited. In general, rates of improvement for these outcomes increase throughout follow-up, regardless of surgical method. One published non-randomized study of RALP versus RRP showed earlier continence recovery with RALP, and suggested that RALP could allow for better and earlier potency recovery compared to RRP. The authors concluded that the literature showed RALP to have a short learning curve and that interesting post-operative results and functional outcomes were demonstrated. They also noted that costs are a major drawback, and recommended that the use of this technology be restricted to high-volume referral centres within the context of evaluation studies. They also indicated that comparative multi-centre randomized trials might allow for a more appropriate comparison with RRP.

The pooled analysis report by El-Hakim et al. (2006) conducted a search of the published literature on robotic prostatectomy (RP), and included select data on open RRP and laparoscopic (LP) prostatectomy from centres of excellence in their comparison. All RP studies included in this analysis were specific to the da Vinci surgical system. Assessed outcomes
included peri-operative outcomes, pathologic parameters, complications, and post-operative outcomes. Weighted arithmetic means were calculated for most of the comparisons. Ten published series of RP with a total of 373 patients were obtained from the literature. Data on RRP was obtained from publications of seven major institutions as well as from one longitudinal population-based cohort (Prostate Cancer Outcomes Study) and a longitudinal observational database of patients with prostate cancer (CaPSURE). Data on LP were obtained from the publications of five urological laparoscopy centres. Weighted mean estimates for peri-operative outcomes are shown in Table 1, and suggest that operative time was shortest for RRP, while estimated blood loss (EB) and need for blood transfusion was lowest in the RP group.

**Table 1: Peri-operative outcomes according to surgical approach reported by El-Hakim et al.**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of studies (sample size)</th>
<th>Installation time (minutes)</th>
<th>Operative time (minutes)</th>
<th>EBL (ml)</th>
<th>Blood transfusion (%)</th>
<th>Case conversion or abortion (%)</th>
<th>Catheter time (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RP</td>
<td>10 (n=373)</td>
<td>32</td>
<td>222</td>
<td>231</td>
<td>3.9</td>
<td>1.1</td>
<td>8.1</td>
</tr>
<tr>
<td>LP</td>
<td>5 (n=1106)</td>
<td>NS</td>
<td>225</td>
<td>505</td>
<td>8.4</td>
<td>1.4</td>
<td>6.1</td>
</tr>
<tr>
<td>RRP</td>
<td>3 (n=3200)</td>
<td>NS</td>
<td>182</td>
<td>727</td>
<td>24</td>
<td>NS</td>
<td>(7-21)*</td>
</tr>
</tbody>
</table>

RP:robotic prostatectomy; RRP:open radical retropubic prostatectomy; LP:laparoscopic prostatectomy; EBL: estimated blood loss; NS: not stated; *Range reported from one study.

Weighted mean estimates for pathological parameters according to surgical approach are provided in Table 2. Parameters included pathological stage (pT2, pT3), total surgical margin rate (SM+), and positive surgical margin rates for organ-confined (pT2/SM+) and non-organ-confined (pT3/SM+) cancers.

**Table 2: Pathological parameters according to surgical approach reported by El-Hakim et al.**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of studies (sample size)</th>
<th>pT2 (% pts)</th>
<th>pT3 (% pts)</th>
<th>Total SM+ (%)</th>
<th>pT2/SM+ (%)</th>
<th>pT3/SM+ (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RP</td>
<td>10 (n=373)</td>
<td>77.5</td>
<td>21.6</td>
<td>15.0</td>
<td>8.5</td>
<td>57.3</td>
</tr>
<tr>
<td>LP</td>
<td>4 (n=1439)</td>
<td>72.4</td>
<td>26.5</td>
<td>19.9</td>
<td>13.8</td>
<td>31.7</td>
</tr>
<tr>
<td>RRP</td>
<td>5 (n=22164)</td>
<td>64.0</td>
<td>32.2</td>
<td>24.1</td>
<td>17.5</td>
<td>42.7</td>
</tr>
</tbody>
</table>

RP:robotic prostatectomy; RRP:open radical retropubic prostatectomy; LP:laparoscopic prostatectomy; pT2: organ-confined cancer; pT3:non-organ confined cancer; SM+:positive surgical margin.

According to these estimates, overall surgical margin rates were lowest in the RP group, and this finding was consistent in patients in organ-confined cancers as well, however surgical margin was highest in the RP group in patients with non organ-confined cancers.

The authors’ analysis of complication and mortality rates is provided in Table 3. A description of which complications were considered as being minor or major was not provided by the authors. According to these data, RP had the lowest complication rates.
Table 3: Complications and mortality rates according to surgical approach reported by El-Hakim et al.\textsuperscript{7}

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of studies (sample size)</th>
<th>Overall complication rate (%)</th>
<th>Minor complication rate (%)</th>
<th>Major complication rate (%)</th>
<th>Mortality rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RP</td>
<td>10 (n=373)</td>
<td>8.3</td>
<td>4.6</td>
<td>3.8</td>
<td>0</td>
</tr>
<tr>
<td>LP</td>
<td>4 (n=1006)</td>
<td>16.8</td>
<td>13.0</td>
<td>4.9</td>
<td>0</td>
</tr>
<tr>
<td>RRP</td>
<td>4 (n=6677)</td>
<td>10.3</td>
<td>6.3</td>
<td>4.0</td>
<td>0.04</td>
</tr>
</tbody>
</table>

RP: robotic prostatectomy; RRP: open radical retropubic prostatectomy; LP: laparoscopic prostatectomy;

The author’s analysis of post-operative outcomes included an assessment of continence and potency. There was a great deal of variability in data collection method and follow-up period in the studies that looked at these outcomes and the data were not analyzed quantitatively. Overall, findings on continence with RP were favorable and comparable to LP and RRP, and comparisons regarding potency were more difficult to assess. The authors’ conclusions were that RP was a promising minimally invasive surgical approach in localized prostate cancer, and that short term clinical and pathological results compared favorably with LP and RRP.

**Randomized controlled trials**

The seven randomized trials retrieved for this review were in four procedures, specifically in adrenalectomy\textsuperscript{8}, tumour-specific mesorectal excision\textsuperscript{9}, Roux-en-Y gastric bypass\textsuperscript{10}, and fundoplication in gastro-oesophageal reflux disease\textsuperscript{11-14} (GORD, also referred to as GERD). Robot-assisted laparoscopic surgery using the da Vinci\textsuperscript{®} robotic surgical system was compared with conventional laparoscopic surgery in all seven studies.

Morino et al.\textsuperscript{8} (2004) reported a trial in adrenalectomy. Twenty consecutive patients with benign lesions of the adrenal gland were randomized to undergo either traditional or robot-assisted lateral flank laparoscopic adrenalectomy. Patients with lesions >10 cm, bilateral lesions, or lesions suspected of being malignant were excluded. The two surgeons who performed the robotic surgery had extensive experience in performing laparoscopic adrenalectomies (>140 cases). To reduce the effect of the learning curve, the study was started after a training period of 10 robotic anti-reflux fundoplications. Data on patient baseline characteristics and peri-operative outcomes were collected (data on costs were also collected and will be reported in the economic section of this report). Ten patients were randomized to each group. There were no significant baseline differences with regards to age (39.5 years), gender (approximately 50% male) and average body mass index (BMI) of 24. The mean diameter of the lesions in these patients was 3.2 cm and the distribution of the side operated (i.e. left or right) was the same in both groups. Patient groups were similar with regards to previous surgery (one patient in the traditional laparoscopy group versus two in the robot-assisted group) and comorbidities (five patients in the traditional laparoscopy group versus six in the robot-assisted group). The indications for surgery in the traditional laparoscopy group included Conn’s adenoma (n=3 patients), Cushing’s adenoma (n=3), phenochromacytoma (n=3), and incidentaloma (n=1). In the robot-assisted group, the indications for surgery were Conn’s adenoma (n=3), phenochromacytoma (n=4), and incidentaloma (n=3). Peri-operative results showed no differences in mortality (n=0 in both groups), post-operative complications (n=0 in both groups), and length of hospital stay (5.4 and 5.7 days). The authors reported that two of the 10 patients randomized to robot-assisted surgery experienced intra-operative complications (severe hypertension in both cases), while no such complications were seen in the standard laparoscopy group. In addition, conversion to standard laparoscopy was required in four of the
patients randomized to robot-assisted surgery, while conversion to other methods (i.e. open surgery) was not required in the standard laparoscopy group. The authors attributed this problem to interference between robot arms, the lack of a bipolar energy source for hemostasis, and the extra time needed to switch instruments. The authors concluded that the two methods were similar with regards to post-operative morbidity and mortality, but that the complication seen in the two patients undergoing robot-assisted surgery was outside the expected range occurring in traditional laparoscopic surgery, and should be verified in a larger number of patients.

