ASERNIP-S

Australian Safety
and Efficacy
Register
of New
Interventional
Procedures-Surgical

Rapid review

Robotic-assisted surgery for urological, cardiac and gynaecological procedures

ASERNIP-S REPORT NO. 75
May 2009

Australian Safety & Efficacy Register of New Interventional Procedures – Surgical

The Royal Australasian College of Surgeons

Robotic-assisted surgery for urological, cardiac and gynaecological procedures

ISBN 978-0-9806299-6-5

Published December 2009

This report should be cited in the following manner:

Thavaneswaran P *et al*. ASERNIP-S Report No. 75. Adelaide, South Australia: ASERNIP-S, May 2009.

Copies of these reports can be obtained from:

ASERNIP-S

PO Box 553,

Stepney, SA 5069

AUSTRALIA

Ph: 61-8-8363 7513

Fax: 61-8-8362 2077

E-Mail: asernips@surgeons.org

http://www.surgeons.org/asernip-s

ASERNIP-S Rapid Review

Disclaimer

This is a rapid systematic review in which the methodology has been limited in one or more areas to shorten the timeline for its completion. Thus, modifications have been made in at least one of the following areas: search strategy, inclusion criteria, assessment of study quality and data analysis.

The methodology used for the rapid review is described in detail, including the limits made for this particular topic. These limitations have been made possible mainly by restricting the specific clinical questions asked, and were applied following the requirements of the specific review topic.

Therefore, this rapid review is a limited evidence-based assessment that is based on a simple systematic search of studies published in the peer reviewed literature. As a result, this rapid review may be used to inform certain questions on this specific review topic.

Table of contents

Executive summary

Objective

Firstly, to evaluate the safety and efficacy of robotic-assisted surgery compared with conventional surgical approaches for commonly performed urological, cardiac and gynaecological procedures, through a rapid systematic review of the literature. Secondly, to summarise the experiences of Australian hospitals and surgeons using this technology, and the views of jurisdictional health representatives and patient advocates regarding this technology, through the use of semi-structured interviews.

Methods

Literature review

Studies were identified by searching PubMed, EMBASE, the Cochrane Library and the York (UK) Centre for Reviews and Dissemination (CRD) databases for studies published from January 1, 2004 to February 20, 2009. The Clinical Trials Database, NHS CRD, NHS HTA, Current Controlled Trials, and the Australian New Zealand Clinical Trials Registry were searched in March 2009 for ongoing and unpublished trials involving robotic-assisted surgery.

Studies considered eligible for critical appraisal and inclusion in the review were limited to English language systematic reviews of primary studies, randomised controlled trials (RCTs) and nonrandomised comparative studies which reported on the use of robotic-assisted surgery for urological, cardiac and gynaecological procedures compared with conventional surgical approaches. Efficacy outcomes examined included operative time, estimated blood loss, length of hospital stay, need for blood transfusion, conversion rates and oncological outcomes including positive surgical margin rates and cancer recurrence. Safety outcomes examined included perioperative and long-term complications and mortality rates.

Data from all included studies were extracted by one reviewer, using standardised data extraction tables that were developed a priori. The accuracy of data extraction was checked by a second reviewer, and any differences were resolved through discussion. As the studies included in this review are a deliberately restricted sample of the current peer-reviewed literature on this topic (resulting from date limits set on the searches), formal statistical pooling (meta-analysis) was not performed. Therefore, the data for the main outcomes of interest were reported narratively.

Australian experience of robotic-assisted surgery

Surgeons from each of the seven Australian hospitals currently using the da Vinci Surgical System were identified via internet searches of publicly available information. Australian jurisdictional health representatives from each state and the Australian Capital Territory were identified via internet searches. The Consumers'

Health Forum of Australia was contacted and asked to provide a shortlist of representatives from patient advocacy organisations with a focus on prostate cancer. In some cases, additional or alternative participants were identified through personal referrals. Informal semi-structured interviews were conducted with individual participants via the telephone. Responses to all questions were deidentified following transcription, then grouped into themes and reported narratively.

Key results and conclusions

Literature review

Despite a proliferation of new publications about robotic-assisted surgery in recent years, no RCTs could be identified for inclusion in this review. The available evidence was made up of nonrandomised comparative studies (either concurrently or historically controlled) that are more likely to be affected by biases inherent to such study designs. One recent systematic review of nonrandomised comparative studies comparing robotic-assisted laparoscopic prostatectomy (RALP) to laparoscopic radical prostatectomy (LRP) and radical retropubic prostatectomy (RRP) was selected for inclusion.

Urological procedures

In terms of efficacy, operative times for RALP were generally shorter than or not significantly different from LRP, but tended to be longer compared with RRP. Length of hospital stay for RALP was shorter than or not significantly different from both LRP and RRP. Both the estimated blood loss and need for transfusion following RALP was either less than, or not significantly different from, that observed following LRP or RRP. In terms of safety, the rate of complications for RALP was generally much lower compared with LRP or RRP; however, safety outcomes were poorly reported across studies.

The current evidence base for other urological procedures that employ robotic-assisted surgery, including radical or partial nephrectomy, radical cystectomy and pyeloplasty, is limited. For these procedures, as with radical prostatectomy, the robotic-assisted approach was generally associated with significantly better or equivalent outcomes for length of hospital stay, estimated blood loss and need for transfusion, when compared with conventional laparoscopic or open approaches. Operative times for robotic-assisted surgery were generally not significantly different to those for conventional approaches. It is difficult to assess the relative safety of robotic-assisted versus conventional approaches for these other urological procedures, due to the limited evidence base.

Cardiac procedures

In terms of efficacy, the limited evidence base revealed that operative times for robotic-assisted mitral valve repair (RMVR) were longer compared to open mitral valve repair (OMVR). Length of hospital stay for RMVR was generally shorter than OMVR and video-assisted endoscopic mitral valve repair (VMVR). Both the

estimated blood loss and need for transfusion following RMVR were not significantly different from that observed following OMVR. In terms of safety, the rate of complications for RMVR was higher compared with VMVR, but lower compared with OMVR.

Gynaecological procedures

Robotic-assisted hysterectomy (RAH) for endometrial cancer staging and cervical cancer was generally associated with significantly better or equivalent outcomes for length of hospital stay, estimated blood loss and need for transfusion, when compared with conventional laparoscopic or open approaches. Operative times for RAH were generally shorter than, or not significantly different from, laparoscopic hysterectomy (LH) but tended to be longer when compared with open hysterectomy (OH). In terms of safety, the rate of complications for RAH was generally lower or not significantly different compared with LH or OH; however, safety outcomes were poorly reported across studies.

The current evidence base for other gynaecological procedures that employ robotic-assisted surgery, including myomectomy, tubal re-anastomosis and sacrocolpopexy, is limited. For these procedures, the robotic-assisted approach was generally associated with significantly better or equivalent outcomes for length of hospital stay and estimated blood loss, when compared with conventional laparoscopic or open approaches. Operative times for robotic-assisted surgery were significantly longer when compared to conventional surgery. It is difficult to assess the relative safety of robotic-assisted surgery for these other gynaecological procedures, due to the limited evidence base; however, in general complication rates were not significantly different when compared to conventional surgical approaches.

Australian experience of robotic-assisted surgery

Interviews were conducted with seven surgeons from six of the seven Australian hospitals that are currently using the da Vinci Surgical System, as well as with a theatre nurse experienced in the set-up and maintenance of the system. Interviews were also conducted with two jurisdictional health representatives from one Australian state and one territory, and two representatives from patient advocacy organisations.

All of the surgeons interviewed for this report agreed that robotic-assisted surgery offered a number of key advantages compared with conventional surgical approaches, including reduced blood loss and postoperative pain, shorter length of hospital stay and a quicker return to normal daily activities. It appears that this technology may also confer an advantage to surgeons, reducing the physical stress of surgery and thus surgeon fatigue. On the other hand the high cost of, and limited access to, robotic-assisted surgery in Australia at present has been identified by surgeons, jurisdictional health representatives and patient advocates as the main drawbacks of this technology.

Jurisdictional health representatives were concerned not only with the significant costs associated with the initial purchase of the technology, but also with the ongoing costs associated with maintenance and training. All parties recognised that robotic-assisted surgery demands more sophisticated training to equip users with sufficient skills to competently handle the technology, as well as a level of multidisciplinary training that was not previously required.

Conclusions

Despite the shortcomings of the available published evidence, robotic-assisted surgery is emerging as an alternative to conventional open or laparoscopic approaches for a range of urological, cardiac and gynaecological procedures. After reviewing the relevant comparative evidence published in the last five years, it seems that robotic-assisted surgery is at least as efficacious as conventional open or laparoscopic surgery, and appears to offer the advantages of decreased blood loss and transfusions with resultant decreases in length of hospital stay without increasing the rate of severe complications. To date, operative times for robotic-assisted approaches have generally been equal to or longer than conventional approaches, although it is likely they have been influenced by the experience of the surgical team and are amenable to improvement with increased experience. These findings from the published literature seem to echo the experiences of the Australian surgeons using this technology who were interviewed for this report.

Many of the limitations of the published evidence used in this review would be overcome by the availability of concurrently-controlled trial evidence. While the undertaking of multicentre RCTs of robotic-assisted surgery is desirable, the problems inherent in attempting to randomise patients who are actively seeking treatment with this technology, which at present is primarily available in private hospitals in Australia, may mean that it is difficult.

Abbreviations and acronyms

ASA	American Society of Anaesthesiologists
BMI	Body Mass Index
CI	Confidence Interval
EBL	Estimated Blood Loss
HRQoL	Health Related Quality of Life
LH	Laparoscopic Hysterectomy
LM	Laparoscopic Myomectomy
LOS	Length Of Stay
LP	Laparoscopic Pyeloplasty
LPN	Laparoscopic Partial Nephrectomy
LRC	Laparoscopic Radical Cystectomy
LRN	Laparoscopic Radical Nephrectomy
LRP	Laparoscopic Radical Prostatectomy
NYHA	New York Heart Association
OH	Open Hysterectomy
OM	Open Myomectomy
OMVR	Open Mitral Valve Repair
ORC	Open Radical Cystectomy
ORN	Open Radical Nephrectomy
ORP	Open Radical Prostatectomy
OS	Open Sacrocolpopexy
OTA	Open Tubal Re-Anastomosis
PSM	Positive Surgical Margin
RAH	Robotic-Assisted Hysterectomy
RALP	Robotic-Assisted Laparoscopic Prostatectomy
RAM	Robotic-Assisted Myomectomy
RAS	Robotic-Assisted Sacrocolpopexy
RATA	Robotic-Assisted Tubal Re-Anastomosis

RMVR	Robotic-Assisted Mitral Valve Repair
RP	Robotic-Assisted Pyeloplasty
RPN	Robotic-Assisted Partial Nephrectomy
RR	Relative Risk
RRC	Robotic-Assisted Radical Cystectomy
RRN	Robotic-Assisted Radical Nephrectomy
RRP	Radical Retropubic Prostatectomy
VMVR	Video-Assisted Endoscopic Mitral Valve Repair
WMD	Weighted Mean Difference

List of tables

Introduction

Objective

Firstly, to evaluate the safety and efficacy of robotic-assisted surgery compared with conventional surgical approaches for commonly performed urological, cardiac and gynaecological procedures, through a rapid systematic review of the literature. Secondly, to summarise the experiences of Australian hospitals and surgeons using this technology, and the views of jurisdictional health representatives and patient advocates regarding this technology, through the use of semi-structured interviews.

Background

The da Vinci® Surgical System

The da Vinci Surgical System (Intuitive Surgical Inc, Sunnyvale, California, USA) is a robotic master-slave telemanipulation system. A master-slave system consists of a remote console where the operating surgeon (master) directs the robotic surgical arms (slave) via a telerobotic videoscopic link.

Elements of the system

Surgical console

The console provides the computer interface between the surgeon and the surgical robotic arms. The surgeon controls the robotic arms through the use of master handles which are located in 'virtual 3D space' below the visual display. The surgeon's hand movements are digitised and transmitted to the robotic arms which perform identical movements in the operative field. Foot controls are used to activate electrocautery and ultrasonic instruments, and for repositioning the master handles as necessary. The surgeon views the surgical field through the binocular visual display in the hood of the console. The robotic arms are deactivated whenever the surgeon's eyes are removed from the display.

Master handles

In addition to providing direction to the robotic arms, the master handles are also used to control other aspects of the video display system and robotic arms, such as endoscope selection and motion scaling ratio. The master handles filter tremor in the surgeon's hands and arms, and provide a degree of tactile feedback. However, the majority of tactile feedback is provided indirectly via the video monitor (i.e. visually) and the tensile feedback available through the robotic arms.

Robotic arm cart

The robotic arm cart is placed beside the patient on the operating table. It holds three or four robotic arms on a central tower. One arm holds the videoscope and the others are used to attach the instrument adapters which are connected to robotic

instrumentation through reusable trocars. Stereoscopic vision is supplied via 30° or 0° specialised 3D scopes which provide the surgeon at the console with binocular vision of the operative field.

EndoWrist® surgical instruments

The robotic surgical instruments have both an elbow joint and a wrist, enabling seven degrees of freedom and two degrees of axial rotation, mimicking the natural motions of open surgery. There is a range of different instruments available which can each be used for up to ten surgical procedures (after which the robotic system deactivates them, preventing further use). The available instruments include:

- microforceps
- long tip forceps
- Cadiere and Cichon tissue forceps
- round tooth forceps
- cautery with spatula
- permanent cautery hook
- scalpel cautery with 15° blade
- scalpel cautery with beaver blade
- Potts scissors
- round tip scissors
- ultrasonic shears
- small clip applier
- graspers
- large needle driver

Current applications of the da Vinci Surgical System

While the number of potential applications for robotic-assisted surgery continues to grow, to date this approach has largely been used for urological, cardiac and gynaecological surgical procedures.

Urological procedures

The most common application of robotic-assisted surgery across all surgical specialties has been radical prostatectomy for the treatment of prostate cancer, which is the most common form of cancer for men (excluding non-melanoma skin cancer) in Australia (AIHW 2008).

Robotic-assisted surgery can also be utilised for a number of other urological procedures. This approach can be used for radical cystectomy, where removal of the

bladder is necessary due to muscle-invasive cancer or other pathologies. In addition, robotic-assisted surgery can be used in pyeloplasty for the treatment of uteropelvic junction obstruction, as well as for radical or partial nephrectomy for the treatment of renal cell carcinoma.

Cardiac procedures

The cardiac procedures which most commonly utilise robotic-assisted surgery are coronary artery bypass grafting (CABG) and mitral valve repair or replacement.

CABG reduces the risk of myocardial infarction in patients suffering from coronary artery disease, which is the largest single cause of death in Australia (AIHW 2009). This procedure involves the grafting of arteries or veins harvested from another part of the patient's body in order to bypass the section of artery which is affected by narrowing, in order to restore optimum blood supply to the myocardium.

Mitral valve repair or replacement is used to treat mitral regurgitation, a condition characterised by an abnormal reversal of blood flow from the left ventricle to the left atrium. Abnormalities of the mitral valve can be caused by disease or a functional lesion, or may be congenital. In the 2007-2008 financial year, there were 2993 claims for treatments related to mitral regurgitation, which provides a conservative estimate of the prevalence of this disease within the Australian population (Medicare Australia 2009).

Gynaecological procedures

The main gynaecological application of robotic-assisted surgery is for the treatment of gynaecological cancers. This approach has been used to treat endometrial cancer, which is the most common gynaecological cancer in Australian women (AIHW 2008). Endometrial cancer staging is one of the most challenging gynaecological procedures, incorporating total hysterectomy and bilateral salpingo-oophorectomy with lymph node sampling or systematic pelvic or para-aortic lymphadenectomy. Cervical cancer can also be treated using robotic-assisted surgery. Surgical treatment for this disease usually includes radical hysterectomy with bilateral pelvic lymphadenectomy (para-aortic lymphadenectomy optional).

Robotic-assisted surgery can also be utilised for a number of other gynaecological procedures. This approach can be used for myomectomy, which is considered to be the gold standard treatment for benign pelvic tumours or fibroids where the preservation of fertility is desired. In addition, robotic-assisted surgery can be used in tubal re-anastomosis for the reversal of prior tubal ligation, as well as for sacrocolpopexy for the surgical correction for vaginal vault prolapse.

