Horizon Scanning in Surgery: Application to Surgical Education and Practice

Robotic laparoscopic adrenalectomy

November 2008

Division of Education
Prepared by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical for the American College of Surgeons

Robotic laparoscopic adrenalectomy
November 2008
Disclaimer

This report is not a comprehensive systematic review. Rather, it is an assessment of an emerging surgical procedure or technology in which the methodology has been limited in one or more areas to shorten the timeline for its completion.

Therefore, this report is a limited evidence-based assessment that is based on a search of studies published in the peer-reviewed literature. This report is based on information available at the time of research and cannot be expected to cover any developments arising from subsequent improvements in health technologies. This report is based on a limited literature search and is not a definitive statement on the safety, effectiveness or cost-effectiveness of the health technology covered.

This report is not intended to be used as medical advice or to diagnose, treat, cure or prevent any disease, nor should it be used for therapeutic purposes or as a substitute for a health professional's advice. The Australian Safety and Efficacy Register of New Interventionsal Procedures – Surgical (ASERNIP-S) does not accept any liability for any injury, loss or damage incurred by use of or reliance on the information.

Objective

This horizon scanning assessment provides short, rapidly completed, "state of play" documents. These provide current information on technologies to alert clinicians, planners and policy makers of the advent and potential impact of a new or emerging procedure or device. This information can then assist clinicians, planners and policy makers to control and monitor the introduction of new health technologies, as well as assist in the prioritization and allocation of resources to promote efficient utilization of available resources.

Introduction

Indication

The adrenal glands are endocrine glands located above the kidneys. They produce the hormones epinephrine and norepinephrine, aldosterone, glucocorticoids, and adrenal androgens. Various benign tumors and cancers (primary or metastatic) can develop at the site of the adrenal glands. These lesions may be functional, meaning that they produce hormones and can result in endocrine disorders, or non-functional, with no hormonal activity (Lal and Duh 2003).

Surgical management of adrenal lesions involves an adrenalectomy, which is the removal of one or both adrenal glands. Traditionally this involved open excision via various approaches (transabdominal, lateral or flank) (Lal and Duh 2003). However, over the last decade laparoscopic (keyhole) surgical techniques have emerged as the treatment of choice for a variety of abdominal diseases, with the first reported laparoscopic adrenalectomy performed in 1992 (Saunders et al 2004). Laparoscopic adrenalectomy is now routinely performed, particularly for benign adrenal lesions (Morino et al 2004). Laparoscopic adrenalectomy can be performed via a transabdominal (also known as transperitoneal) (anterior or lateral) or retroperitoneal (lateral or posterior) approach (Lal and Duh 2003). The laparoscopic technique has been shown to provide benefits in terms of postoperative recovery, hospital stay and overall cost (Wu et al 2008). Indications for laparoscopic adrenalectomy include functional benign lesions (e.g. aldosteronoma, pheochromocytoma, some forms of Cushing's syndrome), non-functional benign lesions (e.g. cortical adenoma, large and symptomatic myelolipoma or cyst) and malignant functional or non-
functional lesions (e.g. some adreno-cortical cancer, malignant pheochromocytoma, metastasis). The role of laparoscopy for very large or malignant adrenal lesions remains controversial (Lal and Duh 2003).

Despite the improvements in patient outcomes associated with laparoscopic adrenalectomy, there are also technical limitations with the standard laparoscopic technique (Morino et al 2004). Such limitations include nonarticulated instruments and fixed entry points which limit maneuverability inside the body, a two-dimensional screen image resulting in loss of visual depth perception, an awkward position for the surgeon at the operating table, and the need for a human assistant to hold and move the camera resulting in the surgeon losing the independent ability to control the operation field. Robotic technology was introduced to the laparoscopic technique in an attempt to overcome some of these problems, and to increase surgical dexterity by eliminating tremors and fatigue and reducing the scale of movement (Morino et al 2004; Wu et al 2008). Robotic systems provide three-dimensional vision and the ability to make intra-abdominal movements in three dimensions (Morino et al 2004). The physical characteristics of the adrenal gland (a small organ located in a deep, fixed, narrow space) are particularly suited to the robotic-assisted technique. There are two robotic systems available for performing robotic-assisted laparoscopic adrenalectomy, the Da Vinci robotic surgical system (Intuitive Surgical Inc., Mountain View, CA, USA) and the Zeus robotic surgical system (former Computer Motion Inc system, Goleta, CA, USA, now owned by Intuitive Surgical Inc., Mountain View, CA, USA) (Wu et al 2008).