A randomized trial of 50 patients undergoing either traditional laparoscopic Roux-en-Y gastric bypass (LRYGB) or totally robotic Roux-en-Y gastric bypass (TRRYGB) was reported by Sanchez et al. in 2005. All procedures were performed by a single laparoscopic fellow who had competed his training in a general surgery residency and had not performed any previous laparoscopic gastric bypass procedures, but who had been trained in a variety of other laparoscopic techniques. The fellow had also received standard training for the da Vinci® surgical system as mandated by the FDA. Patients included in the trial met the minimal criteria for bariatric surgery proposed by the National Institutes of Health Consensus Development Panel report of 1991. Data collected in this trial included patient baseline characteristics, intra-operative and post-operative complications, operative time, and length of stay. Patients were comparable with regards to average age (44 years), gender (90% female), preoperative BMI (44.5), and mean number of comorbidities (2.4). Fifty percent of patients in the LRYGB group and 60% of patients in the TRRYGB group had prior abdominal operations, however this difference was not statistically significant (p=0.392). One patient in the TRRYGB group experienced a minor intra-operative complication, specifically, this second patient required oversewing of a small defect on the gastric pouch found by an intra-operative bubble study. There were no post-operative complications reported, and mean length of stay was the same in both groups (2.72 days). The only significant difference found was in mean operative time, which was 149.4 minutes in the LRYGB group, and 130.8 minutes in the TRRYGB group (p=0.02). The authors also found that differences in operative time were more pronounced in patients with BMIs over 43 (123.5 minutes for TRRYGB versus 153.2 minutes for LRYGB; p=0.009). Operative time decreased with both methods as the number of cases operated on by the surgical fellow increased. The authors concluded that gastric bypass with the da Vinci® surgical system is safe and feasible, with a shortening in operating times observed with increased use of the robotic system, and with that decrease in operating times being maximized in patients with higher BMIs. They also concluded that TRRYGB may be a better approach to gastric bypass when hand-sewing is required, particularly if learned early in a surgeon’s experience.

In 2008, Baik et al. reported a trial of 36 patients who were randomly assigned to undergo robotic tumor-specific mesorectal excision (R-TSME) using the da Vinci® Surgical System, or conventional laparoscopic tumour-specific mesorectal excision (L-TSME). Patients with clinical stage T4 or M1, significant lateral pelvic nodes, or tumour infiltration into the anal sphincter complex were excluded. Surgeon training level with both methods was not stated. Patients groups were comparable in all reported baseline characteristics. The mean age of patients was 57.3±6.3 in the R-TSME group, and 62.0±9.0 in the L-TSME group. Seventy-eight percent of patients were male and average BMI was 23.4 in all patients combined. There were no significant between group differences with regards to American Society of Anesthesiologists (ASA) score or tumour node metastasis staging. Finally patients were similar in mean distance from anal verge, and only one patient in the L-TSME group had undergone a previous abdominal surgery (open radical subtotal gastrectomy). Operative clinical results included operating time, hemoglobin change, days to peristalsis, length of stay, and conversion. Average operating time was 217.1±51.6 minutes in the R-TSME group, and 204.3±51.9 minutes in the L-
TSME group (p=0.477). Hemoglobin change was measured instead of blood loss because it was hypothesized that the latter could not be measured without bias. Hemoglobin change was 0.6±0.6 mg/dl in the R-TSME group and 0.8±1.0 mg/dl in the L-TSME group (p=0.511). Number of days to peristalsis was slightly higher in the L-TSME group (2.4±1.3 days) compared with the R-TSME group (1.8±0.4 days), however this difference was not statistically significant (p=0.071). Length of stay was significantly greater in L-TSME compared with R-TSME (8.7±1.3 days versus 6.9±1.3 days, p<0.001). Surgical method was converted in two patients undergoing L-TSME (p=0.486). There were five cases of post-operative complication, one occurring in the L-TSMF group (intra-abdominal bleeding), and four occurring in the R-TSME group (intraluminal bleeding (1), back pain (2), scrotal swelling (1)). The authors noted that the case of intraluminal bleeding in the R-TSME group was not a robotic-related complication, and that the three other complications in this group were resolved with little impact on length of stay. Finally, specimen quality obtained using the two methods were comparable. The author concluded that TSME was performed safely and effectively using this robotic system.

Draasima et al. 11 (2006) reported a randomized trial of standard laparoscopic Nissen fundoplication (LNF) versus robot-assisted laparoscopic Nissen fundoplication (RNF) in 50 patients with confirmed refractory gastro-oesophageal reflux disease (GORD). All procedures were carried out by surgeons who had performed more than 30 Nissen fundoplications and more than 20 robot-assisted laparoscopic procedures. Among the 62 patients originally considered for the trial, eight refused to participate, one was excluded because of of a need for concurrent laparoscopic choleystectomy, and three had previous abdominal surgery. Baseline characteristics (age, sex, BMI, pre-diagnostic evaluation) and operative data (operating time, intra-operative complications, estimated blood loss, and length of fundoplication) were collected. The primary endpoint of the study was the anatomical result of the procedure as determined by barium oesophageal series (oesophageal manometry and 24-hour pHmetry). A secondary endpoint was quality of life, measured with disease-specific questionnaires (measure not identified) and a general quality of life visual analogue scale (VAS). Patients were comparable at baseline with regards to age (mean=50 years), gender (66% male), and BMI (mean=27.2). All 50 patients received pre-operative anti-secretory medication, and groups were comparable with regards to indication for the procedure, with 90% of patients having insufficient response to medical treatment, and the remaining 10% unwilling to take lifelong medication. Distribution of grade of oesophagitis at endoscopy was also comparable between the two groups at baseline, although grade could not be determined in 5 LNF patients compared with 1 RNF patient (p=0.14). Baseline oesophageal manometry results showed the groups to be the same with regards to end-expiratory lower oesophageal sphincter pressure (1.0 kPa), Nadir end-expiratory lower oesophageal sphincter pressure (0.2 kPa), and between 80-100% of contractions were peristaltic in most patients (96% of RNF patients and 92% of LNF patients). In baseline 24-hour pH monitoring, total oesophageal acid exposure time (that is, the percentage of time with a pH<4.0) was 13.5 in the RNF group and 9.9 in the LNF group (p=0.224). Average quality of life baseline scores in the RNF and LNF groups (respectively) were 65.5 and 71.4 in the symptom index (p=0.162), and 22.5 and 32.5 in the VAS (p-value not reported). With regards to the operative outcomes, the authors reported no significant differences in median operating time or blood loss. Two conversions to open surgery were required in the LNF group, both because of impaired view due to severe obesity and left lobe hepatomegaly. Minor intra-operative complications occurred in seven patients in the LNF group, while none occurred in RNF. Twenty-two RNF and 24 LNF patients had a post-operative endoscopic examination at 3-6 months. Oesophageal manometry results showed improvement in both groups, but no significant between-group differences. Total oesophageal acid exposure time was 0.7 in the RNF group and 0.3 in the LNF group (p=0.088). The average score on the symptom index was zero in both groups. Visual analogue scale scores improved by an average
of 49.5 points in RNF patients, and by 43.5 points in the LNF patients (p=0.284). At six months, two patients in each group required re-intervention. The authors concluded that no additive value of robotic systems for this procedure was detected for up to six months post-surgery, and added that they had stopped routinely using robotic systems in this procedure as costs were substantially higher but outcomes did not appear to be better in the short term.