Purported benefits and drawbacks of the system

The purported benefits and disadvantages of robotic-assisted surgery compared with either minimally invasive laparoscopic interventions, or conventional open surgery for the above-mentioned indications are outlined below.

Benefits

The purported benefits of the da Vinci surgical robotic system are obtained in three key areas:

1. Benefits conferred to patients as a result of minimally invasive surgery compared with open approaches (i.e. less blood loss, better cosmesis, fewer complications, and shorter convalescence) – the robotic system may allow minimally invasive approaches to be used where conventional laparoscopic approaches would not be possible (Murphy et al 2008).
2. Benefits conferred to the operating surgeon as a result of the ergonomic setup of the surgeon console, and expected benefits in surgical performance as a result of the precision of the robotic instrumentation and computer system. These benefits include, the ability to view the surgical field in three dimensions and use natural hand and arm movements (unlike conventional laparoscopic surgery where the laparoscopic instruments are subject to a fulcrum effect) and the ability of the system to filter hand/arm tremor (Murphy et al 2008). In addition, there is evidence to suggest that the learning curve is shorter for robotic compared with laparoscopic surgery (Menon 2003).
3. Benefits conferred to the health system as a result of shorter hospital stay and less patient morbidity, and benefits conferred on society by shorter convalescence for patients (for example resulting in fewer lost days from work) (Murphy et al 2008).

Drawbacks

Suggested drawbacks of robotic-assisted surgery also focus on three key areas:

1. The cost of the system – both the initial cost of the equipment (A$2.5-3 million) and the annual running costs (approximately 5-10% of the purchase cost) (Murphy et al 2008). In addition, specialised training in the use of the robotic system is required which may add further costs.
2. Practical issues with the robotic set-up – the surgeon console, robotic arm cart and video cart may take up considerable space in the operating room and take additional time to prepare. In addition to the robotic system, a patient-side surgical assistant is still required to assist the operating surgeon at the console (Murphy et al 2008).
3. Technical issues with the robotic system – the primary technical concern appears to be the lack of tactile feedback available with the current system. Other issues include the possibility of system breakdown and some lack of flexibility with the surgical robotic arms (Murphy et al 2008).

Regulatory status of the da Vinci Surgical System

The da Vinci Surgical System, formerly known as the Intuitive Surgical™ System, first received 510k clearance from the United States Food and Drug Administration (FDA) in 2000 for general laparoscopic procedures such as gall bladder removal, and is now available worldwide (FDA 2005). Since 2000, the FDA has approved the use of the da Vinci Surgical System for a wide variety of surgical procedures including prostatectomy, hysterectomy, myomectomy, mitral valve repair and CABG surgery. Currently, there are no other robotic telemanipulator systems that are comparable to the da Vinci Surgical System. In 2001 the FDA gave 510k approval to another system called the Zeus Robotic Surgical System, which was manufactured by Computer Motion Inc (Goleta, California, USA), and in 2002 over 30 Zeus systems had been installed in hospitals in the United States. However in 2003, Computer Motion was bought by Intuitive Surgical Inc, and the Zeus system is no longer being marketed (FDA 2005).

In Europe the da Vinci Surgical System has full regulatory clearance and is entitled to affix the CE mark to the system.

In Australia, the da Vinci Surgical System is listed on the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG) (Class IIb) and is distributed by Device Technologies Australia Pty Ltd.

Use of the da Vinci Surgical System in Australia

According to the Intuitive Surgical website (www.intuitivesurgical.com) there are 867 da Vinci units in hospitals around the world, including 647 in the United States, 148 in Europe and 72 in the rest of the world. The Epworth Richmond Hospital in Melbourne was the first Australian hospital to have a da Vinci Surgical System installed, in December 2003. Since then the system has been installed in six other hospitals around Australia, including:

- Epworth Eastern Hospital, Melbourne, Victoria
- Greenslopes Private Hospital, Brisbane, Queensland
- Royal Adelaide Hospital, Adelaide, South Australia
- Royal Brisbane and Women's Hospital, Brisbane, Queensland
- St John of God Hospital, Perth, Western Australia
- St Vincent's Private Hospital, Sydney, New South Wales

The number of patients undergoing robotic-assisted surgery has increased from 152 in 2004 to 803 in 2007 (Murphy et al 2008). Approximately 91% of robotic-assisted operations carried out to date in Australia and New Zealand have been urological procedures, with robotic-assisted laparoscopic radical prostatectomy being the most commonly performed procedure (Murphy et al 2008). Other specialties making use

of robotic-assisted technology include cardiac surgery (7%), gynaecology (1%) and general surgery (1%) (Murphy et al 2008).

Research questions

This rapid review addressed the following specific research questions:

- How safe is robotic-assisted surgery compared with conventional surgical approaches for commonly performed urological, cardiac and gynaecological procedures?
- How effective is robotic-assisted surgery compared with conventional surgical approaches for commonly performed urological, cardiac and gynaecological procedures?
- What are the experiences with respect to cost and resource issues, training and learning curve issues, technical issues and patient issues, of Australian hospitals and surgeons using robotic-assisted surgery for commonly performed urological, cardiac and gynaecological procedures?
- What are the views of Australian jurisdictional health representatives and patient advocates regarding the use of robotic-assisted surgery for commonly performed urological, cardiac and gynaecological procedures?

Methodology

Question one – Literature review

Inclusion criteria

Studies were selected for inclusion in this rapid review on the basis of the criteria outlined below.

Population

Studies of adult human patients (men and women aged 18 years and over) undergoing urological, cardiac and gynaecological procedures that commonly make use of robotic-assisted technology.

Intervention

Included studies involved the use of robotic-assisted technology for:

- Urological surgery: *radical prostatectomy* for localised prostate cancer; *radical or partial nephrectomy* for benign and malignant disease; *radical cystectomy* for muscle-invasive bladder cancer; and *pyeloplasty* for uretero-pelvic junction obstruction.
- Cardiac surgery: *Coronary artery bypass grafting (CABG)* for relief of angina and reducing the risk of subsequent infarction; *mitral valve surgery* for repair of the mitral valve.
- Gynaecological surgery: *hysterectomy* for both benign and malignant disease; *myomectomy* for leiomyomata in women with a fertility desire; *tubal re-anastomosis* after previous tubal ligation; and *prolapse surgery (sacrocolpopexy)* for serious vaginal vault prolapse.

In addition, any other less common applications were noted where identified.

Comparative interventions

The main comparators for robotic-assisted surgery are as follows.

- Urological surgery:
  - *Radical prostatectomy*: Open or laparoscopic surgery.
  - *Radical or partial nephrectomy:* Open or laparoscopic surgery.
  - *Radical cystectomy*: Open or laparoscopic surgery.
  - *Pyeloplasty*: Open or laparoscopic surgery.
- Cardiac surgery*:*
  - *CABG*: Standard CABG with sternotomy and cardiopulmonary bypass (CPB) or minimally invasive direct-vision CABG (MIDCAB) without CPB.
  - *Mitral valve surgery*: Sternotomy or video-assisted endoscopic surgery.

- Gynaecological surgery:
  - *Radical hysterectomy*: Open or laparoscopic surgery.
  - *Myomectomy*: Open or laparoscopic surgery.
  - *Tubal re-anastomosis*: Open or laparoscopic surgery.
  - *Prolapse surgery (sacrocolpopexy)*: Open or laparoscopic surgery.

Outcomes

Studies were included if they contained information on at least one of the following outcomes.

- *Effectiveness*
  - Operative time
  - Blood loss
  - Conversion rate
  - Length of hospital stay
  - Quality of life measures
  - Rate of reintervention
  - Patient satisfaction
  - Postoperative pain
  - Oncological outcomes, including surgical margins and disease-free survival
  - Relevant surgery-specific outcomes, such as biochemical recurrence (radical prostatectomy), urinary continence (radical prostatectomy, cystectomy and hysterectomy), erectile function (radical prostatectomy), long-term durability of repair (mitral valve surgery), fertility (myomectomy and tubal re-anastomosis), and tubal patency rate (tubal re-anastomosis).
- *Safety*
  - Complications/adverse effects (peri/postoperative and long term)
  - Mortality rates

Publication type

Recently published systematic reviews, rather then primary studies, were selected for inclusion in the review and critical appraisal. Systematic reviews were defined as those studies that meet all the following criteria, as defined by Cook et al (1997).

1. Focused clinical question
2. Explicit search strategy
3. Use of explicit, reproducible and uniformly applied criteria for article selection
4. Critical appraisal of the included studies
5. Qualitative or quantitative data synthesis

Where there were two or more systematic reviews with the same inclusion and exclusion criteria, the latest and most complete study was included. In addition, eligible randomised controlled trials (RCTs) published after the search dates of the most recent systematic review were also included.

If no suitable systematic reviews on the topic were available, RCTs, pseudorandomised controlled trials and nonrandomised comparative studies were selected for inclusion in the review. A study was deemed to be an RCT if the author(s) stated explicitly (usually by some variant of the term 'random' to describe the allocation procedure used) that the groups compared in the trial were established by random allocation (Higgins and Green 2005). Studies in which the method of allocation was known but was not considered strictly random (for example, alternation, date of birth and medical record number) were classified as pseudorandomised controlled trials (Higgins and Green 2005).

When overlapping patient groups were reported in studies, only the paper quoting the most complete data set was used.

Relevant grey literature, including health-related reports written for the Australian context, was also included.

Publication date

Included studies were restricted to those published from January 2004 onwards.

Language of publication

Included studies were restricted to those published in English.

Literature search strategies

Databases searched

The following databases were searched for studies published from January 1, 2004 to February 20, 2009:

- The York (UK) Centre for Reviews and Dissemination (CRD) databases
- *The Cochrane Library*
- PubMed
- EMBASE

This review did not include extended searching of conference abstracts, handsearching of journals, contacting authors for unpublished data or pearling of references from retrieved articles. However, extended searching of internet websites that may have contained relevant information on the use of robotic-assisted surgery in the Australian health system was conducted. These websites include the:

- Medical Services Advisory Committee (www.msac.gov.au);

- Health Policy Advisory Committee on Technology (www.horiozonscanning.gov.au);
- Therapeutic Goods Administration (www.tga.gov.au).

Search terms

The search terms used are listed in Table 1 below.

Table 1 Search terms

Surgical indication	Search terms
All indications	robot* OR da Vinci
Urological surgery (Radical prostatectomy)	(robot* OR da Vinci) AND prostate*
Urological surgery (Other)	(robot* OR da Vinci) AND (pyeloplasty OR cystectomy OR nephrectomy OR ureteral OR bladder)
Gynaecological surgery	(robot* OR da Vinci) AND (gynecolog* OR gynaecolog* OR cervix OR cervical OR uter* OR ovar* OR vagina* OR endometri* OR hysterectomy OR (genital* AND female))
Cardiac surgery	(robot* OR da Vinci) AND (cardiac OR valve OR artery bypass OR CABG)

Note: * is a truncation character that retrieves all possible suffix variations of the root word; for example, surg* retrieves surgery, surgical, surgeon, etc.

Ongoing and unpublished trials

The Clinical Trials Database, NHS CRD, NHS HTA, Current Controlled Trials, and the Australian New Zealand Clinical Trials Registry were searched in March 2009 for ongoing and unpublished trials involving robotic-assisted surgery.

Selection of studies

Two reviewers independently applied the inclusion criteria to identify studies that were potentially eligible for selection and appraisal based on their abstracts; these studies were retrieved as full text. The selection criteria were then applied fully to the retrieved studies to identify those to be appraised and included in the review. Full publications that did not meet the inclusion criteria were excluded and the reasons for exclusion were documented (Appendix A).

Data extraction and appraisal of study methodology

Data from all included studies were extracted by one reviewer, using standardised data extraction tables that were developed a priori. The accuracy of data extraction was checked by a second reviewer, and any differences were resolved through discussion. The studies included in the review were classified according to the National Health and Medical Research Council (NHMRC) hierarchy of evidence (Table 2). As the studies included in this review are a deliberately restricted sample of the current peer-reviewed literature on this topic (resulting from date limits set on the searches), formal statistical pooling (meta-analysis) was not performed. Therefore, the data for the main outcomes of interest were reported narratively.

Table 2 National Health and Medical Research Council hierarchy of evidence

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from case-series, either post-test or pre-test/post-test

Source: NHMRC 2000

Where systematic reviews were eligible for inclusion in the review, the methodology of these secondary studies was evaluated with respect to the following factors.

- Did the review ask a focused research question that incorporated the elements of PICO (population, intervention, comparator, outcomes)?
- Were the inclusion and exclusion criteria of the included studies clearly stated?
- Did the review use a clear and comprehensive search strategy?
- Did the review assess the validity of the included studies, and if so, which validity criteria were used?
- Was the analysis or synthesis of the results appropriate?
- Did the review include a summary of its main results, including a discussion of its strengths and limitations?

Where primary studies were eligible for inclusion in the review, the following criteria were used to appraise their methodology, where applicable.

- Were the objectives of the study clearly defined?
- Were the inclusion and exclusion criteria clearly described?
- Was there a clear description of the interventions used?
- Were the characteristics of patients included in the study clearly described?
- Were patients randomly assigned to intervention groups, and if so, was the method of randomisation described?
- Were the results of the randomised assignment of patients to intervention groups concealed from both the patients and staff administering the study until recruitment was complete?

- Was there an attempt made to blind both patients, and staff responsible for measuring outcomes of the intervention, to the interventions that the patients received?
- Was the number of patients who withdrew or dropped out of the study reported? Were the characteristics of these patients described?
- Were the main outcomes of interest adequately reported?
- Were point estimates and measures of variability presented for the primary outcome measures?

Nonrandomised studies were also assessed for other features of study design or execution that may have introduced bias, such as comparability of patient groups at baseline, the method of patient selection and comparability of timing of outcome assessment.

One reviewer appraised the studies. The critical appraisal was checked by a second reviewer, and any differences were resolved through discussion.

Question two - Australian experience of robotic-assisted surgery

Participants

Surgeons from each of the seven Australian hospitals currently using the da Vinci Surgical System were identified via internet searches of publicly available information. In Australia, the majority of robotic-assisted surgical procedures are performed for urological indications; therefore one urologist from each of the seven hospitals was short listed for contact. In addition, one cardiothoracic surgeon and one gynaecological oncologist, each from a different centre, were also short listed for contact. Australian jurisdictional health representatives from each state and the Australian Capital Territory were identified via internet searches. The Consumers' Health Forum of Australia was contacted and asked to provide a shortlist of representatives from patient advocacy organisations with a focus on prostate cancer, which is currently the indication most commonly treated with robotic-assisted surgery in Australia. In some cases, additional or alternative participants were identified through personal referrals.

All prospective participants were initially contacted via email, and the purpose and scope of the study explained. Upon agreeing to participate in the study, all participants were contacted via telephone to confirm a suitable date and time for the interview.

Data collection

Informal semi-structured interviews were conducted with individual participants via the telephone. Each interview was conducted by the same researcher. All interviews were recorded and later transcribed by the researcher who conducted the interviews.

Interview questions

The questions used to guide the discussion during interviews are provided in Appendix B.

Data analysis

Responses to all questions were deidentified following transcription, then grouped into themes and reported narratively.

Results – Literature review

Urological procedures

From the search strategy, 980 potentially relevant articles were identified, of which 86 potentially relevant articles were retrieved. Retrieved studies included systematic reviews and primary studies. In total, 65 retrieved articles were excluded (Appendix A).

A total of 21 studies reporting urological applications of the da Vinci Surgical System, including one systematic review and 20 nonrandomised comparative studies (eight level III-2 and 12 level III-3 studies), were eligible for appraisal and inclusion in this rapid review (Table 3). The most common application of the da Vinci Surgical System was in radical prostatectomy (10 studies). The robotic system has also been used for radical cystectomy (4 studies), radical and partial nephrectomy (4 studies) and pyeloplasty (4 studies).