**Burden of disease**

The true incidence of adrenal lesions remains to be determined. Tumors of the adrenal cortex are reported in 2% of all autopsies in the United States, with the most common lesion being a benign adenoma. The incidence of adrenal carcinoma is approximately 1 case per 1.7 million, accounting for 0.02% of all cancers (Miles et al 2007).

The number of adrenalectomies being performed in the U.S. appears to be increasing (Saunders et al 2004). A Nationwide Inpatient Sample, which includes around 20% of all non-federal hospital discharges in the U.S., was utilized to determine the number of adrenalectomies being performed between 1988 and 2000. In this sample in 2000, there were 1378 patients who underwent an adrenalectomy, giving a rate of 18.5 adrenalectomies per 100,000 hospital discharges. This has increased significantly from 1988, when there was a rate of 12.9 adrenalectomies per 100,000 ($P=0.000003$). This increase in operations corresponds to an increase in the proportion of adrenalectomies being performed for benign neoplasms (25% in 1988-1993 versus 28% in 1994-2000; $P=0.015$). It is hypothesized that this increase may be associated with improved detection of lesions, and also a trend towards surgical referral earlier in the course of the disease. The development of minimally invasive laparoscopic techniques may have led to the removal of lesions which previously would have been left for observation (Saunders et al 2004).

**Procedure description**

The Da Vinci robotic surgical system consists of a robotic manipulator with three arms. The central arm holds the camera and the two other arms hold the surgical instruments. The operating surgeon sits at a remote console to control the robot (Brunaud et al 2008). The Zeus is a similar system, with three separate robotic arms and a remote mobile surgeon console with a video monitor that provides a three-dimensional view (Wu et al 2008).

Robotic laparoscopic adrenalectomy is usually performed transperitoneally with patients in a lateral flank position. The procedure begins with assistants creating a pneumoperitoneum (inflation of the abdomen with gas), placing trocars (hollow ports) for insertion of the robot camera and tools and any other laparoscopic instruments, and connecting the robotic arms. The robotic arms are then controlled by the operating surgeon at the remote console, while the assistants handle the additional laparoscopic instruments inserted in the accessory trocars (Brunaud et al
The operation reproduces a standard laparoscopic adrenalectomy, with exploration of the abdominal cavity, manipulation of the necessary organs to expose the adrenal gland, clipping of the adrenal vein and dissection of the gland, and removal through the accessory port. During the operation, the operating surgeon uses controllers which transmit signals via a computer to the robotic arms and instruments. The system uses wrist-like instruments to improve dexterity. The robot minimizes tremors from the surgeon’s hands and relays smooth motions to the surgical instruments (Morino et al 2004). In the Zeus system, the camera arm of the robotic system can be controlled by voice commands (Wu et al 2008).

Stage of development

The first reported robotic laparoscopic adrenalectomy using the Da Vinci system was performed in 2001 by Horgan et al (2001). Published studies (comparative studies, case series or case reports) on robotic laparoscopic adrenalectomy have been performed in Austria, Belgium, France, Germany, Italy, Japan, Saudi Arabia, Taiwan, UK and the USA.

The two systems which can be used for robotic-assisted laparoscopic adrenalectomy, the Zeus and the da Vinci systems, both have U.S. Food and Drug Administration (FDA) approval. The Da Vinci system was approved for general laparoscopic surgery in 2000 (K990144) to assist in advanced surgical techniques such as cutting and suturing. The Zeus system was approved in 2001 (K003431) (FDA 2008). In 2008, there were 647 Da Vinci surgical systems available in U.S. hospitals, a further 148 systems available within Europe and 72 in the rest of the world (Intuitive Surgical 2008). In 2002, there were more than 30 Zeus systems installed in the U.S (Meadow 2002). However, since the 2003 merger between Intuitive Surgical and Computer Motion, Zeus systems are being supported but no longer actively marketed.

Current treatment and alternatives

- Standard laparoscopic (non-robotic) adrenalectomy: This procedure is the current gold standard, particularly for benign lesions. Contraindications for the laparoscopic technique include non-correctable coagulopathy, cranial hypertension, and cardiac and respiratory disorders that preclude a laparoscopic approach (Lal and Duh 2003). Very large or malignant tumors (such as known invasive adreno-cortical carcinomas) may also be unsuitable for laparoscopic adrenalectomy (Brunaud et al 2004).