A second randomized trial of standard laparoscopic Nissen fundoplication versus robot-assisted laparoscopic Nissen fundoplication also in 50 patients with GORD, was published by Morino et al. in 2006. Surgeon relative experience using both surgical methods was not described in this trial, other than the surgeons had significant experience with laparoscopic surgery. Patient inclusion criteria were clinical GORD that necessitated surgery according to the criteria of Hinder et al. (1994) and an ASA score of I or II, and exclusion criteria were giant hiatal hernia, ASA scores of III or IV, previous upper abdominal surgery, and contraindications to pneumoperitoneum. A pre-operative assessment included endoscopy, barium oesophagography, manometry, and 24-hr pH monitoring. Patient baseline characteristics were collected, and all patients completed a standardized preoperative symptom assessment using the Gastro-oesophageal Reflux Health-Related Quality of Life scale (GORD-HRQOL). Patients were followed up by personal interview at one, three, six, and 12 months after surgery, and outcomes were graded using the GORD-HRQOL. Patients also underwent oesophageal manometry and 24-hr pH monitoring at three months, and endoscopy at six months. The primary and secondary endpoints of this trial were related to cost and resource use and will be reported in the economic section of this review. Patients were similar in their baseline and preoperative characteristics, including average age (45 years), sex ratio (78% male), BMI (26), mean lower oesophageal sphincter pressure (8 mmHg), and 24-hr pH monitoring. Baseline GORD-HRQOL scores were not reported. With regards to outcomes, the authors reported that there were no post-operative complications with either approach, and that mean hospital stay was the same in both groups (2.9 days in standard laparoscopy versus 3.0 days in the robot-assisted group, p=0.588). Mean follow-up was 22.3 (range 6 to 32) months. While follow-up GORD-HRQOL scores were not provided, the authors reported that no clinical differences were found between the two groups with this measure at three, six, and 12 months. None of the 50 patients had endoscopic eosphagitis at 6 months. There were no significant differences between the two groups in lower oesophageal sphincter resting pressure, and post-operative pH values. The authors concluded that their study confirms that robot-assisted laparoscopic Nissen fundoplication is comparable to traditional laparoscopy in terms of complications, mortality, and length of stay in hospital, and current robotic systems are not of significant benefit to routine surgical practice.

El Nakadi et al. also reported a randomized study of standard laparoscopic Nissen fundoplication versus robot-assisted laparoscopic Nissen fundoplication in 2006. All procedures were performed by two surgeons, one of which was a digestive surgeon experienced in Nissen fundoplication, and one which was a general surgeon. Relative experience with robot-assisted surgery was not stated. The authors randomized a total of 20 patients to either surgical procedure. Inclusion criteria included symptoms of pathologic GORD, age greater than 16 years, proven complications of GORD, and treatment failure with a proton pump inhibitor. Exclusion criteria based on manometry included achalasia and diffuse oesophageal spasms, and previous gastric surgery. Post-operative morbidity including dysphagia, repletion, gas-bloating, flatulence, eructation, vomiting, nausea, pain, and diarrhea were documented and evaluated at 1, 3, 6, and 12 months. Eleven patients were randomized to undergo surgery with conventional laparoscopy, and nine patients were randomized to robot-assisted surgery with the da Vinci® surgical system. Patients were similar at baseline with regards to age (46 years), gender distribution (70% male), and BMI (25). In the post-operative period, there were no
significant differences in contrast swallow control, alimentation days (1.81±0.18 in conventional laparoscopy versus 2.11±0.11 in robot-assisted laparoscopy; p=0.21), or length of stay (4.1±0.3 days in conventional laparoscopy versus 4.4±0.2 days in robot-assisted laparoscopy; p=0.284). The number of post-operative complaints in the first month was comparable in both groups (four cases in the conventional laparoscopy group, and three cases in the robot-assisted group). At three months, there were no complaints in the traditional laparoscopy group and four in the robot-assisted surgery group (p<0.013). A single patient from the robot-assisted surgery group presented with gastric torsion at six months and underwent a laparoscopic procedure. All patients were free of pain and dysphagia at one year. The authors concluded that no clear advantage of using robotics was observed.

A fourth randomized study of conventional laparoscopic fundoplication (CLF) versus robot-assisted laparoscopic fundoplication (RALF) in symptomatic GORD was published by Müller-Stich et al. in 2007.14 A total of 40 patients were randomized to undergo surgery with one of the two methods. In this study, RALF was performed by a single surgeon who had passed a learning phase of 30 procedures. Conventional laparoscopic surgery was performed by three different surgeons who were all highly experienced in laparoscopy, as well as by the surgeon performing the robot-assisted surgery. Inclusion criteria required patients to be aged 18 years or more and to have a history of more than six months of symptomatic GORD requiring treatment with a PPI for at least three months. Exclusion criteria were previous major upper abdominal surgery, hiatal hernia with paraesophageal involvement, a BMI greater than 40, and evidence of a primary oesophageal disorder. The pre-operative assessment included endoscopy, 24-hr pH monitoring, and barium swallow. Reflux-related symptoms were recorded using a modified gastrointestinal symptoms rating scale questionnaire (GSRS) and dysphagia was assessed using a 4-point Likert scale, where a score of 1 indicated no symptoms, and scores of 2, 3 and 4 indicated mild, moderate, and severe symptoms, respectively. There were no significant between-group differences at baseline with regards to age (50 years), sex distribution (55% female), and BMI (28). Oesophagitis was also similar in the two groups, as were GSRS scores (RALF:4.0±1.7, CLF:4.4±1.5; p=0.704). With regards to intra-operative events, two cases of bleeding in the CLF group and one case of pneumothorax in the RALF group were reported. There were no conversions or re-operations in either group, nor were there any major post-operative complications. Incidence of minor post-operative dysphagia recorded at discharge was also the same in the two groups (18 RALF patient versus 16 CLF patients, p=1.0). Dysphagia at 30 days was reported by five RALF patients and by four CLF patients (p=1.0), and mean dysphagia scores were the same in both groups (1.3). Two RALF patients and three CLF patients resumed therapy with a PPI at 30 days. Mean reflux scores at this time were 1.3±0.7 in the RALF patients and 1.6±1.3 in the CLF patients (p=0.064). The authors concluded that their trial did not reveal an additional benefit with the use of robot-assisted laparoscopic fundoplication.

A summary of the randomized trials reviewed in this section is provided in Appendix 1.

Economic evaluations

A total of fourteen economic studies were reviewed. Ten of these studies were based on observational data and were conducted in nine indications, with nine studies being cost-comparisons and one a cost-utility analysis. Four studies were based on randomized trials in two indications that have been described in the clinical effectiveness section of this report.8,12-14 Three of these economic evaluations were cost-minimization studies12-14, and one was a cost-comparison8.
The randomized trial in adrenalectomy reported by Morino et al. was conducted in Italy and costs were reported in US dollars. This trial had found higher peri-operative morbidity and a higher rate of conversion in the robotic surgery group. The authors compared standard laparoscopic surgery to da Vinci® robot assisted surgery with regards to total operating costs (e.g. nurse, technical staff, surgical devices, and maintenance), the cost of disposable instruments, and hospital stay. Operating costs were estimated to be US$305 per hour. Total operative time was higher in the robot group (169 minutes versus 115 minutes), as was the cost of disposable instruments (US$1,184 per patient versus US$811 per patient). The cost of hospital stay was similar in the two groups. The average total cost of treatment with standard laparoscopic adrenalectomy was estimated to be US$2,737 per patient, while that of treatment with the robotic system was US$3,466. The authors concluded that laparoscopic adrenalectomy was superior to robot-assisted adrenalectomy in terms of feasibility, morbidity, and cost.