Table 3 Urological studies included in the review

Study	Surgery type	Level of evidence	Number of patients	Follow-up
Ficarra 2009	Prostatectomy	III-2	RALP LRP RRP	NA
Chan 2008	Prostatectomy	III-2	RALP 660 RRP 340	NR
Schroeck 2008	Prostatectomy	III-2	RALP 362 RRP 435	Mean 1.1 years Mean 1.4 years
Srinualnad 2008	Prostatectomy	III-2	RALP 34 LRP 34	NR
Hakimi 2009	Prostatectomy	III-3	RALP 75 LRP 75	Mean 17 months Mean 48 months
White 2009	Prostatectomy	III-3	RALP 50 RRP 50	NR
Caballero-Romeu 2008	Prostatectomy	III-3	RALP 60 LRP 70 RRP 62	Up to 6 months
Laurila 2008	Prostatectomy	III-3	RALP 94 RRP 98	NR
Trabulsi 2008	Prostatectomy	III-3	RALP 50 LRP 190	NR
Webb 2008	Prostatectomy	III-3	RALP 100 ORP 100	Mean 14.3 months Mean 39.8 months
Hemal 2009	Nephrectomy	III-2	RRN 15 LRN 15	Mean 8.3 (range 1 to 12) months Mean 9.1 (range 2 to 12) months
Wang 2009	Nephrectomy	III-2	RPN 40 LPN 62	NR
Caruso 2006	Nephrectomy	III-2	RPN 10 LPN 10	NR
Sterrett 2007	Nephrectomy Cystectomy	III-3	RRN 65 ORN 21 RPN 9 OPN 15 RRC 19 ORC 33	NR
Wang 2007	Cystectomy	III-2	RRC 33 ORC 21	NR
Abraham 2007	Cystectomy	III-3	RRC 14 LRC 20	NR
Guru 2007	Cystectomy	III-3	RRC 16 ORC 17	NR
Link 2006	Pyeloplasty	III-2	RP 10 LP 10	Mean 5.6 [SD 2.2] months
Yanke 2008	Pyeloplasty	III-3	RP 29 LP 116	Median 19 (range 13 to 25) months Median 20 (range 1 to 87) months
Weise 2006	Pyeloplasty	III-3	RP 31 LP 14	Mean 6 (range 1 to 21) months Mean 10 (range 1 to 31) months
Bernie 2005	Pyeloplasty	III-3	RP 7 LP 7	Mean 10 (range 5 to 15) months Mean 24 (range 22 to 30) months

NOTE: LP – laparoscopic pyeloplasty; LPN – laparoscopic partial nephrectomy; LRN – laparoscopic radical nephrectomy; LRP – laparoscopic radical prostatectomy; NA – not applicable; NR – not reported; OPN – open partial nephrectomy; ORC – open radical cystectomy; ORN – open radical nephrectomy; ORP – open radical prostatectomy; RALP – robotic-assisted laparoscopic prostatectomy; RP – robotic-assisted pyeloplasty; RPN – robotic-assisted partial nephrectomy; RRC – robotic-assisted radical cystectomy; RRN – robotic-assisted radical nephrectomy; RRP – radical retropubic prostatectomy.

Radical prostatectomy

Systematic reviews

Appraisal of study quality

The aim of a recent quantitative systematic review by Ficarra et al (2009) was to evaluate the perioperative, functional and oncologic results in comparative studies assessing radical retropubic prostatectomy (RRP), laparoscopic radical prostatectomy (LRP) and robotic-assisted laparoscopic prostatectomy (RALP). The review searched the MEDLINE, EMBASE and Web of Science databases from 1999 to January 2008. The MEDLINE search strategy involved only a free-text protocol using the term radical prostatectomy across the 'Title' and 'Abstract' fields of the records. The following limits were then applied: humans, gender (male), and language (English). The search strategy for the EMBASE and Web of Science databases used the same free-text protocol and the same key words; no limits were applied. Three of the authors separately reviewed the records to select the studies, with any discrepancies being resolved by open discussion. The inclusion criteria were any comparative study comparing RRP to LRP, RRP to RALP, or LRP to RALP. In addition, other significant studies cited in the reference lists of the selected papers were evaluated, as well as further studies published after the systematic search. Papers published only as abstracts and reports from meetings were excluded from the review.

Of the 37 articles that met the review's selection criteria, 23 compared RRP with LRP, 10 compared RRP with RALP, and 4 compared LRP with RALP. However, only data from the 14 studies comparing RRP or LRP with RALP are reported here. All papers were appraised and quantitative data were extracted from the selected studies and recorded in an electronic database. The appraisal methodology was not reported; however, quality control of the electronic data recording was performed on a random sample of papers representing approximately 15% of the included studies. No RCTs comparing RRP or LRP to RALP were identified. Of the 14 included studies, 8 were prospective nonrandomised comparative trials, 4 were retrospective studies comparing contemporary series' of patients, and 2 were retrospective studies that used historical series as a control. A meta-analysis was performed, and the results were expressed as weighted mean differences (WMD) and 95% confidence intervals (CI) for continuous data and relative risk (RR) and 95% CI for dichotomous variables. Due to limitations of the software used, only studies presenting continuous data as mean and standard deviations were included in the meta-analysis. All the authors whose studies presented data in a format that was not suitable for analysis were contacted and asked for missing data. Only a few of these authors provided useful data.

Efficacy

Operative time

Two studies comparing RALP with RRP demonstrated that operative times for RALP were longer than for RRP in the earlier phase of the learning curve, but one study showed that these differences disappeared with a larger cohort of robotic-assisted cases. Studies comparing RALP and LRP showed that when the learning curve was excluded, operative time was similar for LRP and RALP (WMD: -19.39 minutes, 95% CI -49.34 to 88.13; *P*=0.58), particularly in centres with extensive laparoscopic experience.

Estimated blood loss

Five studies showed that RALP was associated with significantly less blood loss compared with RRP. Estimated blood loss (EBL) was similar in RALP and LRP patients (WMD: 19.45, 95% CI -112.53 to 106.73; *P*=0.96).

Length of hospital stay

In four studies, length of hospital stay (LOS) was significantly lower in patients treated with RALP compared with RRP. In two studies, LOS was similar between LRP and RALP.

Transfusions

RALP was associated with significantly lower transfusion rates compared with RRP (RR: 4.51, 95% CI 1.35 to 15.03; *P*=0.01). However, sensitivity analysis limited to the prospective studies showed only a nonstatistically significant trend in favour of RALP (RR: 7.68, 95% CI 0.62 to 95.1; *P*=0.11). In studies comparing RALP and LRP, a nonstatistically significant trend in favour of RALP was observed for transfusion rate (RR: 6.46, 95% CI 0.76 to 55.07; *P*=0.09).

Positive surgical margins

A meta-analysis of six comparative studies comparing RALP with RRP, and reporting data on margin status, demonstrated a statistically significant difference in favour of RALP (RR: 1.58, 95% CI 1.29 to 1.94; *P*<0.00001). In addition, sensitivity analysis on prospective studies reconfirmed a statistically significant advantage for RALP (RR: 1.90, 95% CI 1.24 to 2.89; *P*=0.003). In patients with pathologically localised cancer, RALP was followed by a lower risk of positive surgical margins (RR: 2.23, 95% CI 1.36 to 3.67; *P*=0.002). When RALP was compared to LRP, no statistically significant difference was found in the positive surgical margin (PSM) rate (RR: 0.97, 95% CI 0.65 to 1.46; *P*=0.9).

Pain

One study evaluating pain following RALP or RRP showed a significant reduction in pain scores during postoperative day 1 in RALP patients. Another study observed a significant reduction in pain in RALP patients during the early postoperative hours, but not at postoperative day 1 or 14.

Urinary continence

One study demonstrated that the median time to continence was significantly shorter after RALP compared with RRP ($P<0.05$), while two other studies demonstrated no significant differences between the groups. One study showed no difference in the 6-month postoperative continence rates of RALP and LRP patients.

Erectile function

In one study, the median time to recovery of erectile function was 440 days after RRP and 180 days after RALP, while the median time to intercourse was 700 days after RRP and 340 days after RALP. Another study reported that 12 months after surgery, 70% of RALP patients and 62.8% of RRP patients had recovered erectile function. One study that evaluated erectile function recovery after LRP and RALP reported a nonstatistically significant trend in favour of RALP 3 months after surgery.

Health-related quality of life

The short-term health-related quality of life (HRQoL) of patients undergoing RRP or RALP was evaluated in a single study using the 12-item short form (SF-12) Physical and Mental Health Survey Acute Form preoperatively and each week during postoperative weeks 1–6. This study demonstrated that patients in the RALP group had better physical scores during the whole study period and a quicker return to preoperative values.

Safety

In comparative studies evaluating RALP and RRP, the overall complication rates reported were similar for both groups in nearly all studies; however, one study demonstrated a statistically significant advantage for RALP. With regard to overall complication rates, a nonstatistically significant trend in favour of RALP was demonstrated after meta-analysis (RR: 1.33, 95% CI 0.64 to 2.74; $P=0.44$). This outcome was shown to be robust in a sensitivity analysis that was limited to prospective studies (RR: 1.92, 95% CI 0.65 to 5.66; $P=0.24$). In comparative studies comparing RALP and LRP, contrasting results for complication rates were observed, with one study demonstrating lower complication rates in the RALP group, and another study demonstrating lower rates of complications following LRP. It was suggested that these conflicting results could be explained by differences in surgeon experience with the different techniques. With regard to overall complications, meta-analysis showed that complication rates after RALP or LRP were similar (RR: 1.83, 95% CI 0.78 to 4.31; $P=0.16$), even in sensitivity analysis limited to prospective studies (RR: 1.0, 95% CI 0.23 to 4.29; $P=1.0$).

Authors' conclusions

The authors concluded that while both RALP and LRP are purported to have the advantages typically associated with minimally invasive procedures, such as lower

blood loss and transfusion rates, the systematic review was unable to prove the superiority of any one surgical approach in terms of functional and oncologic outcomes. This may be due to limitations of the current evidence base, highlighting the need for further prospective, multi-centre comparative studies.

Nonrandomised comparative studies

Appraisal of study quality

The search strategy identified nine comparative studies that were published after the search end date of the review by Ficarra et al (2009). Three of the nine studies that utilised the da Vinci Surgical System for RALP compared its use to LRP, five studies compared it to RRP, and one study compared RALP to both LRP and RRP (Table 3).

The objectives of all nine studies were clearly described. Descriptions of the surgical techniques used were absent in two studies (Chan et al 2008; Hakimi et al 2009); however, seven studies provided a clear description of both the robotic and comparator intervention. Two studies (Caballero-Romeu et al 2008; Webb et al 2008) involved procedures performed at more than one centre, while the remaining seven studies involved procedures performed at single-centres. In four studies, both the robotic and comparator procedures were performed by a single surgeon (Srinualnad 2008; Webb et al 2008; Hakimi et al 2009; White et al 2009). All nine studies reported explicit inclusion criteria, and the patient pool typically included those with a diagnosis of clinically localised carcinoma of the prostate. Explicit exclusion criteria were reported in four studies (Caballero-Romeu et al 2008; Laurila et al 2008; Schroeck et al 2008; Webb et al 2008). Excluded patients were those who recently received neoadjuvant hormonal therapy or for whom surgery was contraindicated due to physical status or evidence of progression of disease outside the prostatic capsule.

Three studies reported prospective data collection (Srinualnad 2008; Trabulsi et al 2008; Hakimi et al 2009). Six studies reported that patients were consecutively enrolled (Chan et al 2008; Laurila et al 2008; Schroeck et al 2008; Webb et al 2008; Hakimi et al 2009; White et al 2009). Method of patient allocation was reported in three studies, with patients allocated to treatment group based on either surgeon or patient preference (Chan et al 2008; Schroeck et al 2008; Trabulsi et al 2008). In eight studies, patients in both the robotic and comparator groups were generally well matched for baseline characteristics such as age, preoperative PSA levels, preoperative Gleason score and clinical stage (Chan et al 2008; Laurila et al 2008; Schroeck et al 2008; Srinualnad 2008; Trabulsi et al 2008; Webb et al 2008; Hakimi et al 2009; White et al 2009). Caballero-Romeu et al (2008) reported that patients in the robotic group were younger ($P<0.001$) and had lower PSA levels ($P<0.001$) when compared to patients in the RRP and LRP groups. Sample sizes in five studies were small, with fewer than 100 patients in each treatment group (Caballero-Romeu et al

2008; Laurila et al 2008; Srinualnad 2008; Hakimi et al 2009; White et al 2009). The numbers of patients in each treatment group were generally well-matched, with the exception of two studies (Chan et al 2008; Trabulsi et al 2008).

Blinding of investigators, outcome assessors or patients was not possible due to the nature of the surgery. In one study that reported medium and longer term functional outcomes, all outcomes data were collected by the operating surgeon, which introduces the potential for bias (Hakimi et al 2009). The reporting of outcomes in most studies was limited to perioperative data such as operative time, LOS, EBL, transfusion rate, conversion rate, PSM rate and rate of complications. Three studies reported on medium and longer term outcomes such as urinary continence, erectile function and biochemical recurrence (Caballero-Romeu et al 2008; Srinualnad 2008; Hakimi et al 2009).

None of the nine studies reported any losses to follow-up, with follow-up periods ranging from 6 months up to 48 months postoperatively in the four studies where this was reported (Table 3). In two studies, follow-up times between treatment arms varied considerably, with at least a two-fold difference between groups (Webb et al 2008; Hakimi et al 2009).

Efficacy

Operative time

A total of four studies reported on operative time (Caballero-Romeu et al 2008; Chan et al 2008; Srinualnad 2008; Hakimi et al 2009) (Table 4). In two studies (Caballero-Romeu et al 2008; Hakimi et al 2009), significantly shorter operative times were observed for RALP compared with LRP ($P<0.001$ for both), while one study (Srinualnad 2008) reported no significant difference in operative time for these two techniques. Caballero-Romeu et al (2008) reported no significant difference in operative time between RALP and RRP, while Chan et al (2008) reported that operative times were longer for RALP compared with RRP in patients with large prostates and small prostates ($P<0.001$ for both). In addition, operative times for RALP were longer in patients with large prostates compared with those who had small prostates ($P<0.001$), whereas operative times for RRP were unaffected by prostate size.

Estimated blood loss

EBL was reported in seven studies (Caballero-Romeu et al 2008; Chan et al 2008; Schroeck et al 2008; Srinualnad 2008; Trabulsi et al 2008; Webb et al 2008; Hakimi et al 2009) (Table 4). Two studies (Caballero-Romeu et al 2008; Hakimi et al 2009) reported that EBL for RALP was significantly lower compared with LRP ($P<0.001$ and $P=0.004$, respectively), while two other studies (Srinualnad 2008; Trabulsi et al 2008) reported no significant difference between the two surgical approaches. Two studies (Caballero-Romeu et al 2008; Schroeck et al 2008) reported that EBL was significantly lower for RALP compared with RRP ($P<0.001$ for both), while Chan et

al (2008) reported that EBL was lower for RALP compared with RRP in patients with large prostates and small prostates ($P<0.001$ for both). EBL for both RALP and RRP was unaffected by prostate size (Chan et al 2008). Webb et al (2008) reported no significant difference in EBL between RALP and ORP.

Length of hospital stay

LOS following radical prostatectomy was reported in four studies (Caballero-Romeu et al 2008; Chan et al 2008; Srinualnad 2008; Hakimi et al 2009) (Table 4). LOS was shorter following RALP compared with LRP in two studies (Caballero-Romeu et al 2008; Hakimi et al 2009) ($P<0.001$ and $P<0.0001$, respectively), while one study (Srinualnad 2008) reported no significant difference between the groups. Caballero-Romeu et al (2008) reported shorter LOS following RALP compared with RRP ($P<0.001$), while Chan et al (2008) reported that LOS was shorter following RALP compared with RRP in patients with small prostates ($P<0.001$). LOS for both RALP and RRP was unaffected by prostate size (Chan et al 2008).

Conversions

Conversion rates were reported in six studies (Caballero-Romeu et al 2008; Chan et al 2008; Srinualnad 2008; Trabulsi et al 2008; Webb et al 2008; Hakimi et al 2009) (Table 4). Conversion rates ranged from 0%-2.7% for RALP and 0%-31.4% for LRP. One study (Caballero-Romeu et al 2008) reported a significantly higher rate of conversion during LRP compared with RALP ($P<0.001$).