- Open adrenalectomy: This procedure is used in cases where the laparoscopic technique is contraindicated (e.g. very large or malignant tumors) (Brunaud et al 2004).

- Non-surgical treatment: Treatments which may be used in conjunction with surgery, or as alternative therapy, include pharmacotherapy to correct hormone levels, and chemotherapy and/or radiotherapy to reduce adrenal tumors.

Literature review

PubMed, EMBASE and The Cochrane Library databases were searched using the criteria outlined below. Studies were selected for inclusion on the basis of the criteria outlined in Table 1. From the search strategy, 108 potentially relevant articles were identified. Of these, five comparative studies (including one randomized controlled trial (RCT)) were eligible for inclusion (Brunaud et al 2003; Brunaud et al 2004; Morino et al 2004; Wu et al 2008; Brunaud et al 2008). No systematic reviews were identified on the topic. A number of case series and case reports were identified, which are listed in Appendix A as excluded studies.
Table 1 Inclusion criteria for identification of relevant studies

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publication type</td>
<td>Systematic reviews, randomized and non-randomized comparative studies will be included. Non-systematic reviews, case series and case reports, articles identified as preliminary reports where results are published in later versions, articles in abstract form, letters, editorials, and animal, in-vitro and laboratory studies will be excluded.</td>
</tr>
<tr>
<td>Patient</td>
<td>Patients requiring adrenalectomy for benign or malignant disease</td>
</tr>
<tr>
<td>Intervention</td>
<td>Robot-assisted laparoscopic adrenalectomy</td>
</tr>
</tbody>
</table>
| Outcome          | **Efficacy:** Operative time, blood loss, conversions, hospital stay, quality of life  
                  | **Safety:** Complications/adverse events, mortality                                                                                                                                             |
| Language         | Non-English language articles will be excluded unless they add significantly to the evidence provided by English language studies.                                                              |
| Date             | No date restriction                                                                                                                                                                             |

Search criteria

Keyword/MeSH terms utilized: (robot* OR da vinci OR Zeus) AND adrenal*

Safety and efficacy

Included studies and critical appraisal

A summary of the five included comparative studies, including the one RCT, is shown in Table 2. All five studies compared robotic laparoscopic adrenalectomy to standard laparoscopic adrenalectomy. The five studies covered the years 1996 to 2005, although the robotic-assisted technique was only introduced from 2001. The studies used a transperitoneal/transabdominal approach, with four of the studies using the Da Vinci system and one using the Zeus system.

The RCT by Morino et al (2004) did not provide details of the randomization and implementation method. The other studies were non-randomized, and three of these consisted of a historical control of patients undergoing the standard laparoscopic technique (Brunaud et al 2003; Brunaud et al 2004; Brunaud et al 2008). The other study by Wu et al (2008) had a concurrent comparator group of patients undergoing the standard laparoscopic procedure. For all studies, a consecutive patient sample was used, patient characteristics were comparable at baseline, and in all studies adrenalectomy was performed for a range of indications. The studies clearly defined the interventions and statistical analyses used. The largest study (Brunaud et al 2008) reported results from 109 patients, and it is possible that this study incorporated some patients from previous studies (Brunaud et al 2003; Brunaud et al 2004). However, this could not be determined for certain from the information reported. The studies in general were limited by small sample sizes, lack of randomization, poor reporting of methodological detail and use of a power calculation, and lack of long-term follow-up.
Table 2: Summary of included comparative studies on robotic-assisted laparoscopic adrenalectomy