The randomized trial of robot-assisted versus standard laparoscopic Nissen fundoplication in GORD reported by Morino et al. was also conducted in Italy. Again, the authors compared costs of the operating room, disposable instruments, and the hospital stay. The costs of the operating room were estimated to be €367 per hour. Total operating time for robot assisted surgery was greater (131.3 minutes versus 91.1 minutes) as was the cost of disposable instruments (€1454 per patient versus €100 per patient). The cost of the hospital stay was almost identical in the two groups (€900 per patient for robot assisted surgery versus €870 per patient for conventional laparoscopy). Total average costs were higher in the robot assisted group (€3157 per patient) compared with standard laparoscopy (€1527 per patient). The authors concluded that outcomes were comparable in the two methods, but that costs were higher in the robot-assisted group.

El Nakadi’s trial of robot-assisted versus standard laparoscopic Nissen fundoplication in GORD was conducted in Belgium. Surgical outcomes were comparable for the two groups in this study, with significantly more post-surgical complaints in the robot-assisted surgery group at three months. Among the costs considered in this analysis were those for the hospital stay, pharmacy, surgical procedure costs, nursing salary, initial investment cost per patient, and annual maintenance. The authors assumed that 20 of 500 potential annual procedures using the da Vinci® robot would be fundoplications for GORD. The cost of the hospital stay, pharmacy, and surgical procedure costs were comparable in the two groups. Differences were seen in materials, nursing salary, investment costs, and maintenance. Total average costs without investment and maintenance costs were €5,167 per patient in the conventional laparoscopy group, and €6,973 per patient in the robotic surgery group. When investment costs were taken into consideration, these total average costs were €5,907 and €27,561, respectively. The authors reported that operative times were higher with the da Vinci® system; however, given the data provided, it is not clear how this impacted their cost analysis. The authors concluded that no clear advantage in using robotics in this procedure was observed.

The randomized trial by Müller-Stich et al. was conducted in Germany and Romania and found no benefit of robot-assisted fundoplication in GORD compared with traditional laparoscopy. The authors estimated total operative costs (staff and use of operating room, disposable and reusable instruments, covers and trochars) and hospital stay costs. Total per-patient operative costs were higher in the robot-assisted group (€1534±€111 versus €763±€115; p=0.001) in spite of shorter operating time (88±18 minutes versus 102±19 minutes; p=0.033), and hospital stay costs were higher in the conventional laparoscopy group, but this difference was not statistically significant (€1980±€481 per patient versus €1710±€488 per patient; p=0.086). Total per-patient average costs were higher in the robot-assisted group (€3244±€512 versus €2743±€483; p=0.003). The authors concluded that operating time can be shorter in robot-
assisted surgery if performed by an experienced team, however because costs are higher and short term costs are similar, robot-assisted surgery can not be favoured over conventional laparoscopy regarding peri-operative outcome.

The ten remaining economic evaluations were based on observational studies.

A US cost comparison of retropubic (open), laparoscopic, and robot-assisted radical prostatectomy was reported by Lotan et al.\textsuperscript{15} in 2004. This analysis was performed using a decision-analytic model, with operative time and length of stay with the three surgical methods obtained from the literature, and costs obtained from a single county hospital as well as from the literature. Literature relating to operative time and length of stay were limited to mature series only because the authors did not want to bias against laparoscopic and robotic assisted surgery in that these technologies were relatively recent and may have been affected by a learning curve. Among the costs included in the analysis were operating room expenses, equipment, surgical professional fees, hospital room and board, intravenous fluids and medication, and cost per case for the purchase and maintenance of the robot. The authors assumed that the robot would be used on 300 prostatectomy patients each year. A sensitivity analysis was conducted to evaluate the effect of different numbers of cases per year on the amortized cost per patient for the robotic equipment. Average operating room time was highest in the laparoscopy group (200 minutes) followed by the retropubic surgery group (160 minutes) and the robotic group (140 minutes). Length of stay in the open group was 2.5 days, and lower in the laparoscopic (1.3 days) and robotic (1.2 days) groups. The total average per-patient costs of open, laparoscopic, and robot-assisted radical prostatectomy were US$5,554, US$6,041, and US$7,280, respectively. In the sensitivity analysis, average total per-patient costs in the robot group were approximately US$9,000 when the annual number of cases using the technology was 100, and approximately US$7,000 when the average number of cases was 500 per year. The conclusion made by the authors was that retropubic surgery was the least costly approach, laparoscopic surgery was almost as competitive, and the high cost of robot assisted surgery overshadowed savings made by shorter length of stay.

O’Malley et al.\textsuperscript{16} published a cost-utility analysis comparing laparoscopic remotely-assisted radical prostatectomy (LRARP) with open surgery in 2007. The time horizon for the analysis was one year. This study obtained costs from consecutive patients at a single hospital in Australia, and included fixed capital costs, maintenance, disposables and consumables, surgeons’ fees, and bed days. Estimated fixed capital costs were AUS$1,501 per procedure. Utilities were obtained from prospectively-collected data on all patients undergoing surgery for prostate cancer over a 4 year period at the Vattikuti Institute. The authors added together the incremental costs of fixed capital (AUS$1,501.38), the maintenance contract (AUS$809.15), disposables and consumables (AUS$3,023), and reduction of length of stay (AUS-$3,069.17), to get a total incremental cost of AUS$2,264.35 for LRARP. The incremental quality-adjusted life-years (QALY) gained (as a result of better estimated outcomes in incontinence and erectile dysfunction with LRARP) was approximated to be 0.10. The estimated cost-utility ratio was AUS$24,475 per QALY. The authors noted that this estimate was below the accepted range for cost-effectiveness of pharmaceuticals in Australia, and that this evaluation did not take into account additional benefits such as reduced time away from employment, reduced blood loss, reduced possibility of infection, and reduced scarring.

Bhayani et al.\textsuperscript{17} reported a cost analysis in 2005 that compared computer-assisted (da Vinci\textsuperscript{®}) dismembered pyeloplasty (CP) versus laparoscopic pyeloplasty (LP) in uteropelvic junction (UPJ) obstruction. This study was conducted at a single institution in the United States. All patients undergoing CP in 2004 were matched to a consecutive cohort of patients undergoing
LP on primary UPJ obstruction, dismembered pyeloplasty, comorbidities, and BMI. The CP surgical team had experience with more than 100 computer-assisted surgical cases (including surgical, gynecologic, and urologic). Operating room times were recorded prospectively. Thirteen LP and eight CP patients were included in the analysis. Mean total operating room time was higher in the LP group (210 versus 176 minutes) as was estimated blood loss (129 versus 107 mls). The groups were comparable with regards to length of stay (LP: 2.5 days; CP: 2.3 days), and neither group reported complications. Under the assumption that 150 cases would be treated with the da Vinci® system, the average expected cost of surgery using this technology was US$5616 per patient. Average costs with LP (assuming 200 patients treated per year) were approximately US$3500 per patient. Operating room time in LP would have to increase to 338 minutes to equal the average per-patient costs of CP. The conclusion was that although peri-operative parameters with CP were encouraging, the costs were disadvantageous and that in that institution, it was considered more cost-effective to teach and perform LP than CP.