Transfusions

Transfusion rates were reported in four studies (Caballero-Romeu et al 2008; Chan et al 2008; Srinualnad 2008; Hakimi et al 2009) (Table 4). Transfusion rates ranged from 0%-26.4% for RALP, 0%-48.4% for LRP and 0%-81.5% for RRP. One study (Caballero-Romeu et al 2008) reported that transfusion rates were significantly lower following RALP compared with both LRP and RRP ($P<0.001$ for both), while another study (Srinualnad 2008) reported no significant difference in transfusion rates between RALP and LRP. Chan et al (2008) reported that transfusion rates were significantly lower following RALP compared with RRP in patients with small prostates ($P=0.017$). Hakimi et al (2009) reported similar transfusion rates for RALP and LRP; however, the statistical significance of this relationship was not reported.

Positive surgical margins

A total of seven studies reported on PSM rates following radical prostatectomy (Caballero-Romeu et al 2008; Chan et al 2008; Laurila et al 2008; Schroeck et al 2008; Trabulsi et al 2008; Hakimi et al 2009; White et al 2009) (Table 4). One study (Trabulsi et al 2008) reported that PSM rates were significantly lower following RALP compared with LRP ($P=0.032$), while two other studies (Caballero-Romeu et al 2008; Hakimi et al 2009) reported no significant differences between the two techniques. One study (White et al 2009) reported significantly lower PSM rates for RALP compared with RRP ($P=0.007$), while another study (Chan et al 2008) reported that PSM rates were significantly lower following RALP compared with

RRP in patients with small ($P<0.001$), but not large prostates. Chan et al (2008) reported that PSM rates for RALP and RRP were lower in patients with large prostates compared to patients with small prostates ($P=0.014$ and $P=0.033$, respectively). Three studies reported no significant differences in PSM rates following RALP and RRP (Caballero-Romeu et al 2008; Laurila et al 2008; Schroeck et al 2008).

Urinary continence

Urinary continence, defined as no pad use and no leakage, was reported in three studies (Caballero-Romeu et al 2008; Srinualnad 2008; Hakimi et al 2009). Caballero-Romeu et al (2008) reported that 6 months after surgery, 60% of RALP patients were fully continent, compared with 45.9% and 36.4% of RRP and LRP patients respectively. Hakimi et al (2009) reported that there was no difference in continence rates between the LRP and RALP groups at 3 months (LRP 54.6% (41/75) vs RALP 65.3% (49/75), $P=0.24$), 6 months (LRP 65.3% (49/75) vs RALP 74.7% (56/75), $P=0.28$) or 12 months (LRP 89.3% (67/75) vs RALP 93.3% (70/75), $P=0.56$) post surgery. Similarly, Srinualnad (2008) reported that the continence rate 1 month post surgery was not significantly different in patients who underwent RALP (29.4%, 10/34) compared with those who underwent LRP (14.7%, 5/34).

Erectile function

One study reported on return to erectile function following prostatectomy, defined as the ability to maintain an erection sufficient for intercourse with or without the use of oral phosphodiesterase-5 inhibitors (Hakimi et al 2009). Erectile function rates in patients who underwent a bilateral nerve sparing LRP or RALP were not significantly different at 3 months (LRP 20% (9/45) vs RALP 31.4% (16/51), $P=0.24$), 6 months (LRP 48.9% (22/45) vs RALP 66.7% (34/51), $P=0.09$) or 12 months (LRP 71.1% (32/45) vs RALP 76.5% (39/51), $P=0.64$) post surgery. Similarly, erectile function rates in patients who underwent a unilateral nerve sparing LRP or RALP were not significantly different at 3 months (LRP 10% (1/10) vs RALP 14.3% (1/7), $P=1.0$), 6 months (LRP 40% (4/10) vs RALP 42.9% (3/7), $P=1.0$) or 12 months (LRP 40% (4/10) vs RALP 57.1% (4/7), $P=1.0$) post surgery.

Biochemical recurrence

One study (Hakimi et al 2009) reported on biochemical recurrence following prostatectomy, with 6.7% (5/75) of patients in the LRP group and 5.3% (4/75) of patients in the RALP group demonstrating biochemical recurrence (defined as a prostate-specific antigen level >0.2 ng/dL) at a mean follow-up of 48 and 17 months, respectively.

Table 4 Comparison of key efficacy and safety outcomes for robotic-assisted or conventional radical prostatectomy

Study	Number of patients	Operative time (mins)*	Estimated blood loss (mL)*	Length of hospital stay (days)*	Conversions n/N (%)	Transfusions n/N (%)	Positive surgical margins n/N (%)	Complications n/N (%)
Chan 2008 III-2	*Large prostate* RALP 81 RRP 27 *Small prostate* RALP 579 RRP 313	 233.7 [51.3] 139.5 [28.9] *P*<0.001 204.6 [38.3] 141.0 [31.1] *P*<0.001	 152.1 [199.3] 593.5 [292.2] *P*<0.001 139.2 [153.3] 495.3 [320.6] *P*<0.001	 1.3 [1.3] 1.4 [0.4] *P*=NS 1.1 [0.5] 1.3 [0.4] *P*<0.001	 1/81 (1.2%) 5/579 (0.9%)	 0/81 (0%) 0/27 (0%) 5/579 (0.9%) 11/313 (3.5%) *P*=0.017	 8/81 (9.9%) 5/27 (19%) *P*=NS 110/579 (19%) 111/313 (35.5%) *P*<0.001	NR
Schroeck 2008 III-2	RALP 362 RRP 435	NR	Med: 150 (100 – 173) Med: 800 (500 – 1200) *P*<0.001	NR	NR	NR	106/362 (29.3%) 122/435 (28%) *P*=NS	NR
Srinualnad 2008 III-2	RALP 34 LRP 34	239.4 [107.4] 226.5 [64.2] *P*=NS	657.4 [319.1] 772.1 [291.6] *P*=NS	6.9 [2.0] 8.0 [2.8] *P*=NS	0/34 (0%) 0/34 (0%)	9/34 (26.4%) 10/34 (29.5%) *P*=NS	NR	1/34 (2.9%) 6/34 (17.6%) *P*=NR
Hakimi 2009 III-3	RALP 75 LRP 75	199 (75 – 360) 232 (170 – 385) *P*<0.001	230 (50 – 1500) 311 (100 – 800) *P*=0.004	1.95 (1 – 7) 3.4 (2 – 12) *P*<0.0001	2/75 (2.7%) 0/75 (0%) *P*=NR	1/75 (1.3%) 0/75 (0%) *P*=NR	9/75 (12%) 10/75 (13.7%) *P*=NS	12/75 (16%) 15/75 (20%) *P*=NR
White 2009 III-3	RALP 50 RRP 50	NR	NR	NR	NR	NR	11/50 (22%) 18/50 (36%) *P*=0.007	NR
Caballero-Romeu 2008 III-3	RALP 60 RRP 62 LRP 70	Med: 210 (158 - 240) Med: 210 (160 - 240) Med: 345 (315 - 375) *P*<0.001	Med: 400 (213 – 500) Med: 1500 (1200 – 2000) Med: 1275 (700 – 2000) *P*<0.001	Med: 5 (4 - 6) Med: 8 (7 - 9) Med: 8 (5 - 10) *P*<0.001	0/60 (0%) 22/70 (31.4%) *P*<0.001	10.7% 81.5% 48.4% *P*<0.001	30.9% 51.9% 46.3% *P*=NS	25/60 (41.7%) 53/62 (85.5%) 53/70 (75.7%) *P*=NR
Laurila 2008 III-3	RALP 94 RRP 98	NR	NR	NR	NR	NR	11/88 (13%) 12/84 (14%) *P*=NS	NR
Trabulsi 2008 III-3	RALP 50 LRP 190	NR	287 (50 – 1500) 370 (50 – 3200) *P*=NS	NR	0/50 (0%) 7/197 (3.6%) *P*=NR	NR	3/50 (6%) 35/190 (18%) *P*=0.032	NR
Webb 2008 III-3	RALP 100 ORP 100	NR	Med: 450 (80 - 1700) Med: 500 (100 - 1500) *P*=NS	NR	0/100 (0%)	NR	NR	4/100 (4%) 13/100 (13%) *P*=NR

NOTE: LRP – laparoscopic radical prostatectomy; Med – median; NR – not reported; NS – not significant; RALP – robotic-assisted laparoscopic prostatectomy; RRP – radical retropubic prostatectomy; * figures presented as mean and [standard deviation] or (range) unless otherwise stated.

Safety

A total of four studies reported on safety outcomes, primarily perioperative complication rates, following radical prostatectomy (Caballero-Romeu et al 2008; Srinualnad 2008; Webb et al 2008; Hakimi et al 2009) (Table 4). The rate of complications following RALP was lower compared with LRP and RRP; however, the statistical significance of these relationships was not reported.

The overall incidence of complications across studies was 15.6% for RALP, compared with 41.3% for LRP and 40.7% for RRP (Table 5). The most common complications following RALP were urinary tract infections and urinary retention, while fever and bladder neck contracture were the most common complications following LRP and RRP respectively.

Mortality rates were reported in one study, which stated that there were no deaths in either the RALP or LRP group (Hakimi et al 2009) (Table 5).

Table 5 Adverse events reported for robotic-assisted or conventional radical prostatectomy

Outcome	Technique		
	Robotic n/N	Standard laparoscopic n/N	Open n/N
Mortality	0/75 (0%) (1 study)	0/75 (0%) (1 study)	NR
Complications			
Urinary tract infection	12/235 (3 studies)	7/104 (2 studies)	9/162 (2 studies)
Wound infection	2/60 (1 study)	5/70 (1 study)	3/62 (1 study)
Skin dehiscence	1/60 (1 study)	4/70 (1 study)	2/62 (1 study)
Urinary fistula	1/60 (study)	7/70 (1 study)	1/62 (1 study)
Mictional syndrome	2/60 (1 study)	7/70 (1 study)	8/62 (1 study)
Fever (>38°C)	1/60 (1 study)	8/70 (1 study)	8/62 (1 study)
Bladder neck contracture	2/235 (3 studies)	5/145 (2 studies)	15/162 (2 studies)
Haematoma	3/60 (1 study)	1/70 (1 study)	5/62 (1 study)
Rectal damage	0/60 (1 study)	4/70 (1 study)	3/62 (1 study)
Thromboembolism	2/60 (1 study)	1/70 (1 study)	1/62 (1 study)
Other cardiovascular alterations	1/60 (1 study)	2/70 (1 study)	4/62 (1 study)
Postoperative bleeding	1/135 (2 studies)	1/70 (1 study)	2/62 (1 study)
Joint pain	0/60 (1 study)	1/70 (1 study)	2/62 (1 study)
Pneumonia	1/60 (1 study)	0/70 (1 study)	1/62 (1 study)
Caecal damage	1/60 (1 study)	0/70 (1 study)	1/62 (1 study)
Acute peritonitis	1/60 (1 study)	1/70 (1 study)	0/62 (1 study)
Abdominal abscess	1/60 (1 study)	1/70 (1 study)	0/62 (1 study)
Bladder lithiasis	1/60 (1 study)	1/70 (1 study)	1/62 (1 study)
Biliary colic/cholecystitis	0/60 (1 study)	2/70 (1 study)	0/62 (1 study)
Deep vein thrombosis	1/75 (1 study)	NR	NR
Ileus	3/75 (1 study)	1/75 (1 study)	NR
Prolonged Jackson Pratt drainage (>1 week)	1/75 (1 study)	6/75 (1 study)	NR
Urinary retention	4/109 (2 studies)	2/109 (2 studies)	NR
Ureteric injury	NR	1/34 (1 study)	NR
Pulmonary emboli	NR	2/109 (2 studies)	NR
Anastomotic stricture	NR	1/75 (1 study)	NR
Haematuria	NR	1/75 (1 study)	NR
Lymphocele	NR	2/75 (1 study)	NR
Total incidence of complications	42/269 (15.6%) (4 studies)	74/179 (41.3%) (3 studies)	66/162 (40.7%) (2 studies)

NOTE: NR - not reported; Table includes data from the following studies: Hakimi 2009, Srinualnad 2008, Caballero-Romeu 2008 and Webb 2008.

Radical and partial nephrectomy

Nonrandomised comparative studies

Appraisal of study quality

Two of the four studies compared robotic-assisted partial nephrectomy (RPN) to laparoscopic partial nephrectomy (LPN), one study compared robotic-assisted radical nephrectomy (RRN) to laparoscopic radical nephrectomy (LRN) and another study compared RRN to open radical nephrectomy (ORN) and RPN to open partial nephrectomy (OPN) (Table 3).

The objectives of all four studies were clearly described. Two studies provided a clear description of both the robotic and comparator intervention (Hemal and Kumar 2009; Wang and Bhayani 2009), while one study only described the robotic intervention (Caruso et al 2006). Each of the four studies involved procedures performed at single-centres and in two studies both the robotic and comparator procedures were performed by a single surgeon (Hemal and Kumar 2009; Wang and Bhayani 2009). Two studies reported explicit inclusion criteria, and the patient pool typically included those with a diagnosis of clinically localised renal cell carcinoma (Hemal and Kumar 2009; Wang and Bhayani 2009). Explicit exclusion criteria were not reported in any of the studies.

Two studies utilised prospective data collection (Sterrett et al 2007; Hemal and Kumar 2009). Patients were consecutively enrolled in three studies (Caruso et al 2006; Sterrett et al 2007; Wang and Bhayani 2009). Method of patient allocation was reported in two studies, with patients being allocated to treatment group based on patient preference in both studies (Hemal and Kumar 2009; Wang and Bhayani 2009). In all four studies, patients in both the robotic and comparator groups were generally well matched for baseline characteristics such as age, gender, body mass index (BMI), American Society of Anaesthesiologists (ASA) score, and comorbidities such as hypertension and diabetes. Sample sizes in all four studies were small, with fewer than 100 patients in each treatment group; however, the numbers of patients in each treatment group were generally well-matched.

Blinding of investigators, outcome assessors or patients was not possible due to the nature of the surgery. The reporting of outcomes in most studies was limited to perioperative data such as operative time, LOS, EBL, transfusion rate, PSM rate, conversion rate and rate of complications. In addition, one study reported on analgesic requirement and cancer recurrence following surgery (Hemal and Kumar 2009).

Sterrett et al (2007) reported that 1 patient each in the OPN and ORN groups and 2 patients in the RRN group, died following surgery and were lost to follow-up. Follow-up periods ranged from 8.3 months up to 9.1 months postoperatively in the one study where this was reported (Table 3).

Efficacy

Operative time

All four studies reported on operative time (Table 6). In one study (Wang and Bhayani 2009), significantly shorter operative times were observed for RPN compared with LPN (P=0.04), while another study (Hemal and Kumar 2009) reported significantly longer operative times for RRN compared with LRN (P=0.001). No differences in operative times were seen between RRN and ORN or RPN and OPN in one study (Sterrett et al 2007), or between RPN and LPN in another study (Caruso et al 2006).

Estimated blood loss

EBL was reported in all four studies (Table 6). One study reported that EBL for RRN was significantly lower compared with ORN (P<0.05) (Sterrett et al 2007). No differences in EBL were seen between RPN and LPN in two studies (Caruso et al 2006; Wang and Bhayani 2009), between RRN and LRN in one study (Hemal and Kumar 2009), or between RPN and OPN in another study (Sterrett et al 2007).

Length of hospital stay

All four studies reported on LOS (Table 6). One study (Wang and Bhayani 2009) reported that LOS was significantly shorter following RPN compared with LPN (P=0.03), while another study (Sterrett et al 2007) reported that LOS was shorter following RRN compared with ORN (P<0.05). No significant differences in LOS were observed between RPN and LPN in one study (Caruso et al 2006), between RRN and LRN (Hemal and Kumar 2009), or between RPN and OPN (Sterrett et al 2007). In addition, Hemal and Kumar (2009) reported that the mean convalescence following RRN (2.3 [SD 0.5] weeks) was not significantly different when compared with LRN (2.2 [SD 0.4] weeks).

Conversions

Conversion rates were reported in three studies (Caruso et al 2006; Hemal and Kumar 2009; Wang and Bhayani 2009) (Table 6). Conversion rates for RPN and RRN (4.8%-20%) tended to be higher compared to those for LPN or LRN (0%-10%); however, the statistical significance of these relationships was not reported in any of the three studies.

Transfusions

Transfusion rates were reported in all four studies (Table 6). One study reported no differences in transfusion rates between RRN and ORN or RPN and OPN (Sterrett et al 2007), while another study reported no difference between RRN and LRN (Hemal and Kumar 2009). One study reported that there were no transfusions following RPN or LPN (Caruso et al 2006). Another study reported low transfusion rates following RPN and LPN; however, the statistical significance of this relationship was not reported (Wang and Bhayani 2009).