<table>
<thead>
<tr>
<th>Study</th>
<th>Level of evidence</th>
<th>Study period</th>
<th>Procedure</th>
<th>RA Device</th>
<th>Patients (age given as mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brunaud et al 2003</td>
<td>III-3</td>
<td>2000-2002 Consecutive patients from single institution</td>
<td>Bilateral transperitoneal LA or RA</td>
<td>Da Vinci</td>
<td>RA: 14 patients (age 46.1±4.1; indications: Conn’s adenoma (n=5), pheochromocytoma (n=2), Cushing adenoma (n=4), non secreting adenoma (n=2), Cushing’s disease (n=1)) LA: 14 patients (age 43.7±3.2; indications: Conn’s adenoma (n=4), pheochromocytoma (n=6), Cushing adenoma (n=1), non secreting adenoma(n=3))</td>
</tr>
<tr>
<td>Brunaud et al 2004</td>
<td>III-3</td>
<td>2000-2003 Consecutive patients from single institution</td>
<td>Bilateral transabdominal LA or RA</td>
<td>Da Vinci</td>
<td>10M/23F RA: 19 patients (age 48.0±2.9; indications: aldosteronoma (n=8), pheochromocytoma (n=4), cortisol-producing adenoma (n=5), non secreting adenoma (n=2) LA: 14 patients (age 44.8±3.3; indications: aldosteronoma (n=3), pheochromocytoma (n=7), cortisol-producing adenoma (n=1), non secreting adenoma (n=3))</td>
</tr>
<tr>
<td>Morino et al 2004</td>
<td>II</td>
<td>2002-2002 Consecutive patients from single institution</td>
<td>Lateral flank LA or RA</td>
<td>Da Vinci</td>
<td>RA: 10 patients (age 38.7 (19-68); 4M/6F; indications: Conn’s adenoma (n=3), pheochromocytoma (n=4), incidentaloma (n=3) LA: 10 patients (age 40.3 (23-72); 5M/5F; indications: Conn’s adenoma (n=3), Cushing’s adenoma (n=3), pheochromocytoma (n=3), incidentaloma (n=1)) No difference between groups for characteristics</td>
</tr>
<tr>
<td>Wu et al 2008</td>
<td>III-2</td>
<td>2003-2005 Consecutive patients from single institution</td>
<td>Transperitoneal LA or RA</td>
<td>Zeus</td>
<td>RA: 5 patients (age 58.2±12.2 years; 2M/3F; indications: cortical adenoma (n=4), pheochromocytoma (n=1)) LA: 7 patients (age 56.3±7.8 years; 2M/5F; indications: cortical adenoma (n=7))</td>
</tr>
<tr>
<td>Brunaud et al 2008</td>
<td>III-3</td>
<td>1996-2005 Consecutive patients from single institution (1996-2001 for LA, 2001-2005 for RA)</td>
<td>Bilateral transperitoneal LA or RA</td>
<td>Da Vinci</td>
<td>RA: 50 patients (age 49.6 years (23-75); 19M/31F; indications: aldosteronoma (n=21), pheochromocytoma (n=11), incidentaloma (n=9), Cushing adenoma (n=7), hyperplasia (Cushing) (n=2)) LA: 59 patients (age error – reported as 5.1 (17-76); 23M/35F; indications: aldosteronoma (n=13), pheochromocytoma (n=17), incidentaloma (n=13), Cushing adenoma (n=8), hyperplasia (Cushing) (n=8) No difference between groups</td>
</tr>
</tbody>
</table>

F = female; LA = traditional laparoscopic adrenalectomy; M = male; RA = robotic laparoscopic adrenalectomy; SD = standard deviation

**Efficacy**

All five studies compared operative time between robotic laparoscopic adrenalectomy and standard laparoscopic adrenalectomy (Table 3). Brunaud et al (2003) and Wu et al (2008) found that operative time was significantly longer for robotic compared with standard laparoscopic adrenalectomy, but only when robotic setup time was included. Both Morino et al (2004) and Brunaud et al (2008) found the total operation time to be significantly longer in robotic compared to standard laparoscopic adrenalectomy, and Morino et al (2004) also found skin-to-skin time to be longer in the robotic group. However, Brunaud et al (2008) did find that after a learning curve of 20 patients, there was no difference in operative time between the robotic and standard laparoscopic procedure. Increased experience lead to a significant reduction in operation time for the robotic technique (Brunaud et al 2008). The study by Brunaud et al (2004) found no
significant difference in operative time between the robotic and the standard laparoscopic technique.

Brunaud et al (2003) and Brunaud et al (2008) also reported mean operation room time, with the earlier study finding no significant difference between robotic and standard laparoscopic adrenalectomy, and the larger, more recent study finding mean room time for the robotic procedure to be significantly longer than for standard laparoscopic adrenalectomy (Table 3). None of the four studies which reported on length of hospital stay found a significant difference between the robotic and standard laparoscopic groups (Table 3). Brunaud et al (2004) found no significant difference between the robotic and the standard laparoscopic patient groups in terms of duration of postoperative ileus, fasting or drainage ($P=ns$).