Morgan et al.18 (2005) compared the hospital costs of robotically-assisted cardiac procedures with those of conventional techniques. This study was based in the United States. A retrospective chart review was conducted on 20 patients who underwent atrial septal defect (ASD) closure and 20 patients who underwent mitral valve repair (MVR) with either robot-assisted surgery or a conventional sternotomy (ten patients per group). Hospital cost data were obtained from the author’s hospital decision support system, and included intra-operative costs (operating room time, perfusion, supplies, medications, labs, respiratory services) and post-operative costs (intensive care unit (ICU), room, medications, radiology, other tests, physical therapy). Based on the institutional cost of the da Vinci® robotic system, its annual maintenance costs, as well as the assumptions that the system has a five-year life-span and 100 procedures would be performed annually, an additional US$2,800 was added to the intra-operative costs of each robotic case. Robotic-assisted and conventional surgery ASD patients were comparable with regards to demographic and clinical characteristics, as were MVR patients in the two groups. For ASD patients, total average costs per-patient were US$11,622±$3,231 in the robotic-assisted surgery group, and US$10,660±$2,991 in the conventional sternotomy group (p=0.518). In the MVR patients, these costs were US$14,538±$1,697 in the robotic-assisted surgery group, and US$13,894±2,774 in the conventional sternotomy group (p=0.539). When the initial capital investment for the robotic surgical system was added to intra-operative costs, total average per-patient costs for ASD and MVR patients in the robotic-treated groups were US$15,395 and US$17,982, respectively. The most important intra-operative cost-drivers in both ASD and MVR patients were operating room time and supplies, both of which were higher in the robotic surgery group. With regards to post-operative cost-drivers, ICU stay and room charges had the most impact in both ASD and MVR patients, with these average costs being higher in the conventional sternotomy group. The authors concluded that the absolute cost of robotic surgery was higher than conventional surgery after taking into account the costs of the robot; however, operating room costs are likely to decrease as surgeons become more familiar with robotic technology. In addition, possible improvements in post-operative quality of life may make a robotic approach cost-effective.

Advincula et al. reported a comparison of short-term outcomes and costs in robot-assisted versus traditional laparoscopic abdominal myomectomy in 2007.19 This study was conducted in the United States. A case-control retrospective chart review collected data on 58 patients (29 per group) at a single hospital. Patients were matched on the weight of the excised leiomyomata, BMI, and age. Outcome data included operative time, length of stay, blood loss, intra-operative and post-operative complications. Cost data were obtained from the hospital accounting system and from reimbursement data for hospital and professional charges.
Abdominal myomectomies were performed by six senior faculty obstetricians and gynecologists, while all robot-assisted laparoscopic myomectomies were performed by the lead investigator. Patients were on average 35 years of age, had a BMI of 26, and the average weight of their excised leiomyomatas was 226 grams. Operative time was significantly greater in the robotic group (231±85 minutes versus 154±43 minutes; p<0.0001), but length of stay was significantly shorter in this group (1.48±0.95 days versus 3.62±1.50 days; p<0.0001). Patients undergoing robotic surgery experienced less blood loss (196±229 ml versus 365±473 ml; p=0.0112). There were no intra-operative complications in the traditional laparoscopy group compared with one event in the robot-assisted surgery group. A total of 14 post-operative complications in 12 patients were observed in the traditional surgery group, compared with three complications in the robotic group. Total professional and hospital costs associated with traditional surgery were US$18,065±$8,005 per patient, while this total in the robot-assisted surgery group was US$36,030±$6,946 (p=0.0002). The authors noted lower nursing, laboratory, and pharmacy costs in the traditional laparoscopic myomectomy group, but attributed the greater part of the difference in total average costs between the two groups to significantly higher operating department costs in the robotic group (US$16,916±$2,668 per patient versus US$2,165±$429 per patient; p<0.0001). These higher operating department costs were largely due to the surgical system’s five-year depreciated cost per patient. The authors concluded that while the higher relative cost of the robotic approach is not unexpected, decreased estimated blood loss, lower complication rates, and length of stay may have a societal benefit that outweighs the financial impact.

Heemskerk et al.\textsuperscript{20} (2007) reported a comparative retrospective study of costs and time consumption in robot-assisted versus conventional laparoscopic Nissen fundoplication in GORD. The study was conducted in the Netherlands. Eleven patients who underwent robot-assisted surgery were matched for age and sex to eleven patients who underwent conventional laparoscopy. Total treatment costs were based on admission costs, diagnostic costs, material costs, and wage costs. Groups were shown to be comparable with respect to age, gender distribution, length of stay, complications, and incidence of dysphagia. Total procedure time was higher in the robotic group (220 minutes versus 173 minutes; p=0.028). Total average per-patient costs were higher in the robotic surgery group as well (€4364 versus €3376) with this difference being largely explained by the difference in material costs (€1765 per patient for the robot-assisted surgery versus €780 per patient for conventional laparoscopy). The authors concluded that the use of robotic assistance in this procedure was safe and feasible, but resulted in longer operating time and higher costs without proven benefit at present.

Heemskerk led another team that compared time use and costs in robot-assisted versus conventional laparoscopic rectopexy for rectal prolapse.\textsuperscript{21} This study was also conducted in the Netherlands and was published in 2007. Thirty-three patients were non-randomly assigned to one of the two surgical methods. Primary endpoints were procedure time, hospital stay, and costs. Costs included hospital stay and treatment, surgical material costs, and staff salaries. Patient groups were comparable with regards to gender ratio, however the conventional laparoscopy group was younger (47 versus 55 years; p=0.021), and was more likely to have a previous abdominal surgery (71% versus 47%), prolapsed surgery (29% versus 16%), and uterus extirpation (36% versus 16%) although these differences were not statistically significant. Post-operative outcomes were similar in the two groups. Procedure time was significantly less in the conventional surgery group (113 versus 152 minutes; p=0.04) and length of stay was not significantly higher (4.3 versus 3.5 days; p=0.527). Total average per-patient costs in the robotic-assisted and conventional laparoscopic rectopexy groups were €3,673±€4,911 and €3,116±€4,165, respectively. The difference in average cost per patient was largely explained by the cost of the da Vinci\textsuperscript{®} unit (€889 per patient), and higher hospital admittance costs in the da Vinci\textsuperscript{®} Surgical Robotic System.
conventional laparoscopy group (difference of €466). The authors concluded that robot-assisted laparoscopic rectopexy is safe and feasible but results in increased time and higher costs than conventional laparoscopy.

In 2008, Bell et al.\textsuperscript{22} reported costs and outcomes in endometrial cancer staging via traditional laparotomy (40 patients), standard laparoscopy (30 patients), and robotic techniques (40 patients) at a US hospital. All procedures were performed by the same surgeon. Patient data were obtained by retrospective chart review, and costs were obtained from hospital financial records. Costs were classified as direct (radiology, pharmacy, laboratory, central supplies, surgery procedure (time-based), surgery supplies, recovery unit time, anesthesia, and room and board) and indirect (overhead) costs. The cost of the da Vinci\textsuperscript{®} surgical system was amortized over five years and included in the direct cost calculations, as were service agreement costs; however, the amount of these calculations were not stated. Patients were significantly different with respect to average age (laparotomy: 72.3±12.5 years; laparoscopy: 68.4±11.9 years; robotic: 63.0±10.1 years), but were not significantly different in mean BMI and uterine weight. Operative time was significantly higher with robotic surgery compared with laparotomy (184.0±41.3 minutes versus 108.6±41.4 minutes; p=0.0001), but not compared with laparoscopy (171.1±36.2 minutes; p=0.14). Estimated blood loss was significantly lower in the robotic surgery group compared with laparotomy (166.0±225.0 cc versus 316.8±282.1 cc; p=0.01) and lower than with laparoscopy (253.0±427.7 cc) however this difference was not statistically significant (p=0.25). The average number of nodes was comparable in the three groups. Average length of stay was longest for the laparotomy group (4.0 days) followed by the robotic group (2.3 days) and the laparoscopy group (2.0 days). Post-operative complications rates were 27.5% in laparotomy cases, 20.0% in laparoscopy, and 7.5% in robotic surgery. The authors also measured time to return to normal activities and found this to be highest in the laparotomy group (52 days), followed by the laparoscopy group (31.6 days) and the robotic group (24.1 days). Total average per-patient costs in the three surgical groups were US$12,944 (laparotomy), US$7,570 (laparoscopy), and US$8,212 (robotic). The two main factors accounting for the relatively high average costs in laparotomy were indirect overhead costs and room and board. The authors attributed most of the difference in costs of laparoscopic and robotic surgery to the amortization of the robot and the disposable instruments. The authors concluded that while operating times may be higher with robotic surgery compared with laparotomy, robotic surgery is equivalent to laparoscopy and may result in better patient outcomes (return to normal activities). Standard laparotomy was the most expensive procedure, followed by robotic surgery, and laparoscopy.