Positive surgical margins

A total of two studies reported on PSM rates (Caruso et al 2006; Wang and Bhayani 2009) (Table 6). One study reported that no difference in the PSM rate was observed following RPN or LPN (Wang and Bhayani 2009). Another study reported low PSM rates following RPN and LPN; however, the statistical significance of this relationship was not reported (Caruso et al 2006).

Cancer recurrence

One study reported that when patients were followed-up clinically, symptomatically and with imaging studies after RRN (8.3 months) and LRN (9.1 months), no local, port site or distant recurrences were observed (Hemal and Kumar 2009).

Analgesic requirement

Hemal and Kumar (2009) reported that the mean analgesic requirement following RRN (14.3 [SD 0.1] mg morphine equivalent) was not significantly different when compared with LRN (14.4 [SD 0.2] mg morphine equivalent).

Table 6 Comparison of key efficacy and safety outcomes for robotic-assisted or conventional radical or partial nephrectomy

Study	Number of patients	Operative time (mins)*	Estimated blood loss (mL)*	Length of hospital stay (days)*	Conversions n/N (%)	Transfusions n/N (%)	Positive surgical margins n/N (%)	Complications n/N (%)
Hemal 2009 III-2	RRN 15 LRN 15	221 [19.1] 175.3 [40.9] *P*=0.001	210.3 [21.1] 195 [31.3] *P*=NS	3.5 [0.1] 3.4 [0.2] *P*=NS	1/15 (6.7%) 0/15 (0%) *P*=NR	3/15 (15%) 2/15 (13.3%) *P*=NS	NR	5/15 (33.3%) 4/14 (26.7%) *P*=NR
Wang 2009 III-2	RPN 40 LPN 62	140 156 *P*=0.04	136 173 *P*=NS	2.5 2.9 *P*=0.03	2/42 (4.8%) 3/65 (4.6%) *P*=NR	2/40 (5%) 1/62 (1.6%) *P*=NR	1/40 (2.5%) 1/62 (1.6%) *P*=NS	6/40 (15%) 8/62 (12.9%) *P*=NR
Caruso 2006 III-2	RPN 10 LPN 10	279 253 *P*=NS	240 200 *P*=NS	2.6 2.65 *P*=NS	2/10 (20%) 1/10 (10%) *P*=NR	0/10 (0%) 0/10 (0%)	0/10 (0%) 1/10 (10%) *P*=NR	3/10 (30%) 2/10 (20%) *P*=NR
Sterrett 2007 III-3	RRN 65 ORN 21 RPN 9 OPN 15	236 [87] 240 [92] *P*=NS 299 [78] 249 [63] *P*=NS	Med: 100 (10 - 2000) Med: 500 (75 - 4000) *P*<0.05 Med: 400 (25 - 3000) Med: 300 (50 - 1000) *P*=NS	Med: 4 (1 - 61) Med: 6 (3 - 10) *P*<0.05 Med: 6 (2 - 7) Med: 6 (4 - 55) *P*=NS	NR NR	13/65 (20%) 4/21 (19%) *P*=NS 1/9 (11%) 5/15 (33%) *P*=NS	NR NR	12/65 (18%) 3/21 (14%) *P*=NS 1/9 (11%) 0/15 (0%) *P*=NS

NOTE: LPN – laparoscopic partial nephrectomy; LRN – laparoscopic radical nephrectomy; Med – median; NR – not reported; NS – not significant; OPN – open partial nephrectomy; ORN – open radical nephrectomy; RPN – robotic-assisted partial nephrectomy; RRN – robotic-assisted radical nephrectomy; * figures presented as mean and [standard deviation] or (range) unless otherwise stated.

Safety

Safety outcomes following partial nephrectomy, primarily perioperative complication rates, were reported in three studies (Caruso et al 2006; Sterrett et al 2007; Wang and Bhayani 2009), while two studies reported on safety outcomes following radical nephrectomy (Sterrett et al 2007; Hemal and Kumar 2009) (Table 6). The rate of complications following RPN and LPN were similar; however, the statistical significance of these relationships was not reported (Caruso et al 2006; Wang and Bhayani 2009). Sterrett et al (2007) reported that no significant differences were observed in the rate of perioperative complications following RRN and ORN, or RPN and OPN. Similarly, Hemal and Kumar (2009) reported no significant differences in the rate of intraoperative or postoperative complications following RRN and LRN.

The overall incidence of complications across studies was 18% for RPN compared with 13.9% for LPN, and 33.3% for RRN compared with 26.7% for LRN (Table 7).

Mortality rates were reported in one study (Sterrett et al 2007), which stated that 7% (1/15) of patients died following OPN compared with 0% (0/9) of patients following RPN (P=1.0), while 4.8% (1/21) of patients died following ORN compared with 3.1% (2/65) of patients following RRN (P=1.0) (Table 7).

Table 7 Adverse events reported for robotic-assisted or conventional radical or partial nephrectomy

Outcome	Technique					
	Partial nephrectomy			Radical nephrectomy		
	Robotic n/N	Standard laparoscopic n/N	Open n/N	Robotic n/N	Standard laparoscopic n/N	Open n/N
Mortality	0/9 (0%) (1 study)	NR	1/15 (7%) (1 study)	2/65 (3.1%) (1 study)	NR	1/21 (4.8%) (1 study)
Complications						
Cardiopulmonary	3/40 (1 study)	3/62 (1 study)	NR	NR	NR	NR
Thromboembolic	1/40 (1 study)	0/62 (1 study)	NR	NR	NR	NR
Haematoma	1/40 (1 study)	1/62 (1 study)	NR	NR	NR	NR
Pseudoaneurysm	0/40 (1 study)	2/62 (1 study)	NR	NR	NR	NR
Urinary leak	1/40 (1 study)	1/62 (1 study)	NR	NR	NR	NR
Exploration	0/40 (1 study)	1/62 (1 study)	NR	NR	NR	NR
Vascular/haemorrhage	NR	NR	NR	2/15 (1 study)	1/15 (1 study)	NR
Wound infection	NR	NR	NR	1/15 (1 study)	1/15 (1 study)	NR
Ileus	NR	NR	NR	2/15 (1 study)	1/15 (1 study)	NR
Incisional hernia	NR	NR	NR	0/15 (1 study)	1/15 (1 study)	NR
Bleeding	2/10 (1 study)	1/10 (1 study)	NR	NR	NR	NR
Urinary retention	1/10 (1 study)	NR	NR	NR	NR	NR
Colonic pseudo-obstruction	NR	1/10 (1 study)	NR	NR	NR	NR
Total incidence of complications	9/50 (18%) (2 studies)	10/72 (13.9%) (2 studies)		5/15 (33.3%) (1 study)	4/15 (26.7%) (1study)	

NOTE: NR - not reported; Table includes data from the following studies: Wang 2009, Hemal 2009, Caruso 2006 and Sterrett 2007.

Radical cystectomy

Nonrandomised comparative studies

Appraisal of study quality

Three of the four studies that utilised the da Vinci Surgical System for radical cystectomy (RRC) compared its use to open surgery (ORC), while the remaining study compared it to laparoscopic surgery (LRC) (Table 3).

The objectives of all four studies were clearly described. Two studies provided a clear description of both the robotic and comparator intervention (Abraham et al 2007; Wang et al 2007). All four studies involved procedures performed at single-centres and in one study both the robotic and comparator procedures were performed by a single surgeon (Wang et al 2007). None of the four studies reported explicit inclusion or exclusion criteria.

Each of the four studies reported that data was collected prospectively and that patients were consecutively enrolled. Method of patient allocation was reported in one study, with patients allocated to treatment group based on patient preference (Guru et al 2007). In all four studies, patients in both the robotic and comparator groups were generally well matched for baseline characteristics such as age, gender, BMI, ASA score, and clinical stage, however one study (Wang et al 2007) did report that there were more men in the RRC group compared with the ORC group (P=0.003). Sample sizes in all four studies were relatively small, with fewer than 100 patients in each treatment group. The numbers of patients in each treatment group were generally well-matched.

Blinding of investigators, outcome assessors or patients was not possible due to the nature of the surgery. The reporting of outcomes in most studies was limited to perioperative data such as operative time, LOS, EBL, transfusion rate, conversion rate, PSM rate and rate of complications. In addition, one study reported on pain and analgesic requirement following surgery (Guru et al 2007), while another study reported on the time taken to return to regular diet and oral intake following surgery (Abraham et al 2007).

Sterrett et al (2007) reported that 1 patient each in the ORC and RRC groups died as a result of sepsis following surgery and were lost to follow-up. Follow-up periods were not reported in any of the studies (Table 3).

Efficacy

Operative time

Three studies reported on operative time (Abraham et al 2007; Sterrett et al 2007; Wang et al 2007) (Table 8). In two studies (Sterrett et al 2007; Wang et al 2007), significantly longer operative times were observed for RRC compared with ORC (P<0.05 and P=0.03, respectively), while another study reported no significant difference in operative time between RRC and LRC (Abraham et al 2007).

Estimated blood loss

EBL was reported in three studies (Abraham et al 2007; Sterrett et al 2007; Wang et al 2007) (Table 8). Two studies (Sterrett et al 2007; Wang et al 2007) reported that EBL for RRC was significantly lower compared with ORC ($P<0.05$ and $P=0.002$, respectively), while another study (Abraham et al 2007) reported that EBL for RRC was significantly lower compared with LRC ($P=0.00009$).

Length of hospital stay

Three studies reported on LOS (Abraham et al 2007; Sterrett et al 2007; Wang et al 2007) (Table 8). In two studies (Sterrett et al 2007; Wang et al 2007), significantly shorter hospital stays were observed for RRC compared with ORC ($P<0.05$ and $P=0.007$, respectively), while another study (Abraham et al 2007) reported no significant difference in LOS between RRC and LRC.

Conversions

Conversion rates were reported in three studies (Abraham et al 2007; Guru et al 2007; Wang et al 2007) (Table 8). One study reported that conversion rates for RRC and LRC were not significantly different (Abraham et al 2007). Two studies reported low conversion rates for RRC (Guru et al 2007; Wang et al 2007).

Transfusions

Transfusion rates were reported in two studies (Abraham et al 2007; Sterrett et al 2007) (Table 8). One study (Abraham et al 2007) reported that the transfusion rate for RRC was significantly lower compared with LRC ($P=0.0011$), while another study reported no difference in the transfusion rates for RRC and ORC (Sterrett et al 2007).

Positive surgical margins

A total of two studies reported on PSM rates (Abraham et al 2007; Wang et al 2007) (Table 8). One study reported no difference in PSM rates between RRC and ORC (Wang et al 2007). Another study reported low PSM rates for RRC and LRC; however, the statistical significance of this relationship was not reported (Abraham et al 2007).

Pain

Guru et al (2007) reported that average Likert pain perception scores were not significantly different between patients who underwent RRC or ORC; however, the amount of morphine sulphate equivalent used was significantly higher following ORC on all postoperative days compared with RRC (main effect, $P=0.007$). In addition, 81.3% (13/16) of patients had epidural analgesia following ORC compared with 18.8% (3/16) of patients following RRC (Guru et al 2007).

Days to oral intake and regular diet

One study reported that short-term recovery, as indicated by the time to oral intake (RRC mean 2.3 [SD 5] days vs LRC mean 6.1 [SD 5.2] days, $P=0.012$) and resumption of regular diet (RRC mean 3.7 [SD 0.5] days vs LRC mean 7 [SD 6.9]

days, *P*=0.011) was quicker following RRC compared with LRC (Abraham et al 2007).

Table 8 Comparison of key efficacy and safety outcomes for robotic-assisted or conventional radical cystectomy

Study	Number of patients	Operative time (mins)*	Estimated blood loss (mL)*	Length of hospital stay (days)*	Conversions n/N (%)	Transfusions n/N (%)	Positive surgical margins n/N (%)	Complications n/N (%)
Wang 2007 III-2	RRC 33 ORC 21	Med: 390 (210 - 570) Med: 300 (165 - 540) *P*=0.03	Med: 400 (100 - 1200) Med: 750 (250 - 2500) *P*=0.002	Med: 5 (4 - 18) Med: 8 (5 - 28) *P*=0.007	1/33 (3%)	NR	2/33 (6%) 3/21 (14.2%) *P*=NS	7/33 (21.2%) 5/21 (23.8%) *P*=NS
Abraham 2007 III-3	RRC 14 LRC 20	410 (340 - 545) 419 (275 - 527) *P*=NS	212 (50 - 500) 653 (300 - 1400) *P*=0.00009	Med: 6 (4 - 7) Med: 6 (4 - 32) *P*=NS	0/14 (0%) 3/20 (15%) *P*=NS	6/14 (42.8%) 14/20 (70%) *P*=0.0011	1/14 (7.1%) 0/20 (0%) *P*=NR	4/14 (28%) 14/20 (70%) *P*=NR
Guru 2007 III-3	RRC 16 ORC 17	NR	NR	NR	1/16 (6.3%)	NR	NR	NR
Sterrett 2007 III-3	RRC 19 ORC 33	606 [171] 396 [116] *P*<0.05	Med: 500 (50 - 4000) Med: 850 (100 - 10200) *P*<0.05	Med: 8 (4 - 23) Med: 10 (2 - 55) *P*<0.05	NR	10/19 (53%) 23/33 (70%) *P*=NS	NR	6/19 (32%) 10/33 (30%) *P*=NS

NOTE: LRC – laparoscopic radical cystectomy; Med – median; NR – not reported; NS – not significant; ORC – open radical cystectomy; RRC – robotic-assisted radical cystectomy; * figures presented as mean and [standard deviation] or (range) unless otherwise stated.

Safety

A total of three studies reported on safety outcomes, primarily perioperative complication rates, following radical cystectomy (Abraham et al 2007; Sterrett et al 2007; Wang et al 2007) (Table 8). Two studies reported no significant differences in the rate of complications following RRC and ORC (Sterrett et al 2007; Wang et al 2007). In one study, the rate of complications following LRC was higher compared with RRC; however, the statistical significance of this relationship was not reported (Abraham et al 2007).

The overall incidence of complications across studies was 29.8% for RRC, compared with 95% for LRC and 23.8% for ORC (Table 9). The most common complication following both RRC and LRC was prolonged ileus.

Mortality rates were reported in two studies (Sterrett et al 2007; Wang et al 2007) (Table 9). Sterrett et al (2007) reported that 3% (1/33) of patients died following ORC compared with 5% (1/19) of patients following RRC (P=1.0). Wang et al (2007) reported that there were no deaths following RRC or ORC.

Table 9 Adverse events reported for robotic-assisted or conventional radical cystectomy

Outcome	Technique		
	Robotic n/N	Standard laparoscopic n/N	Open n/N
Mortality	1/52 (1.9%) (2 studies)	NR	1/54 (1.9%) (2 studies)
Complications			
Delayed ileus	1/14 (1 study)	NR	NR
Prolonged ileus	4/33 (1 study)	3/20 (1 study)	1/21 (1 study)
Abscess	1/33 (1 study)	1/20 (1 study)	1/21 (1 study)
Enterocutaneous fistula	1/33 (1 study)	1/20 (1 study)	NR
Wound dehiscence	NR	NR	1/21 (1 study)
Respiratory failure	NR	1/20 (1 study)	1/21 (1 study)
Myocardial infarction	1/14 (1 study)	NR	1/21 (1 study)
Left obturator nerve injury	1/14 (1 study)	NR	NR
Bleeding	NR	2/20 (1 study)	NR
Rectal injury	NR	1/20 (1 study)	NR
Urine leak	1/14 (1 study)	2/20 (1 study)	NR
Hypertension	1/14 (1 study)	NR	NR
Atrial fibrillation	1/14 (1 study)	NR	NR
Dehydration	1/14 (1 study)	NR	NR
Arm cellulitis	NR	1/20 (1 study)	NR
Deep vein thrombosis	NR	1/20 (1 study)	NR
Ileus	1/14 (1 study)	1/20 (1 study)	NR
Stomal stenosis	NR	1/20 (1 study)	NR
Conduit obstruction	NR	1/20 (1 study)	NR
Rectal-urethral fistula	NR	1/20 (1 study)	NR
Partial small bowel obstruction	NR	1/20 (1 study)	NR
Internal iliac artery injury	NR	1/20 (1 study)	NR
Total incidence of complications	14/47 (29.8%) (2 studies)	19/20 (95%) (1 study)	5/21 (23.8%) (1 study)

NOTE: NR – not reported; Table includes data from the following studies: Abraham 2007 and Wang 2007.