Blood loss was reported by three studies (Brunaud et al 2003; Wu et al 2008; Brunaud et al 2008) (Table 3); however, only the study by Brunaud et al (2008) found a significant difference between robotic and standard laparoscopic adrenalectomy for this measure. In this study, patients who had the robotic technique lost significantly less blood than those who had the standard laparoscopic technique.

Another key efficacy outcome is the number of procedures which required a conversion to a different technique. This may be reported as a conversion from the robotic technique to the standard laparoscopic technique, or a conversion from either a robotic or standard laparoscopic adrenalectomy to an open adrenalectomy (laparotomy) (Table 3). Morino et al (2004) found that 4/10 robotic patients (40%) had to be converted to standard laparoscopy, while 1/14 patients (7%) in the robotic group (Table 3) study and 1/50 patients (2%) in the Brunaud et al (2008) study had to be converted from the robotic to the standard laparoscopic technique. These conversions were due to technical problems (malposition of trocars or inadequate visualization) or clinical issues such as intraoperative bleeding. Conversion rates to open adrenalectomy were similar for both the robotic and standard laparoscopic groups in the studies by Brunaud et al (2003), Brunaud et al (2008) and Morino et al (2004) reported no conversions to the open technique. Wu et al (2008) reported that none of the 12 patients in this study required a conversion to a different technique.

The study by Brunaud et al (2004) also measured quality of life using the SF-36 tool, which evaluates physical functioning, social functioning, bodily pain, general health perceptions, vitality, role limitations due to emotional health problems, role limitations due to physical health problems, and mental health. The study found that there was no significant difference between the robotic and the standard laparoscopic patient groups for all the SF-36 quality of life scores at day 4 and week 6 postoperation. The exception was for the subscore “role limitations due to emotional problems” which was higher (corresponding to a better health status) in the robotic group at six weeks ($P=0.03$). There was no significant difference between the robotic and the standard laparoscopic patient groups for state and trait anxiety (measured using an anxiety-targeted psychological questionnaire (STAI)), and postoperative pain, quality of sleep and sleep duration were reported to be similar between the two groups (Brunaud et al 2004).

Safety

Intraoperative complications were reported in several studies (Table 3). In the study by Brunaud et al (2003) the robotic and standard laparoscopic groups each experienced intraoperative complications which did not require conversions in 3/14 patients (21%). In the robotic group, one of these complications was a malfunctioning of the robot camera. Morino et al (2004) found that 2/10 patients (20%) in the robotic group had severe intraoperative hypertension, while no patients in the standard laparoscopic group experienced intraoperative complications. However, the authors acknowledge that the small sample size makes it difficult to determine whether this finding is significant, and whether it can be attributed to robotic manipulation (Morino et al 2004). Wu et al (2008) reported that there were no perioperative complications in either the robotic or
standard laparoscopic groups, and that there were no injuries related to use of the robot, and no robot malfunctions.

Four studies reported on postoperative complications (Table 3). Morino et al (2004) reported that there were no postoperative complications in either the robotic or the standard laparoscopic patient groups. In the three studies by Brunaud et al (2003; 2004; 2008), reported postoperative complications included pneumonia, pleural effusion, urinary infection, urinary retention and wound infection. Postoperative complication rates appeared similar between the robotic and standard laparoscopic groups, with the largest study finding that 5/50 patients (10%) in the robotic group and 9/59 patients (15%) in the standard laparoscopic group experienced complications (Brunaud et al 2008). The study by Brunaud et al (2004) performed a statistical analysis and found no significant difference between the groups for postoperative complications. There were no deaths in the robotic or the standard laparoscopic groups in the four studies which reported this measure.
### Table 3: Safety and efficacy results for comparative studies on robotic-assisted laparoscopic adrenalectomy