Breitenstein et al. (2008) reported a cost comparison of a matched case-control study in robotic-assisted versus laparoscopic cholesystectomy.\textsuperscript{23} The study was conducted in Switzerland and costs were reported in US dollars. Fifty consecutive patients undergoing elective robotic-assisted procedures were matched on age, gender, ASA score, histological finding of inflammation (acute, chronic, or both), and surgical experience to 50 elective laparoscopic cholecystectomy patients. Costs were classified according to operating room costs (surgery, anesthesiology, consumables, and an amortized amount per case relating to the acquisition cost of the robot or the laparoscopic system), and ward costs (preoperative, operative, post-operative). The amortization per case was estimated to be US$1275 for the robotic system (based on a purchase price of US$1,275,000, an additional annual maintenance fee of US$127,500, an amortization of 5 years, and 300 surgical cases per year), and US$38.30 for the laparoscopic system (purchase price of US$72,250, annual maintenance cost of US$4,250, 5 year amortization and 500 cases per year). Patient groups were comparable with regards to age, gender, BMI, and clinical characteristics, as well as intra-operative and post-operative outcomes. The total mean cost of surgery with the robotic system was higher
(US$7,985±$1,761 per patient versus US$6,255±$1,956 per patient, mean difference: US$1,730), with most of this cost difference attributed to consumables (US$1,126 versus US$495) and the amortized cost of equipment (US$1,275 versus US$38.30). The authors concluded that robotic-assisted cholecystectomy shows no benefits over conventional methods in terms of clinical outcome, and its costs are significantly higher because of extensive costs of capital and consumables and is therefore not justifiable.

In a final study published in 2008, Park et al.\textsuperscript{24} reported a cost-comparison of conventional thoracotomy, video-assisted thoracic surgery (VATS), robot-assisted VATS, and all VATS in pulmonary lobectomy. The study was conducted at a single institution in the United States. Costs were obtained retrospectively from the institution’s database. Cost details were not provided because of an institutional policy restricting publication of actual cost data. Over a one-year period, 269 patients underwent thoracotomy lobectomy, and 99 patients underwent VATS, with 12 of these procedures being robot-assisted. Type of surgery was determined by the individual surgeon’s recommendations based on multiple factors including patient preference, surgeon’s expertise, and nature of the disease. Average total per-patient costs for thoracotomy, VATS, and robot assisted VATS were US$8,368, US$399, and US$4380, respectively. The higher costs in thoracotomy were attributed to greater length of stay and surgeons’ fees, while the higher cost of robot-assisted VAT compared with regular VAT was attributed to the cost of the robotic equipment. The conclusion was that the costs associated with a minimally-invasive VATS approach to lobectomy were substantially lower than those resulting from thoracotomy, and while robot-assisted VATS increases the costs of this procedure, increased use over time will reduce the cost of each new case.

A summary of the economic studies reviewed in this section is provided in Appendix 2.

Limitations

The meta-analysis and systematic review both reported some benefit of robot-assisted surgery in prostatectomy compared with other techniques; however, these reports were largely based on observational (non-randomized) data.

Seven randomized trials in four indications did not find an advantage to robot-assisted surgery over other methods; however, these studies had several limitations. First, sample sizes in these studies were small and many were of short duration. This may have limited the ability to assess relative long-term outcomes and complications associated with the technologies compared in this report. It is also difficult to assess whether surgical skill in performing operations using the various surgical techniques was comparable in each of the trials. For example, in one study\textsuperscript{10}, both procedures were performed by a single surgeon, who may have been more capable with one technique over another. In another trial\textsuperscript{14}, all robotic surgeries were performed by a single surgeon, while conventional laparoscopic surgery was performed by four surgeons. Unless all trial surgeries are performed by a team of surgeons who are equally experienced in both techniques, the surgeon effect remains a potential source of bias.

Considering the variety of indications in which this technology is used, very few randomized trials were retrieved. No trials were found in prostate cancer, the most common indication.

Economic studies are largely cost-comparisons. Only one cost-effectiveness (cost-utility) study was retrieved and it was not well-reported. Better assessment of patient outcomes, including quality of life, would be required to evaluate the cost-effectiveness of this technology. Quality of life was addressed in only three of the studies reviewed; quality of life data were poorly reported.
in all three of the studies, and quality of life was not considered relative to costs in two. Our review of the literature found two studies\textsuperscript{25,26} that looked at quality of life with different surgical approaches (including robot-assisted), however, neither of the studies were based on randomized data and are therefore prone to selection bias.

While four of the economic studies were based on randomized data, limitations previously noted regarding these studies could also impact their economic findings. The ten economic studies that were based on observational data could be affected by selection bias as well.

Economic studies may also be influenced by features of the health care system from which they originate, which costs are included, and how those costs are measured. The studies reviewed in this report were obtained from a number of settings, and this should be considered when making generalizations in a Canadian context. Included costs were not consistent across the studies. Also, estimated per-patient costs for the robotic equipment were affected by the manner in which costs were amortized and the assumptions regarding the number of surgeries performed with the equipment. These issues should be considered before making generalizations from one institution to another with the reported economic findings.

Some cost analyses were conducted without consideration or reporting of outcomes, making interpretation of the economic findings more difficult.

**CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:**

The findings of this review suggest that robotic surgery using the da Vinci\textsuperscript{®} system may have some clinical benefit over other methods in prostatectomy; however, this finding is based largely on observational data. Randomized trials in a limited number of indications show no clinical benefit of using robotic surgery although these trials also have methodological limitations.

Economic assessments suggest that surgery using the da Vinci\textsuperscript{®} surgical system is more expensive compared with most other surgical methods, and in several indications. The main reason is high capital and operating costs. Again, these studies have methodological limitations, and cost-effectiveness assessments which take into account the value of relative benefits are lacking.

There is a need for well-designed randomized trials of this technology in several indications, with a concurrent assessment of patient outcomes including quality of life and costs.

Estimation of expected per-patient costs for this technology at a given institution must consider the institution’s accounting practices (i.e. with regards to amortization) as well as the expected number of patients that will be treated with this technology in each indication.

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## APPENDICES:

### Appendix 1: Clinical effectiveness results from seven randomized trials of da Vinci® robotic surgical system assisted laparoscopic surgery