Pyeloplasty

Nonrandomised comparative studies

Appraisal of study quality

Each of the four studies that utilised the da Vinci Surgical System for pyeloplasty (RP) compared its use to laparoscopic pyeloplasty (LP) (Table 3).

The objectives of all four studies were clearly described. Two studies provided a clear description of both the robotic and comparator intervention (Weise and Winfield 2006; Yanke et al 2008). Two studies involved procedures performed at single-centres (Bernie et al 2005; Yanke et al 2008) and two studies reported that both the robotic and comparator procedures were performed by a single surgeon (Bernie et al 2005; Link et al 2006). All four studies reported explicit inclusion and the patient pool typically included those with primary ureteropelvic junction obstruction. One study reported explicit exclusion criteria stating that patients with previous ipsilateral renal surgery of any type were excluded (Link et al 2006).

Two of the four studies reported prospective data collection (Link et al 2006; Weise and Winfield 2006), while only one study reported that patients were consecutively enrolled (Link et al 2006). Method of patient allocation was reported in one study, with patients allocated to treatment group based on patient preference (Bernie et al 2005). In all four studies, patients in both the robotic and comparator groups were generally well-matched for baseline characteristics such as age, gender and BMI. Sample sizes in all four studies were generally small, with fewer than 100 patients in each treatment group. The numbers of patients in each treatment group were well-matched in two studies (Bernie et al 2005; Link et al 2006).

Blinding of investigators, outcome assessors or patients was not possible due to the nature of the surgery. The reporting of outcomes in most studies was limited to perioperative data such as operative time, LOS, EBL, surgical success rate, conversion rate and rate of complications. In addition, two studies reported on pain and renal function following surgery (Bernie et al 2005; Weise and Winfield 2006).

Follow-up periods in the four studies ranged from 5.6 months up to 24 months (Table 3). One study reported that 21.4% (3/14) of patients in the LP group and 6.5% (2/31) of patients in the RP group were lost to follow-up (Weise and Winfield 2006).

Efficacy

Operative time

Three studies reported on operative time (Bernie et al 2005; Link et al 2006; Weise and Winfield 2006) (Table 10). One study (Link et al 2006) reported significantly longer operative times for RP compared with LP (P=0.018), while another study reported no significant difference in operative times between RP and LP (Weise and

Winfield 2006). One study reported similar operative times for RP and LP; however, the statistical significance of this relationship was not reported (Bernie et al 2005).

Estimated blood loss

EBL was reported in three studies (Bernie et al 2005; Link et al 2006; Weise and Winfield 2006) (Table 10). Two studies (Link et al 2006; Weise and Winfield 2006) reported no significant differences in EBL following RP and LP. In one study EBL was higher following RP compared with LP; however, the statistical significance of this relationship was not reported.

Length of hospital stay

LOS was reported in three studies (Bernie et al 2005; Link et al 2006; Weise and Winfield 2006) (Table 10). Two studies (Link et al 2006; Weise and Winfield 2006) reported no significant differences in LOS following RP and LP. In one study LOS was similar following RP and LP; however, the statistical significance of this relationship was not reported.

Conversions

Conversion rates were reported in one study, which stated that no patients in either the RP or LP group required a conversion to open surgery (Weise and Winfield 2006) (Table 10).

Transfusions

None of the four studies reported on transfusion rates.

Surgical success rate

A total of three studies reported on surgical success rates (Link et al 2006; Weise and Winfield 2006; Yanke et al 2008) (Table 10). One study reported that all RP and LP procedures were successful (Link et al 2006). Another study reported that while all RP procedures were successful, there were a number of failures in the LP group; however the statistical significance of this relationship was not reported (Yanke et al 2008). One study reported similar surgical success rates for RP and LP; however the statistical significance of this relationship was not reported (Weise and Winfield 2006).

Pain

Bernie et al (2005) reported that in RP patients, the mean visual analog pain score improved from 8 preoperatively to 2 postoperatively; however, pain scores were not reported for LP patients. Weise and Winfield (2006) reported that in the RP group 83% (24/29) of patients had no pain, 14% (4/29) of patients had occasional mild pain and 3% (1/29) of patients had significant pain postoperatively, compared with 73% (8/11), 27% (3/11) and 0% (0/11) respectively, in the LP group.

Renal function

Bernie et al (2005) reported that all RP and LP patients demonstrated an improvement in renal function of between 30% and 44%, as well as normalisation of

excretion activity. Weise and Winfield (2006) reported that in the RP group 44% (10/23) of patients had a significant improvement in renal function, 52% (12/23) of patients had no change in renal function and 4% (1/23) of patients had a significant decrease in renal function postoperatively, compared with 25% (2/8), 75% (6/8) and 0% (0/8) respectively, in the LP group.

Table 10 Comparison of key efficacy and safety outcomes for robotic-assisted or conventional pyeloplasty

Study	Number of patients	Operative time (mins)*	Estimated blood loss (mL)*	Length of hospital stay (days)*	Conversions n/N (%)	Transfusions n/N (%)	Surgical success rate n/N (%)	Complications n/N (%)
Link 2006 III-2	RP 10 LP 10	100.2 [9.1] 80.7 [21.9] *P*=0.018	*P*=NS†	*P*=NS†	NR	NR	10/10 (100%) 10/10 (100%)	1/10 (10%) 0/10 (0%) *P*=NR
Yanke 2008 III-3	RP 29 LP 116	NR	NR	NR	NR	NR	29/29 (100%) 103/116 (88.8%) *P*=NR	NR
Weise 2006 III-3	RP 31 LP 14	Med: 271 (207 - 444) Med: 299 (193 - 376) *P*=NS	Med: <100 (10 - 300) Med: <100 (20 - 200) *P*=NS	Med: 2 (1 - 3) Med: 2 (2 - 5) *P*=NS	0/31 (0%) 0/14 (0%)	NR	19/29 (66%) 7/11 (64%) *P*=NR	2/31 (6%) 2/14 (14%) *P*=NR
Bernie 2005 III-3	RP 7 LP 7	324 (252 - 420) 312 (240 - 390) *P*=NR	60 (50 - 100) 40 (5 - 200) *P*=NR	2.5 (2 - 6) 3 (2 - 4) *P*=NR	NR	NR	NR	2/7 (28.6%) 2/7 (28.6%)

NOTE: LP – laparoscopic pyeloplasty; Med – median; NR – not reported; NS – not significant; RP – robotic-assisted pyeloplasty; * figures presented as mean and [standard deviation] or (range) unless otherwise stated; † article stated that there was no significant difference between groups for this outcome, but did not provide data.

Safety

A total of three studies reported on safety outcomes, primarily perioperative complication rates, following pyeloplasty (Bernie et al 2005; Link et al 2006; Weise and Winfield 2006) (Table 10). The rate of complications following RP and LP were similar; however, the statistical significance of these relationships was not reported.

The overall incidence of complications across studies was 12.5% for RP, compared with 19% for LP (Table 11).

Mortality rates were not reported in any of the three studies (Table 11).

Table 11 Adverse events reported for robotic-assisted or conventional pyeloplasty

Outcome	Technique	
	Robotic n/N	Standard laparoscopic n/N
Mortality	NR	NR
Complications		
Urinary tract infection	2/38 (2 studies)	NR
Urine leak	2/41 (2 studies)	NR
Haematoma	NR	1/14 (1 study)
Ileus	1/31 (1 study)	NR
Umbilical hernia	NR	1/14 (1 study)
Haematuria	1/7 (1 study)	NR
Anastomotic leak	NR	2/7 (1 study)
Total incidence of complications	6/48 (12.5%) (3 studies)	4/21(19%) (2 studies)

NOTE: NR – not reported; Table includes data from the following studies: Weise 2006, Link 2006 and Bernie 2005.

Cardiac procedures

From the search strategy, 475 potentially relevant articles were identified of which 16 potentially relevant articles were retrieved. Retrieved studies included systematic reviews and primary studies. In total, 12 retrieved articles were excluded (Appendix A).

A total of four nonrandomised comparative studies (one level III-2 and three level III-3) reporting on the use of the da Vinci Surgical System for mitral valve repair were eligible for appraisal and inclusion in this rapid review (Table 12).

Table 12 Cardiac studies included in the review

Study	Surgery type	Level of evidence	Number of patients	Follow-up
Woo 2006	Mitral valve repair	III-2	RMVR 25 OMVR 39	NR
Folliguet 2006	Mitral valve repair	III-3	RMVR 25 OMVR 25	Mean 24 months
Tabata 2006	Mitral valve repair	III-3	RMVR 5 OMVR 123	Mean 45 [SD 10] months Mean 54 [SD 32] months
Chitwood 2005	Mitral valve repair	III-3	RMVR 100 VMVR 341*	NR

NOTE: NR – not reported; OMVR – open mitral valve repair; RMVR – robotic-assisted mitral valve repair; VMVR – video-assisted endoscopic mitral valve repair; *included 92 mitral valve replacements.

Mitral valve repair

Appraisal of study quality

Three of the four studies that utilised the da Vinci Surgical System for mitral valve repair compared its use to OMVR, while the remaining study compared it to VMVR (Table 12).

The objectives of all four studies were clearly described. Similarly, each of the four studies provided a clear description of both the robotic and comparator intervention. All four studies involved procedures performed at single-centres and in one study both the robotic and comparator procedures were performed by a single surgeon (Woo and Nacke 2006). Three of the four studies reported explicit inclusion criteria, and the patient pool typically included those with a diagnosis of mitral regurgitation due to posterior leaflet insufficiency, myxomatous valve disease, functional mitral regurgitation or infectious endocarditis (Chitwood 2005; Folliguet et al 2006; Tabata and Cohn 2006). Explicit exclusion criteria were reported in two studies (Folliguet et al 2006; Woo and Nacke 2006). Excluded patients were those with annulus calcifications, coronary lesions, or aortic or tricuspid valve pathology, as well as those whose condition required CABG or aortic valve surgery as they were approached obligatorily by sternotomy. Patients were also excluded if they suffered from pulmonary disease, as they would be unable to tolerate single lung ventilation.

One study reported prospective data collection (Folliguet et al 2006), while data was collected retrospectively in the three remaining studies. Only one study reported that patients were consecutively enrolled (Woo and Nacke 2006). Method of patient allocation was reported in one study, with patients allocated to treatment group based on either surgeon or patient preference (Woo and Nacke 2006). In two studies, patients in both the robotic and comparator groups were well-matched for baseline characteristics such as age, gender, ventricular function, New York Heart Association (NHYA) Class and comorbidities such as history of myocardial infarction, cerebrovascular accidents, peripheral vascular disease and diabetes (Folliguet et al 2006; Woo and Nacke 2006). In the two remaining studies, baseline characteristics of patients were poorly reported. Sample sizes in two studies were small, with less than 40 patients in each treatment group (Folliguet et al 2006; Woo and Nacke 2006). In the two remaining studies the numbers of patients in each treatment group were not matched, with significantly smaller numbers of patients in the robotic group (Chitwood 2005; Tabata and Cohn 2006).

Blinding of investigators, outcomes assessors or patients was not possible due to the nature of the surgery. The reporting of outcomes in most studies was limited to perioperative data such as operative time, LOS, EBL, transfusion rate and rate of complications. Three studies reported on the need for reoperation (Chitwood 2005; Folliguet et al 2006; Tabata and Cohn 2006).

Losses to follow-up were reported in two studies (Chitwood 2005; Woo and Nacke 2006). Chitwood (2005) reported that 8 patients in the VMVR group and 2 patients in the RMVR group died within 6 weeks following surgery and were lost to follow-up. Woo and Nacke (2006) reported that 1 patient in the OMVR group was lost to follow-up due to postoperative mortality. Similarly, Tabata and Cohn (2006) reported that 2 patients in the OMVR group died within 30 days of surgery and were lost to follow-up. Follow-up periods ranged from 24 months up to 54 months postoperatively in the two studies where this was reported (Table 12).

Efficacy

Operative time

Two studies reported on operative time (Chitwood 2005; Folliguet et al 2006) (Table 13). One study (Folliguet et al 2006) reported that operative times were longer for RMVR compared with OMVR (P=0.002). Another study reported similar operative times for RMVR and VMVR; however, the statistical significance of this relationship was not reported (Chitwood 2005).

Estimated blood loss

EBL was reported in one study (Folliguet et al 2006) (Table 13). This study reported that EBL for RMVR was not significantly different compared with OMVR.

Length of hospital stay

All four studies reported on LOS (Table 13). In two studies (Woo and Nacke 2006; Folliguet et al 2006), significantly shorter hospital stays were observed for RMVR compared with OMVR (P=0.039 and P=0.05, respectively). Two other studies reported a shorter LOS for RMVR compared with OMVR (Tabata and Cohn 2006) and VMVR (Chitwood 2005); however, the statistical significance of these relationships was not reported.

Conversions

Conversion rates were reported in one study, which stated that in the RMVR group, one patient required a conversion to an open procedure (Folliguet et al 2006) (Table 13).

Transfusions

Transfusion rates were reported in three studies (Chitwood 2005; Folliguet et al 2006; Tabata and Cohn 2006) (Table 13). One study reported no significant difference in the rate of transfusion following RMVR and OMVR (Folliguet et al 2006). Another study reported higher transfusion rates following VMVR compared with RMVR; however, the statistical significance of this relationship was not reported (Chitwood 2005). Tabata and Cohn (2006) reported the transfusion rate for the OMVR group, but did not provide data for the RMVR group. Woo and Nacke (2006) did not report on transfusion rates, however did state that the mean packed red blood cell transfusion was 2.8 units (SEM 0.6) in the RMVR group compared with 5 units (SEM 1.0) in the OMVR group (P=0.04).

Reoperation

The rate of reoperation for recurrent mitral regurgitation was reported in three studies (Chitwood 2005; Folliguet et al 2006; Tabata and Cohn 2006) (Table 13). The rate of reoperation following RMVR was lower compared with OMVR (Folliguet et al 2006; Tabata and Cohn 2006) and similar compared with VMVR (Chitwood 2005); however, the statistical significance of these relationships was not reported.

Table 13 Comparison of key efficacy and safety outcomes for robotic-assisted or conventional mitral valve repair

Study	Number of patients	Operative time (mins)*	Estimated blood loss (mL)*	Length of hospital stay (days)*	Conversions n/N (%)	Transfusions n/N (%)	Reoperation n/N (%)	Complications n/N (%)
Woo 2006 III-2	RMVR 25 OMVR 39	NR	NR	7.1 [0.9] † 10.6 [2.1] † *P*=0.039	NR	NR	NR	1/25 (4%) 1/39 (2.6%) *P*=NR
Folliguet 2006 III-3	RMVR 25 OMVR 25	241 [53.3] 188 [24.3] *P*=0.002	477.2 [212.5] 566.2 [201.8] *P*=NS	7 9 *P*=0.05	1/25 (4%)	2/25 (8%) 4/25 (16%) *P*=NS	0/25 (0%) 1/25 (4%) *P*=NR	7/25 (28%) 4/25 (16%) *P*=NR
Tabata 2006 III-3	RMVR 5 OMVR 123	NR	NR	6.6 [5.3] 7.9 [6.3] *P*=NR	NR	NR 66/123 (53.7%)	0/5 (0%) 7/123 (5.7%) *P*=NR	1/5 (20%) 46/123 (37.4%) *P*=NR
Chitwood 2005 III-3	RMVR 100 VMVR 341	283.2 [54] 261 [96] *P*=NR	NR	4.8 [3.8] 6.5 [9.2] *P*=NR	NR	15/100 (15.0%) 101/341 (29.6%) *P*=NR	2/100 (2%) 6/249 (2.4%) *P*=NR	5/100 (2%) 15/341 (4.4%) *P*=NR

NOTE: NR – not reported; NS – not significant; OMVR – open mitral valve repair; RMVR – robotic-assisted mitral valve repair; VMVR – video-assisted endoscopic mitral valve repair; * figures presented as mean and [standard deviation] or (range) unless otherwise stated; † standard error of the mean.