<table>
<thead>
<tr>
<th>Study</th>
<th>Key efficacy outcomes</th>
<th>Key safety outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Operative time (mins) (mean±SD)</td>
<td>Blood loss (mL) (mean±SD)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Brunaud et al 2003
Operative time (not including robotic setup time): RA: 111±9; LA: 83±7 (p=0.057)
Total operative time (including robotic setup time): RA: 139±9; LA: 83±7 (p=0.002)
Operation room time: RA: 204±9; LA: 174±12 (p=ns)
For RA, mean operative time reduced from 122 mins for first 7 patients to 98 minutes for most recent 7 patients (P=0.19)
At 12 hours: RA: 55±16; LA: 57±8 (p=ns)
Conversion to laparotomy: RA: 1 (7%); LA: 1 (7%)
Reasons for conversion: RA: intraoperative bleeding; LA: polycystic kidneys made dissection impossible
Conversion to laparotomy: RA: 1 (2%); LA: NA
Conversion to laparotomy: RA: 3 (6%); LA: 4 (7%)
Reasons for conversion: RA: inadequate visualization with Da Vinci robotic system (n=1, converted to LA), intraoperative bleeding (n=3, converted to open); LA: NR
Mortality: RA: 0; LA: 0
Perioperative complications: RA: 5 patients (10%) (1 grade I and 4 grade II complications); pneumonia (n=3), urinary tract infection (n=1), wound infection (n=1); LA: 9 patients (15%) (6 grade I, 2 grade II, and 1 grade III complications)
No perioperative deaths in RA or LA group.

Brunaud et al 2004
Operative time: RA: 107±6.6; LA: 86±7.8 (P=NS)
NR
NR
NR
Postoperative complications: RA: 3 (urine retention (n=1), left pleural effusion (n=1), urinary infection (n=1)); LA: 2 (urine retention (n=1), pneumonia (n=1)) (P=NS)
Mortality: RA: 0; LA: 0

Morino et al 2004
Total operative time: RA: 169 (136-215); LA: 115.3 (95-155) (P<0.01)
Skin to skin time: RA: 107 (77-154); LA: 82.1 (55-120) (P<0.01)
NR
Conversion to laparoscopy: RA: 4; LA: NA
Conversion to laparotomy: RA: 0; LA: 0
Reasons for conversion: malposition of robotic trocars (2), difficulty in obtaining homeostasis (1), prolonged operative time (1)
NR
Intraoperative complications: RA: 2 (severe intraoperative hypertension (n=2)); LA: 0
Postoperative complications: RA: 0; LA: 0
Mortality: RA: 0; LA: 0

Wu et al 2008
Robotic setup time: RA: 20.0±5.0; LA: NA
Total operation time: RA: 188.0±30.5; LA: 131.4±29.0 (P=0.022)
Resection time: RA: 168.0±30.7; LA: 131.4±29.0 (p=0.05)
RA: 90.0±54.8; LA: 85.7±37.8 (P=1.0)
RA: 0; LA: 0
RA: 4.0±0.7; LA: 3.4±0.5 (P=0.148)
No perioperative complications in the series and no injuries related to the use of the robot or robot malfunction.

Brunaud et al 2008
Mean robot setup time:
RA: 5 (2-8); LA: NA
Mean operative time: RA: 104 (60-180); LA: 87 (50-160) (P<0.002)
Mean room time: RA: 189 (130-305); LA: 159 (100-232) (P<0.0001)
No difference in operative time between RA and LA patients after a learning curve of 20 patients (RA: 87; LA: 77, P=ns).
For RA, mean operative time reduced from 116 mins for first 20 patients to 87 minutes from most recent group of patients (patients 21 to 50) (P=0.0003)
RA: 49; LA: 71 (P<0.001)
Conversion to laparoscopy: RA: 1 (2%); LA: NA
Conversion to laparotomy: RA: 3 (6%); LA: 4 (7%)
Reasons for conversion: RA: inadequate visualization with Da Vinci robotic system (n=1, converted to LA), intraoperative bleeding (n=3, converted to open); LA: NR
Mortality: RA: 0; LA: 0
Perioperative complications: RA: 5 patients (10%) (1 grade I and 4 grade II complications); pneumonia (n=3), urinary tract infection (n=1), wound infection (n=1); LA: 9 patients (15%) (6 grade I, 2 grade II, and 1 grade III complications)
No perioperative deaths in RA or LA group.