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Procedure and indication</th>
<th>Sample size</th>
<th>Patient Characteristics</th>
<th>Study Results</th>
<th>Author Conclusion</th>
</tr>
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<tbody>
<tr>
<td>Morino et al.® (2004)</td>
<td>Adrenalectomy in benign lesions of the adrenal gland</td>
<td>20 (10 per group)</td>
<td>Age: 39.5 years Gender: 50% male BMI: 24 Mean diameter lesions: 3.2 cm</td>
<td>No mortality or post-operative complications in either group, and similar LOS (5.4 and 5.7 days). Two robot-assisted surgery patients experienced intra-operative complications (severe hypertension) and conversion to standard laparoscopy was required in 4 patients.</td>
<td>The two methods were similar with regards to post-operative morbidity and mortality, but that the complication seen in the two patients undergoing robot-assisted surgery was outside the expected range occurring in traditional laparoscopic surgery, and should be verified in a larger number of patients.</td>
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<tr>
<td>Sanchez et al.® (2005)</td>
<td>Roux-en-Y gastric bypass in morbid obesity</td>
<td>50 (25 per group)</td>
<td>Age: 44 years Gender: 10% male BMI: 44.5 Comorbidities: 2.4 Prior abdominal surgery: 55%</td>
<td>No post-operative complications; Mean LOS in both groups = 2.72 days; Mean operative time: Laparoscopy: 149.4 minutes, Robotic: 130.8 minutes, p = 0.02; Differences in operative time more pronounced in patients with BMI &gt; 43: Laparoscopy: 153.2 minutes, Robotic: 123.5 minutes, p = 0.009.</td>
<td>Gastric bypass with the da Vinci® surgical system is safe and feasible, with shorter operating times during a surgeon’s learning curve, and with that decrease being maximized in patients with higher BMIs.</td>
</tr>
<tr>
<td>Baik et al.® (2008)</td>
<td>Tumour-specific mesorectal excision (TSME) in rectal cancer</td>
<td>36 (18 per group)</td>
<td>Age: 60 years Gender: 78% male BMI: 23.4</td>
<td>Average operating time: R-TSME: 217.1±51.6 minutes, L-TSME: 204.3±51.9 minutes; Hemoglobin change: R-TSME: 0.6±0.6 mg/dl, L-TSME: 0.8±1.0; Number of days to peristalsis: L-TSME: 2.4±1.3 days, R-TSME: 1.8±0.4 days, p = 0.071; LOS: L-TSME: 8.7±1.3 days, R-TSME: 6.9±1.3 days, p &lt; 0.001; Conversion in 2 L-TSME cases; Post-operative complications: L-TSME: 5 cases, R-TSME: 4 cases</td>
<td>TSME was performed safely and effectively using this robotic system.</td>
</tr>
<tr>
<td>Author (year)</td>
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<td>Draaisma et al.¹¹ (2006)</td>
<td>Nissen fundoplication in GORD</td>
<td>50 (25 per group)</td>
<td>Age: 50 years Gender:66% male BMI: 27.2 Baseline QOL: 68.5</td>
<td>No significant difference in median operating time or blood loss. Two conversions to open surgery in laparoscopic group. Minor intra-operative complications in 7 laparoscopy patients. At 3-6 months, oesophageal manometry showed improvement in both groups, but no significant between-group differences. Total oesophageal acid exposure time in robotic group=0.7 and in laparoscopy group=0.3, (p=0.088). Average score on the symptom index zero in both groups. VAS scores improved by 49.5 points in robotic patients, and 43.5 points in laparoscopy patients (p=0.284). Two patients in each group required re-intervention at 6 months.</td>
<td>No additive value of robotic systems for this procedure was detected up to 6 months post-surgery. Authors stopped routinely using robotic systems in this procedure as costs were substantially higher but outcomes did not appear to be better in the short term.</td>
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<tr>
<td>Morino et al.¹² (2006)</td>
<td>Nissen fundoplication in GORD</td>
<td>50 (25 per group)</td>
<td>Age: 45 years Gender: 78% male BMI: 26 Mean lower oesophageal sphincter pressure: 8 mmHg</td>
<td>No post-operative complications. Mean hospital stay same in both groups (2.9 days in standard laparoscopy versus 3.0 days in the robot-assisted group, p=0.568). No clinical differences at 3, 6, and 12 months with GORD-HRQOL. No cases of endoscopic oesophagitis at 6 months, and no significant differences between groups in lower oesophageal sphincter resting pressure and post-operative pH values.</td>
<td>Study confirms that robot-assisted laparoscopic Nissen fundoplication is comparable to traditional laparoscopy in terms of complications, mortality, and length of stay in hospital, and current robotic systems are not of significant benefit to routine surgical practice.</td>
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<tr>
<td>Author (year)</td>
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<tr>
<td>El Nakadi et al. (2006)</td>
<td>Nissen fundoplication in GORD</td>
<td>20 (11 laparoscopy and 9 robotic)</td>
<td>Age: 46 years Gender:70% male BMI: 25.</td>
<td>Post-operative period: no significant differences in contrast swallow control, alimentation days (1.81±0.18 in laparoscopy vs. 2.11±0.11 robotic; p=0.21), or length of stay (4.1±0.3 days laparoscopy vs. 4.4±0.2 days in robotic; p=0.284). Post-operative complaints in 1st month comparable (4 cases in laparoscopy, 3 cases in the robotic). At 3 months, no complaints laparoscopy, four in robotic group (p&lt;0.013). One patient from robotic group presented with gastric torsion at 6 months and underwent a laparoscopic procedure.</td>
<td>No clear advantage of using robotics was observed.</td>
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<tr>
<td>Müller-Stich et al. (2007)</td>
<td>Fundoplication in GORD</td>
<td>40 (20 per group)</td>
<td>Age: 50 years Gender:45% male BMI: 28 GSRS: Robotic: 4.0±1.7, laparoscopic: 4.4±1.5; p=0.704</td>
<td>Intra-operative events: 2 cases of bleeding with laparoscopy and 1 case pneumothorax in robotic group. No conversions, re-operations, or major post-operative complications. Minor post-operative dysphagia recorded at discharge same in both groups. At 30 days: dysphagia same in both groups, two robotic and 3 laparoscopy patients resumed therapy with a PPI, and mean reflux scores were 1.3±0.7 in robotic patients and 1.6±1.3 in laparoscopy patients (p=0.064).</td>
<td>Trial did not reveal an additional benefit with the use of robot-assisted laparoscopic fundoplication.</td>
</tr>
</tbody>
</table>

The comparator in all seven trials was surgery using traditional laparoscopy. GORD: gastro-oesophageal reflux disease; L-TSME: laparoscopic tumor-specific mesorectal excision; R-TSME: robot-assisted tumor-specific mesorectal excision; BMI: body mass index; LOS: length of stay; QOL: quality of life; VAS: visual analogue scale; GORD-HRQOL: Gastro-oesophageal Reflux Health-Related Quality of Life Scale; GSRS: Gastrointestinal Symptoms Rating Scale; PPI: proton pump inhibitor.
## Appendix 2: Economic studies of the da Vinci® robotic surgical system