Safety

All four studies reported on safety outcomes, primarily perioperative complication rates, following mitral valve repair (Chitwood 2005; Folliguet et al 2006; Tabata and Cohn 2006; Woo and Nacke 2006) (Table 13). The rate of complications was higher following RMVR compared with OMVR in two studies (Folliguet et al 2006; Woo and Nacke 2006), while one study reported a higher rate of complications following OMVR (Tabata and Cohn 2006); however, the statistical significance of these relationships was not reported. One study reported a higher rate of complications following VMVR compared with RMVR; however, the statistical significance of this relationship was not reported (Chitwood 2005).

The overall incidence of complications across studies was 9% for RMVR, compared with 4.4% and 27.3% for VMVR and OMVR, respectively (Table 14). The most commonly reported complication following both RMVR and VMVR was bleeding, while atrial fibrillation was the most common complication following OMVR.

Mortality rates were reported in all 4 studies, with rates of 1.3%, 2.3% and 1.6% reported for RMVR, VMVR and OMVR, respectively (Table 14).

Table 14 Adverse events reported for robotic-assisted or conventional mitral valve repair

Outcome	Technique		
	Robotic n/N	Video-assisted endoscopic n/N	Open n/N
Mortality	2/155 (1.3%) (4 studies)	8/341 (2.3%) (1 study)	3/187 (1.6%) (3 studies)
Complications			
Bleeding	4/150 (3 studies)	15/341 (1 study)	7/187 (3 studies)
Wound infection	0/25 (1 study)	NR	3/162 (2 studies)
Transient ischaemic attack	1/25 (1 study)	NR	2/25 (1 study)
Groin lymphocele	3/25 (1 study)	NR	0/25 (1 study)
Pulmonary pleural effusion	1/25 (1 study)	NR	0/25 (1 study)
Peripheral embolus	1/25 (1 study)	NR	0/25 (1 study)
Atrial fibrillation	1/5 (1 study)	NR	28/123 (1 study)
Stroke	1/100 (1 study)	NR	1/123 (1 study)
Pulmonary insufficiency	NR	NR	6/123 (1 study)
Pacemaker implantation	NR	NR	4/123 (1 study)
Respiratory failure	1/100 (1 study)	NR	NR
Bowel ischaemia	1/100 (1 study)	NR	NR
Total incidence of complications	14/155 (9%) (4 studies)	15/341 (4.4%) (1 study)	51/187 (27.3%) (3 studies)

NOTE: NR – not reported; Table includes data from the following studies: Chitwood 2005, Woo 2006, Folliguet 2006 and Tabata 2006.

Gynaecological procedures

From the search strategy, 229 potentially relevant articles were identified, of which 26 potentially relevant articles were retrieved. Retrieved studies included systematic reviews and primary studies. In total, seven retrieved articles were excluded (Appendix A).

A total of 19 articles were eligible for appraisal and inclusion in this rapid review (Table 15). All 19 articles reported results from nonrandomised comparative studies (three level III-2, four level III-2/3 and 12 level III-3 studies) reporting gynaecological applications of the da Vinci Surgical System. The most common application was radical hysterectomy for endometrial cancer staging (6 studies), and the treatment of early stage (5 studies in 6 articles) or advanced stage (1 study) cervical cancer. Two cervical cancer articles (Nezhat et al 2008a; Nezhat et al 2008b) reported the same results from the same patient population and for the purposes of this review were considered to be the same study. One additional study involved the use of robotic-assisted hysterectomy (RAH) for benign gynaecological conditions. The robotic system has also been used in myomectomy for the treatment of myomas or leiomyoma (2 studies), as well as for tubal re-anastomosis (2 studies) and sacrocolpopexy for the treatment of vaginal vault prolapse (1 study).

Table 15 Gynaecological studies included in the review

Study	Surgery type	Level of evidence	Number of patients	Follow-up
Veljovich 2008	Total hysterectomy*	III-2/3	RAH 25 LH 4 OH 131	45 days
Seamon 2009	Total hysterectomy*	III-3	RAH 105 LH 76	NR
Bell 2008	Total hysterectomy*	III-3	RAH 40 LH 30 OH 40	NR
Boggess 2008a	Total hysterectomy*	III-3	RAH 103 LH 81 OH 138	NR
DeNardis 2008	Total hysterectomy*	III-3	RAH 56 OH 106	Up to 6 weeks
Gehrig 2008	Total hysterectomy*	III-3	RAH 49 LH 32	NR
Magrina 2008	Radical hysterectomy**	III-2/3	RAH 27 LH 31 OH 35	Mean 27.1 (range 10 to 50) months
Nezhat 2008a,b	Radical hysterectomy**	III-2/3	RAH 13 LH 30	Mean 12 months Mean 29 months
Boggess 2008b	Radical hysterectomy**	III-3	RAH 51 OH 49	NR
Ko 2008	Radical hysterectomy**	III-3	RAH 16 OH 32	Up to 20 months
Lambaudie 2008	Radical hysterectomy***	III-3	RAH 12 OH 20	NR
Sert 2007	Radical hysterectomy**	III-3	RAH 7 LH 8	Median 14 (range 13 to 18) months Median 25 (range 20 to 36) months
Payne 2008	Total hysterectomy‡	III-3	RAH 100 LH 100	NR
Nezhat 2008c	Myomectomy	III-2	RAM 15 LM 35	NR
Advincula 2007	Myomectomy	III-2	RAM 29 OM 29	NR
Rodgers 2007	Tubal re-anastomosis	III-2	RATA 26 OTA 41	Up to 5 years
Dharia Patel 2008	Tubal re-anastomosis	III-3	RATA 18 OTA 10	Mean 8.9 months Mean 13.2 months
Geller 2008	Sacrocolpopexy	III- 3	RAS 73 OS 105	Up to 6 weeks

NOTE: LH – laparoscopic hysterectomy; LM – laparoscopic myomectomy; NR – not reported; OH – open hysterectomy; OM – open myomectomy; OTA – open tubal anastomosis; OS – open sacrocolpopexy; RAH – robotic-assisted hysterectomy; RAM – robotic-assisted myomectomy; RATA – robotic-assisted tubal anastomosis; RAS – robotic-assisted sacrocolpopexy;*endometrial cancer staging; **early stage cervical cancer; ***advanced stage cervical cancer; ‡benign gynaecological conditions.

Total hysterectomy for endometrial cancer staging

Nonrandomised comparative studies

Appraisal of study quality

Six studies on total hysterectomy for endometrial cancer staging were included for comparison (Table 15). All studies were level-III evidence with the exception of one study which was level III-2/3 as it used both historical and contemporary controls (Veljovich et al 2008). These studies focused on comparing perioperative surgical outcomes for RAH versus laparoscopic hysterectomy (LH) or open hysterectomy (OH) for endometrial cancer staging. In Veljovich et al (2008), comparative data was only available for a subset of patients who underwent endometrial cancer staging. The results for patients with heterogenic indications were not included in this review. The study by Gehrig et al (2008) investigated surgical outcomes specifically for an obese and morbidly obese patient population. The authors failed to describe clearly what type of hysterectomy was being performed (for example, radical, total or vaginal), and the purpose, extent and sequence of surgical staging tended to be poorly explained. Two studies (Bell et al 2008; Gehrig et al 2008) did not report the da Vinci robot protocol, particularly the set-up, placement of trocars and instrumentation.

Basic inclusion criteria were explicit. The sample size, and the study period for each surgical procedure were consistently described. Most robotic data were collected prospectively upon robotic program implementation. Selection of comparative cohorts involved retrospective analysis of patient records at the relevant institution. The majority of studies appeared to be single-centre with one surgeon performing all procedures, with the exception of Seamon et al (2009) who reported that two surgeons performed the minimally invasive surgery. Few exclusion criteria were stipulated.

There was variability of reporting of patient characteristics in the studies. Patient characteristics that were most commonly reported by the authors included age and BMI (all 6 studies), and tumour characteristics (4 studies). Patient comorbidities and uterine mass were poorly reported. Differences in preoperative patient characteristics between comparative cohorts were reported as statistically insignificant with few exceptions. Bell et al (2008) reported a statistically younger RAH group compared to the LH (P=0.03) and OH groups (P=0.0005). Three studies reported a statistically greater BMI in the RAH groups compared to LH (P=0.0008) (Boggess et al 2008); OH (P=0.0001) (DeNardis et al 2008), and LH groups (P<0.001) (Seamon et al 2009). Seamon et al (2009) also reported statistically greater tumour size in the RAH compared to the LH cohort (P=0.009).

All six studies uniformly reported the outcomes of operative time, EBL, LOS, rate of complications and total lymph node yield. Four studies reported conversion rates, one study (DeNardis et al 2008) reported the rate of positive nodes excised, and two

studies reported the rate of surgical staging (Gehrig et al 2008; Seamon et al 2009). Results were reported as means and standard deviations in three out of six studies (Bell et al 2008; Boggess et al 2008; DeNardis et al 2008). The remaining three studies reported the majority of values as medians and ranges. Long-term oncological outcomes such as recurrence, disease-free survival and mortality were not reported.

Efficacy

Operative time

Five studies compared operative time between RAH and LH cohorts (Table 16). Three studies reported a significantly shorter operative time for RAH versus LH cohorts (Boggess et al 2008a; Gehrig et al 2008; Seamon et al 2009), while two studies found no significant difference (Bell et al 2008; Veljovich et al 2008). Four studies compared operative time between RAH and OH cohorts (Bell et al 2008; Boggess et al 2008a; DeNardis et al 2008; Veljovich et al 2008). All four studies reported significantly longer operative times for RAH compared with OH.

Estimated blood loss

Five studies compared EBL between RAH and LH cohorts (Table 16). Three out of five studies reported significantly lower blood loss for the RAH cohort compared with the LH cohort (Boggess et al 2008a; Gehrig et al 2008; Seamon et al 2009), while Veljovich et al (2008) and Bell et al (2008) found no significant difference. Four studies compared EBL between RAH and OH cohorts (Bell et al 2008; Boggess et al 2008a; DeNardis et al 2008; Veljovich et al 2008). All four studies reported significantly lower EBL in the RAH compared with OH cohorts.

Length of hospital stay

Three out of the five studies which compared LOS between RAH and LH reported a significantly shorter LOS in the RAH cohort (Boggess et al 2008a; Gehrig et al 2008; Seamon et al 2009) (Table 16). Veljovich et al (2008) and Bell et al (2008) found no significant difference between the RAH and LH groups. All four studies reporting comparisons between RAH and OH demonstrated statistically shorter LOS for the RAH cohort (Bell et al 2008; Boggess et al 2008a; DeNardis et al 2008; Veljovich et al 2008).

Conversions

A total of 19 conversions were reported for the RAH group in four studies (313 operations in total) (Boggess et al 2008a; DeNardis et al 2008; Gehrig et al 2008; Seamon et al 2009) (Table 16). Twenty-seven conversions were reported for the LH group in three studies (189 operations in total) (Boggess et al 2008; Gehrig et al 2008; Seamon et al 2009). Veljovich et al (2008) reported a 2% conversion rate; however, it was unclear whether this result related to the subset of endometrial cancer staging or the larger heterogenic population. Seamon et al (2009) reported one conversion in RAH group as a result of difficult dissection secondary to robotic arm collisions, in addition to the presence of extensive pelvic adhesions.

*Transfusion*s

Four out of six studies reported transfusion rates (Bell et al 2008; Boggess et al 2008a; DeNardis et al 2008; Seamon et al 2009) (Table 16). Two of these studies reported significantly lower transfusion rates in the RAH compared with the OH (DeNardis et al 2008) or LH cohort (Seamon et al 2009), while the other two studies found no significant difference between groups.

Lymph node retrieval

Six studies reported lymph node retrieval (Table 16). Five studies compared lymph node retrieval between RAH and LH cohorts. Of these, two studies reported a significantly higher lymph node yield in the RAH compared with the LH cohort (Boggess et al 2008a; Gehrig et al 2008). The remaining three studies found no significant difference in lymph node yield between cohorts (Bell et al 2008; Veljovich et al 2008; Seamon et al 2009). Of the four studies that compared lymph node yield between RAH and OH (Bell et al 2008; Boggess et al 2008a; DeNardis et al 2008; Veljovich et al 2008), one study reported a statistically higher lymph node yield in the RAH compared with OH cohort (Boggess et al 2008a).

Rate of completion of surgical staging

Gehrig et al (2008) reported that 45/49 women (92%) underwent complete staging in the RAH cohort, while 27/32 women (84%) had complete staging in the LH group (*P*=NR). Seamon et al (2009) also reported this outcome and found that 79/92 patients (85.9%) in the RAH group and 55/56 patients (98.2%) in the LH underwent complete surgical staging (*P*=NR).

Positive nodes

The study by DeNardis et al (2008) reported positive node yield and found no significant difference between groups (RAH mean 3 [SD 5.6] and OH mean 10 [SD 9.4]; *P*=0.34).

Pain

One study reported that no patients required intravenous narcotics postoperatively (Gehrig et al 2008).

Return to normal activity

Bell et al (2008) reported that the mean time to return to normal activity for RAH patients (24.1 days) was significantly shorter compared to the LH (31.6 days; *P*=0.005) or open (52 days; *P*<0.0001) patient cohorts. .

Table 16 Comparison of key efficacy and safety outcomes for robotic-assisted or conventional hysterectomy for endometrial cancer staging

Study	Number of patients	Operative time (mins)*	Estimated blood loss (mL)*	Length of hospital stay (days)*	Conversions n/N (%)	Transfusions n/N (%)	Total lymph node retrieval per patient*	Complications n/N (%)
Veljovich 2008 III-2/3	RAH 25 LH 4 OH 131	283† (171 – 443)[a] 255† (220 – 305)[b] 139† (69 – 294)[c] a v b: *P*=NS a v c: *P*<0.0001	66.6† (10 – 300)[a] 75† (50 – 100)[b] 197.6† (25 – 900)[c] a v b: *P*=NS a v c: *P*<0.0001	1.68† (0.71 – 8.96)[a] 1.2† (0.92 – 2.0)[b] 5.29† (0.54 – 24)[c] a v b: *P*=NS a v c: *P*<0.0001	2%	NR	17.5† (2-32)[a] 20.3† (7-39)[b] 13.1† (1-42)[c] a v b: *P*=NS a v c: *P*=NS	5/25 (20%) NR 38/131 (29%) *P*=NS
Seamon 2009 III-3	RAH 105 LH 76	242 [53] 287 [55] *P*<0.001	88† (20 – 500) 200† (50 – 650) *P*<0.001	Med: 1.0 (1 – 46) Med: 2 (1 – 9) *P*<0.001	13/105 (12.4%) 20/76 (26.3%) *P*=0.017	3/92 (3%) 10/56 (18%) *P*<0.002	31 33 *P*=NS	11/85 (13%) 8/58 (14%) *P*=NS
Bell 2008 III-3	RAH 40 LH 30 OH 40	184.0 [41.3][a] 171.1 [36.2][b] 108.6 [41.4][c] a v b: *P*=NS a v c: *P*= 0.0001	166.0 [225.9][a] 253.0 [427.7][b] 316.8 [282.1][c] a v b: *P*=NS a v c: *P*=0.01	2.3 [1.3][a] 2.0 [1.2][b] 4.0 [1.5][c] a v b: *P*=NS a v c: *P*=0.0001	NR	2/40 (5%) 3/30 (10%) 6/40 (15%) *P*=NS	17.0 [7.8][a] 17.1 [7.1][b] 14.9 [4.8][c] a v b: *P*=NS a v c: *P*=NS	3/40 (7.5%)[a] 8/30 (20.0%)[b] 11/40 (27.5%)[c] a v b: *P*=0.03 a v c: *P*=0.015
Boggess 2008a III-3	RAH 103 LH 81 OH 138	191.2 [36.0][a] 213.4 [34.7][b] 146.5 [48.8][c] a v b: *P*<0.0001 a v c: *P*<0.0001	74.5 [101.2][a] 145.8 [105.6][b] 266.0 [184.5][c] a v b: *P*<0.0001 a v c: *P*<0.0001	1.0 [0.2][a] 1.2 [0.5][b] 4.4 [2.0][c] a v b: *P*=0.001 a v c: *P*<0.001	3/103 (2.9%) 4/81 (4.9%) *P*=NS	1/103 (1%)[a] 2/81 (2.5%)[b] 2/138 (1.5%)[c] a v b: *P*=NS a v c: *P*=NS	32.9 [26.2][a] 23.1 [11.4][b] 14.9 [11.3][c] a v b: *P*<0.0001 a v c: *P*<0.0001	6/103 (5.8%)[a] 11/81 (13.6)[b] 41/138 (29.7)[c] a v c: *P*<0.0001 a v b: *P*=NS
DeNardis 2008 III-3	RAH 56 OH 106	177 [55] 79 [17] *P*=0.0001	105 [77] 241 [115] *P*<0.0001	1.0 [0.5] 3.2 [1.2] *P*<0.0001	3/56 (5.4%)	0/56 (0%) 9/106 (8.5%) *P*=0.005	18.6 [12.4] 18.0 [9.6] *P*=NS	11/56 (20%) 65/106 (61%) *P*=NR
Gehrig 2008 III-3	RAH 49 LH 32	189 (111 – 263) 215 (156 – 324) *P*=0.0004	50 (25 – 300) 150 (50 – 700) *P*<0.0001	1.02 (1 – 2) 1.27 (1 – 4) *P*=0.0119	0/49 (0%) 3/32 (9.4%) *P*=NR	NR	31.4 (6 – 73) 24 (3 – 59) *P*=0.0040	6/49 (12%) 7/32 (22%) *P*=NR

NOTE: LH – laparoscopic hysterectomy; Med – median; NR – not reported; NS – not significant; OH open hysterectomy; RAH – robotic assisted hysterectomy; v – versus; * figures presented as mean and [standard deviation] or (range) unless otherwise stated; † not specified whether mean or median.