LA = traditional laparoscopic adrenalectomy; NA = not applicable; NR = not reported; NS = non significant; RA = robotic laparoscopic adrenalectomy; SD = standard deviation
Cost impact

The initial purchase cost of a robotic surgical system is high, with both the Da Vinci and Zeus systems being sold for approximately $US1 million. Maintenance and training are also required (Meadows 2002). The cost of the robotic procedure per patient was compared with the cost of the standard laparoscopic procedure in the comparative study by Morino et al (2004). The study found that the cost of the robotic procedure was $US3466, while the standard laparoscopic procedure was less, at $US2737 ($P<0.01). The higher cost of the robotic procedure was due to the longer operative time and the higher cost for disposable instruments (Morino et al 2004). A case series by Winter et al (2006) also assessed the cost impact of the new robotic procedure. In this study, operative and total hospital charges for all adrenalectomies performed at the institution between April 2001 and January 2004 were examined. Median operative charges (operating-room and supply charges) were $US8,645 for robotic laparoscopic adrenalectomy, $US6,414 for standard laparoscopic adrenalectomy, and $US3,666 for open adrenalectomy. Median total hospital charges, which incorporated hospitalization time, were $US12,977 for robotic laparoscopic adrenalectomy, $US11,599 for standard laparoscopic adrenalectomy, and $US14,600 for open adrenalectomy. The total hospital charges for the robotic group were not significantly different from the standard laparoscopy ($P=0.09) or open group ($P=0.5) (Winter et al 2006).

Clinical practice guidelines and consensus statements

A consensus document on robotic surgery has been produced by The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) (Herron et al 2008). The document states that reports of solid organ surgery such as adrenalectomy have shown the feasibility of robotic surgery, but have demonstrated increased cost and have failed to show clinical benefit (Herron et al 2008). However, it is not clear what evidence was used to formulate this consensus statement.

Training and education impact

Training and educational issues surrounding the use of robotic surgery were not addressed in the studies identified. However, the consensus document on robotic surgery by SAGES does provide guidance regarding the level and type of surgical training required for performing therapeutic robotic procedures and the process of credentialing. The document also highlights the obligations of the robotic companies (as mandated by the FDA) for providing technical training (Herron et al 2008). At the time of writing, the use of robotic laparoscopic adrenalectomy is associated with high initial cost which may limit its diffusion for this indication. However, in hospitals where the da Vinci system is available and is utilized for various other indications, the cost may be less prohibitive. If this technology continues to diffuse across the USA, a formal training program may be required.

Summary

The robotic laparoscopic adrenalectomy tended to have a longer operation time than the standard laparoscopic adrenalectomy, which was in part due to a longer robotic setup time. Several studies noted that switching instruments on the robotic arms, and the lack of routine use of an energy source (such as the Ligasure device) to fuse blood vessels, may also have contributed to an extended operation time (Brunaud et al 2008; Morino et al 2004). However, this difference in operation time could be minimized with increased experience. The rate of conversion from the robotic to standard laparoscopic technique ranged from 0% to 40% in the included studies. This variation reflects the small sample size in the studies, with the largest study (Brunaud et al 2008) reporting that only 2% of robotic procedures required conversion to the standard laparoscopic technique. Rate of conversion to the open
Robotic laparoscopic adrenalectomy

November 2008

Technique was similar in the robotic and standard laparoscopic groups. Length of hospital stay and quality of life were not significantly different between the robotic and standard laparoscopic adrenalectomy, and only one study found blood loss to be less in the robotic group. The robotic procedure was comparable to the standard laparoscopic technique in terms of morbidity and mortality.

The included studies also noted the technical advantages and disadvantages of the robotic surgical systems. Benefits include 3-dimensional visualization with enhanced depth perception, comfortable handling and improved dexterity (Brunaud et al 2008). However, disadvantages include the lack of tensile feedback to the surgeon, a currently limited range of robotic instruments, and the lack of proximity of the surgeon to the patient should significant complications arise (Morino et al 2004; Wu et al 2008).

Recommendation

Based on the available evidence, robotic laparoscopic adrenalectomy is comparable to the standard laparoscopic technique in terms of safety and efficacy. Operative time tends to be longer in the robotic operation, but this difference is minimized with increasing experience in the technique. The initial purchase cost of a robotic surgical system is high, continued maintenance is required, and the required disposable instruments also cost more than for the standard laparoscopic procedure. As the evidence does not currently indicate a significant clinical benefit in using the robotic-assisted technique over the standard laparoscopic procedure, this increased cost is an important drawback. Further studies with larger sample sizes are required to determine whether there are any safety and efficacy benefits that warrant the increased financial outlay.

References

General references


Included studies


Included for cost section only

# Appendix A

## Studies excluded from this assessment

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Julien JS, Ball D, Schulick R. Robotic cortical-sparing adrenalectomy in a patient with von hippel-lindau disease and</td>
<td>Case report</td>
</tr>
</tbody>
</table>

Case report

Case report

Case report

Case report

Case report

Case report

Case report

Case report