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Setting</th>
<th>Procedure and Indication</th>
<th>Clinical data source</th>
<th>Type of economic evaluation</th>
<th>Comparator</th>
<th>Clinical results</th>
<th>Costs included</th>
<th>Results</th>
<th>Conclusions</th>
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</thead>
<tbody>
<tr>
<td>Morino et al. (2004)</td>
<td>Italy</td>
<td>Adrenalectomy in benign lesions of the adrenal gland</td>
<td>RT n=20</td>
<td>CC</td>
<td>Laparoscopy</td>
<td>Higher peri-operative morbidity and conversion in robotic group</td>
<td>Operating costs, disposables, hospital stay</td>
<td>Robot: US$3,466 per case; Laparoscopy US$2,737 per case</td>
<td>laparoscopic adrenalectomy superior to robot-assisted adrenalectomy in terms of feasibility, morbidity, and cost</td>
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<tr>
<td>Morino et al. (2006)</td>
<td>Italy</td>
<td>Nissen fundoplication in GORD</td>
<td>RT n=50</td>
<td>CM</td>
<td>Laparoscopy</td>
<td>Outcomes comparable</td>
<td>OR, disposables, hospital stay</td>
<td>Robot: €3157 per case; Laparoscopy €1527 per case</td>
<td>Outcomes comparable in the two methods, but costs were higher in the robot-assisted group</td>
</tr>
<tr>
<td>El Nakadi et al. (2006)</td>
<td>Belgium</td>
<td>Nissen fundoplication in GORD</td>
<td>RT n=20</td>
<td>CM</td>
<td>Laparoscopy</td>
<td>Surgical outcomes comparable with significantly more post-surgical complaints in robotic group at 3 months</td>
<td>Hospital stay, pharmacy, procedure costs, nursing, initial investment cost per patient, annual maintenance.</td>
<td>Without investment costs: Robot: €6,973 per case; Laparoscopy: €5,167 per case; With investment costs: Robot: €27,561 per case; Laparoscopy €5,907 per case</td>
<td>No clear advantage in using robotics in this procedure was observed</td>
</tr>
<tr>
<td>Author (Year)</td>
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<td>Müller-Stich et al. (2007)</td>
<td>Germany and Romania</td>
<td>Fundoplication in GORD</td>
<td>RT n=40</td>
<td>CM</td>
<td>Laparoscopy</td>
<td>Outcomes comparable</td>
<td>OR, disposables, hospital stay</td>
<td>Robot: €3244 per case</td>
<td>Operating time can be shorter in robot-assisted surgery if team experienced, but costs higher and short term costs similar; robot-assisted surgery not favored over conventional laparoscopy.</td>
</tr>
<tr>
<td>Lotan et al. (2004)</td>
<td>United States</td>
<td>Radical prostatectomy in prostate cancer</td>
<td>Literatur e, decision -analytic model</td>
<td>CC</td>
<td>Retropubic (open) and laparoscopy</td>
<td>NR</td>
<td>OR, equipment, surgical professional fees, room and board, intravenous fluids and medication, purchase and maintenance of robot</td>
<td>Robot: US$7,280 per case</td>
<td>Retropubic surgery was least costly approach, laparoscopic surgery almost as competitive, and high cost of robot assisted surgery overshadowed savings made by shorter length of stay</td>
</tr>
<tr>
<td>O’Malley et al. (2007)</td>
<td>Australia</td>
<td>Radical prostatectomy in prostate cancer</td>
<td>OBS, not specified</td>
<td>Cost-Utility</td>
<td>Open surgery</td>
<td>NR</td>
<td>Hospital stay, equipment, maintenance contract, consumables</td>
<td>ICER: AUS$24,475 /QALY</td>
<td>ICER below accepted range for cost-effectiveness of pharmaceuticals in Australia and does not fully account for benefits of robotic surgery</td>
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<td>Author (Year)</td>
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| Bhayani et al.17 (2005) | United States | Pyeloplasty in uteropelvic junction obstruction                     | OBS n=21             | CC                          | Laparoscopy | EBL and OR time higher with laparoscopy, but groups similar in other outcomes    | OR, cost of equipment               | Robot: US$5616 per case  
Laparoscopy: US$3500 per case | Peri-operative parameters with robotic surgery encouraging, however costs disadvantageous and institution considered it more cost-effective to teach and perform laparoscopic surgery |
| Morgan et al.18 (2005)  | United States | Cardiac surgery: ASD closure and MVr                               | RCR n=20             | CC                          | Sternotomy | OR, perfusion, supplies, medications, labs, radiology, other tests, respiratory services, ICU, room, physical therapy, cost of robotic equipment | ASD closure:  
Robot: US$11,622 per case  
Sternotomy: US$10,660 per case  
MVr: Robot: US$14,538 per case  
Sternotomy: US$13,894 per case  
With cost of robotic equipment:  
ASD closure: US$15,395 per case  
MVr: US$17,982 per case | OR time and supplies higher in robotic group. ICU charges and room higher in sternotomy. Absolute cost of robotic surgery higher after accounting costs of robot. OR costs may decrease as surgeons become familiar with robotic technology. Possible improvements in post-operative QOL may make robotic approach cost-effective |
<table>
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<tr>
<th>Author (Year)</th>
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<tbody>
<tr>
<td>Advincula et al. (2007)</td>
<td>United States</td>
<td>Abdominal myomectomy of leiomyomata</td>
<td>CCS n=58</td>
<td>CC</td>
<td>Laparotomy</td>
<td>Robotic group had longer OR time but shorter LOS, less blood loss, and fewer complications</td>
<td>Hospital and professional charges</td>
<td>Robot: US$36,030 per case, Laparotomy: US$18,065 per case</td>
<td>Cost difference attributed to significantly higher OR costs in robotic group due to cost of equipment. While higher cost of robotic approach not unexpected, decreased EBL, fewer complications, and decreased LOS may have societal benefit that outweighs financial impact.</td>
</tr>
<tr>
<td>Heemskerk et al. (2007)</td>
<td>Netherlands</td>
<td>Nissen fundoplication in GORD</td>
<td>CCS n=22</td>
<td>CC</td>
<td>Laparoscopy</td>
<td>NR</td>
<td>Admission costs, treatment, diagnostics, materials, wages</td>
<td>Robot: €4,364 per case, Laparoscopy €3,376 per case</td>
<td>use of robotic assistance safe and feasible, but resulted in longer operating time and higher costs without proven benefit</td>
</tr>
<tr>
<td>Heemskerk et al. (2007)</td>
<td>Netherlands</td>
<td>Rectopexy for rectal prolapse</td>
<td>OBS n=33</td>
<td>CC</td>
<td>Laparoscopy</td>
<td>Outcomes comparable but procedure time less in laparoscopy</td>
<td>Hospital stay and treatment, surgical material costs, equipment and staff salaries</td>
<td>Robot €3,673 per case, Laparoscopy €3,116 per case</td>
<td>Equipment costs higher in robotic group but hospital costs higher in laparoscopy. Robot-assisted laparoscopic rectopexy safe and feasible but results in increased time and higher costs than conventional laparoscopy</td>
</tr>
<tr>
<td>Author (Year)</td>
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<td>Procedure and Indication</td>
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<tr>
<td>Bell et al. (2008)</td>
<td>United States</td>
<td>Endometrial cancer staging</td>
<td>RCR n=110</td>
<td>CC</td>
<td>Laparotomy and laparoscopy</td>
<td>EBL lower in robotic group and LOS longest in laparotomy. OR time highest in robotic but comparable to laparoscopy. Post-operative complications highest in laparotomy (27.5%) and lowest in robotic (7.5%). Time to return to normal activities highest in laparotomy (52 days) and lowest in robotic (24 days)</td>
<td>radiology, pharmacy, laboratory, central supplies, surgery, surgical supplies, recovery unit, anesthesia, room, overhead, cost of equipment</td>
<td>Robot: US$8,212 per case Laparoscopy US$7,570 per case Laparotomy: US$12,944 per case</td>
<td>High laparotomy costs attributed overhead and room and board. Robotic surgery equivalent to laparoscopy and may result in better patient outcomes.</td>
</tr>
<tr>
<td>Breitenstein et al. (2008)</td>
<td>Switzerland</td>
<td>Cholecystectomy in symptomatic cholecystolithiasis</td>
<td>CCS n=50</td>
<td>CC</td>
<td>Laparoscopy</td>
<td>Comparable intra-operative and post-operative outcomes</td>
<td>OR (surgery, anesthesia, consumables, equipment, ward costs</td>
<td>Robot: US$7,985 per case Laparoscopy US$6,255 per case</td>
<td>Robotic-assisted cholecystectomy shows no benefits over conventional methods in clinical outcome and costs significantly higher because of extensive costs of capital and consumables</td>
</tr>
<tr>
<td>Author</td>
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<tr>
<td>Park et al. (2008)</td>
<td>United States</td>
<td>Pulmonary lobectomy in lung cancer</td>
<td>OBS n=368</td>
<td>CC</td>
<td>Thoracotomy, VATS, and robot-assisted VATS</td>
<td>NR</td>
<td>LOS, surgeon's fees, equipment</td>
<td>Robot-VATS: US$4380 per case, Thoracotomy US$8,368 per case, VATS: US$399 per case</td>
<td></td>
</tr>
</tbody>
</table>

RT: randomized trial; OBS: observational; CC: cost comparison; CM: cost minimization; CCS: case control study; RCR: retrospective chart review; GORD: gastro-oesophageal reflux disease; ASD: atrial septal defect; MVr: mitral valve repair; OR: operating room; ICU: intensive care unit; QOL: quality of life; EBL: estimated blood loss; ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life-year; VATS: video assisted thoracic surgery; NR: not reported