Safety

Four studies reported overall rates of complications (Bell et al 2008; Boggess et al 2008; Gehrig et al 2008; Seamon et al 2009) (Table 16). Veljovich et al (2008) reported rates of major and minor complications for RAH and OH cohorts (LH data was lacking), while DeNardis et al (2008) reported rates of perioperative (major and minor) and postoperative complications (Table 16). One study reported a significantly lower overall rate of complications in the RAH versus the LH cohort (Bell et al 2008), while three other studies found no significant difference between these cohorts (Boggess et al 2008a; Gehrig et al 2008; Seamon et al 2009). Two studies reported a significantly lower overall rate of complications in the RAH versus the OH cohorts (Bell et al 2008; Boggess et al 2008a), and DeNardis et al (2008) also reported a higher rate of complications in the OH group. The latter found a significant difference between perioperative and minor complications in favour of the RAH group ($P<0.01$) but no significant difference for delayed complications (1–6 weeks following surgery).

Table 17 compares the overall incidence of reported complications for each cohort using data from all six studies. The overall incidence of complications across studies was 10.1% for RAH, 14.1% for LH and 37.3% for OH. The most common adverse events following RAH surgery were hernia, lymphatic and vaginal complications which were similar in the LH cohort but less frequent in the OH cohort. The most common complications following OH tended to be major adverse events such as cardiac events, GI injury, haematological complications, pulmonary events, renal events, as well as fever, wound complications and urinary events.

Table 17 Adverse events reported for robotic-assisted or conventional hysterectomy for endometrial cancer staging

Outcome	Technique		
	Robotic n/N	Standard laparoscopic n/N	Open n/N
Mortality	NR	NR	NR
Complications			
Bleeding requiring re-operation	1/40 (1 study)	0/30 (1 study)	0/40 (1 study)
Cardiac event	1/260 (4 studies)	2/167 (3 studies)	7/309 (3 studies)
Cellulitis	0/103 (1 study)	0/81 (1 study)	5/138 (1 study)
Cerebrovascular accident (stroke)	0/128 (2 studies)	0/81 (1 study)	2/269 (2 studies)
Cholecystitis	0/103 (1 study)	0/81 (1 study)	1/138 (1 study)
Cystotomy	0/103 (1 study)	1/81 (1 study)	0/138 (1 study)
Deep vein thrombosis/ venous thromboembolic event)	0/235 (3 studies)	2/167 (3 studies)	1/178 (2 studies)
Fever	2/56 (1 study)	NR	17/106 (1 study)
GI injury/ complication (including enterotomy, ileus, bowel obstruction, *c. difficile* colitis)	6/340 (5 studies)	2/199 (4 studies)	18/284 (3 studies)
Haematological complication (anaemia/ nonspecified infectious disease)	1/81 (2 studies)	NR	16/237 (2 studies)
Hernia (port site, incisional, or umbilical)	5/192 (3 studies)	3/143 (3 studies)	1/178 (2 studies)
Lymphatic related complications (Lymphoedema/lymphocyst/lymphocele)	4/273 (5 studies)	2/143 (3 studies)	2/415 (4 studies)
Nerve injury/ neurologic event (genito-femoral, palsy, transient neuropathy)	1/309 (5 studies)	4/199 (4 studies)	5/309 (3 studies)
Nonspecified infection (wound or urinary tract)	1/25 (1 study)	NR	7/131 (1 study)
Pulmonary event (failure, atelectasis, embolism, oedema)	4/76 (4 studies)	0/137 (2 studies)	14/375 (3 studies)
Renal failure/ complication	0/81 (2 studies)	NR	6/237 (2 studies)
Superficial phlebitis	0/40 (1 study)	1/30 (1 study)	0/40 (1 study)
Thrush	0/56 (1 study)	NR	1/106 (1 study)
Urinary retention/ delayed voiding	1/96 (2 studies)	0/30 (1 study)	2/146 (2 studies)
Urinary tract infection	1/251 (3 studies)	1/137 (2 studies)	7/244 (2 studies)
Vaginal complication (vaginal cuff hematoma, dehiscence, seroma, vaginal leak, rectovaginal fluid collection/abscess)	7/273 (5 studies)	5/143 (3 studies)	5/415 (4 studies)
Vessel injury (eg. vena cava)	1/235 (3 studies)	2/167 (3 studies)	0/178 (2 studies)
Wound complication (dehiscence, infection)	1/224 (4 studies)	3/111 (2 studies)	38/415 (4 studies)
Total incidence of complications	37/365 (10.1%) (6 studies)	28/119 (14.1%) (4 studies)	155/415 (37.3%) (4 studies)

NOTE: NR - not reported; Table includes data from the following studies: Veljovich 2008, Gehrig 2008, Bell 2008, DeNardis 2008, Boggess 2008a and Seamon 2009.

Radical hysterectomy for cervical cancer

Nonrandomised comparative studies

Appraisal of study quality

Six primary studies were included for comparison (Table 15). Five of these studies involved early stage cervical cancer, comparing the feasibility of RAH to LH (Sert et al 2007; Nezhat et al 2008a,b); RAH to OH (Boggess et al 2008b; Ko et al 2008); and RAH to LH and OH (Magrina et al 2008). A sixth study compared the feasibility of RAH to OH for advanced stage cervical cancer (Lambaudie et al 2008). All studies consisted of level III-2 or III-3 evidence.

Basic inclusion criteria were explicit. The sample size and study period for each surgical procedure were consistently described. It was difficult to determine whether the RAH cohort data was collected prospectively or retrospectively in several studies. Two studies were described as prospective (Lambaudie et al 2008; Nezhat et al 2008a,b) and one was described as retrospective (Ko et al 2008). The majority of the studies involved a historical cohort/control and the RAH cases were undertaken in a subsequent period upon implementation of the RAH program at the particular institution. Patient records were obtained for historical cohorts based on surgical procedure and indication (i.e. LH or OH). Exclusion criteria were generally poorly described. Nezhat et al (2008a) described uterine metastatic disease, large cervical lesion, inadequate bone marrow, compromised renal/hepatic function and pregnancy as exclusions for laparoscopic surgery.

In the early stage cervical cancer studies, cancer stage distribution 1A1 – IIB was most commonly reported. Squamous cell carcinoma and adenocarcinoma were the most common histological type reported. There was variability of reporting of patient characteristics. Patient characteristics that were most commonly reported included age, BMI, cancer staging, cancer type and uterine mass. The majority of these data were reported uniformly in the studies and statistical analysis between patient procedure groups was also provided (Sert et al 2007; Boggess et al 2008b; Ko et al 2008; Nezhat et al 2008a). Baseline patient characteristics were poorly reported in Lambaudie et al (2008) where data was not statistically evaluated between groups. The method of reporting patient characteristics by Lambaudie et al (2008) was less clear since multiple surgical procedures and indications were described overall for the group but these were not described on an individual basis. Magrina et al (2008) reported matching baseline characteristics but the raw data were not provided. It is unknown whether the authors made any statistical assessment of their baseline data. Overall, in the studies that provided baseline characteristics there were no statistical differences between patients in the RAH group and comparator groups with only one exception. Boggess et al (2008b) reported a statistically higher age in the RAH cohort compared to the OH cohort (P=0.029), and a statistically greater number of previous abdominal surgeries in the RAH compared to OH cohort (P=0.004).

Operative time, EBL and LOS were reported uniformly between studies. Complications and node retrieval were reported in all studies except Magrina et al (2008). Outcome measures were clearly reported in three studies (Boggess et al 2008b; Ko et al 2008; Nezhat et al 2008a,b) including mean values and standard deviation or range. The remaining three studies did not report measures of variability. While node retrieval was the most commonly reported parameter in relation to lymphadenectomy, the measure was not defined and its significance was not explained in any of the studies. Conversion to OH was reported in four out of six studies. Cancer recurrence data were reported in four out of six studies, but follow-up did not exceed a mean of 29 months. Surgical margins were reported in four studies (Sert et al 2007; Ko et al 2008; Lambaudie et al 2008; Nezhat et al 2008a). Three out of four studies reported whether margins were positive or negative. Pathology of the lymph nodes and lymphovascular invasion were reported in two studies (Ko et al 2008; Nezhat et al 2008a). Oncological outcomes such as survival and mortality were not reported as long-term data was lacking.

Efficacy

Operative time

Three studies compared RAH to LH (Sert et al 2007; Magrina et al 2008; Nezhat et al 2008a,b) (Table 18). Magrina et al (2008) reported significantly shorter operative time in the RAH compared with the LH cohort, whereas Sert et al (2007) and Nezhat et al (2008a,b) reported no significant difference between these groups. Three studies statistically compared operative time for RAH versus OH cohorts, with variable results (Boggess et al 2008b; Ko et al 2008; Lambaudie et al 2008) (Table 18). Boggess et al (2008b) reported a statistically shorter operative time for RAH compared with OH, Ko et al (2008) reported a significantly longer operative time in the RAH compared with the OH cohort, and Lambaudie et al (2008) reported no significant difference between the RAH and OH cohorts. The operative time for comparative studies involving early cervical cancer cases did not demonstrate any notable difference compared with that of the comparative study for advanced cervical cancer, although these were not statistically compared.

Estimated blood loss

All studies reported EBL with the exception of Lambaudie et al (2008) (Table 18). These studies consistently reported a lower EBL for the RAH group compared with both the LH and OH groups, and this difference was statistically significant in the studies by Sert et al (2007), Ko et al (2008) and Boggess et al (2008b). Magrina et al (2008) reported a statistical difference between RAH and OH only.

Length of hospital stay

All six studies reported LOS (Table 18). These studies consistently reported statistically shorter LOS in the RAH group compared with LH and OH cohorts. These differences were statistically significant in all studies, with the exceptions of

Nezhat et al (2008a,b) who compared RAH to LH, and Magrina et al (2008) who did not report statistical assessment between RAH and LH cohorts.

Conversions

Four studies reported conversions rates (Sert et al 2007; Boggess et al 2008b; Ko et al 2008; Nezhat et al 2008a) (Table 18). No conversions were reported in the RAH cohorts in all studies. Conversion rates ranged from 0%–12.5% in the LH cohorts (Sert et al 2007; Nezhat et al 2008).

Transfusions

Three studies reported transfusion rates (Boggess et al 2008b; Ko et al 2008; Lambaudie et al 2008) (Table 18) which all compared RAH to OH. Out of these three studies, only one transfusion was reported in the RAH cohort (Ko et al 2008). No statistical differences were reported although there was a trend towards lower transfusion rates in the RAH compared to OH cohort in all studies.

Cancer recurrence

Four out of six studies reported recurrence of cancer (Sert et al 2007; Ko et al 2008; Magrina et al 2008; Nezhat et al 2008a,b) (Table 18). Ko et al (2008) reported that one patient with a positive surgical margin in the RAH cohort experienced tumour recurrence at 4 months. Another patient in the OH cohort was reported to have a large tumour with deep invasion and experienced recurrence of a paraspinal mass at 20 months. The other studies reported no cancer recurrence at the time of follow-up (mean maximum follow-up reported by Nezhat et al (2008a,b) of 29 months). These results were of questionable value in showing durability of patient outcomes because the follow-up periods were quite short.

Lymph node retrieval

Five out of six studies reported lymph node yield, with the exception of Magrina et al (2008) (Table 18). Boggess et al (2008b) reported a significantly higher lymph node yield in the RAH compared with the OH cohort, while the other studies did not find any statistically significant differences between groups.

Lymphovascular invasion and positive nodes

Two studies reported the number of patients with lymphovascular involvement and positive lymph nodes (Ko et al 2008; Nezhat et al 2008a) (Table 18). Ko et al (2008) reported no statistical difference between the number of patients in the RAH group with lymphovascular involvement compared with the OH cohort. This study reported no significance difference in the number of positive nodes between the two cohorts. Nezhat et al (2008a) reported a lower number of patients with lymphovascular involvement and positive nodes in the RAH cohort compared with the LH cohort, but the statistical significance of these relationships was not reported.

Surgical margins

Four out of six studies made some report of surgical margins (Sert et al 2007; Ko et al 2008; Lambaudie et al 2008; Nezhat et al 2008). Sert et al (2007) reported right

parametric margins (RAH 2.5cm, LH 1.8cm; *P*=0.165), left parametric margins (RAH 2.8cm, LH 1.8cm; *P*=0.073), and vaginal edge (RAH 1.7cm, LH 2.2cm; *P*=0.710). Ko et al (2008) reported the rate of positive margins (RAH 0/16 (0%), OH 2/32 (6.25%); *P*=0.546). Nezhat et al (2008) reported one patient with positive vaginal margins in the LH cohort. Lambaudie et al (2008) reported 12 robotic cases of advanced cervical cancer which received surgical management after concomitant chemoradiation and brachytherapy. Surgical margins were positive in only one case (8.3%) reported to have inframillimetric positive margins.

Table 18 Comparison of key efficacy and safety outcomes for robotic-assisted or conventional hysterectomy for cervical cancer

Study	Number of patients	Operative time (mins)*	Estimated blood loss (mL)*	Length of hospital stay (days)*	Conversions n/N (%)	Transfusions n/N (%)	Cancer recurrence n/N (%)	Total lymph node retrieval per patient*	Lymphovascular invasion (positive pelvic nodes) n/N	Complications n/N (%)
Early stage cervical cancer										
Magrina 2008 III-2/3	RAH 27 LH 31 OH 35	189.9[a] 220.4[b] 166.8[c] a v b: *P*<0.001 b v c: *P*<0.001	133[a] 208[b] 433[c] a v c: *P*<0.05 b v c: *P*<0.05	1.7[a] 2.4[b] 3.6[c] a v c: *P*<0.05 b v c: *P*<0.05	NR	NR	0/27 (0%) 0/31 (0%) 0/35 (0%)	NR	NR	NR
Nezhat 2008a,b III-2/3	RAH 13 LH 30	323 (232 – 453) 318 (200 – 464) *P*=NS	157 (50 – 400) 200 (100 – 500) *P*=NS	2.7 (2 – 6) 3.8 (2 – 11) *P*=NS	0/13 (0%) 0/30 (0%) *P*=NR	NR	0/13 (0%) 0/30 (0%) *P*=NR	24.7 (11 – 51) 31 (10 – 61) *P*=NS	9/13 (1/13 nodes) 16/30 (3/30 nodes) *P*=NR	6/13 (46%) 13/30 (43%) *P*=NS
Boggess 2008b III-3	RAH 51 OH 49	210.9 [45.5] 247.8 [48.8] *P*=0.0002	96.5 [85.8] 416.8 [188.1] *P*<0.0001	1 3.2 *P*<0.0001	0/51 (0%)	0/51 (0%) 4/49 (8.2%) *P*=NS	NR	33.8 [14.2] 23.3 [12.7] *P*=0.0003	NR	4/51 (7.8%) 8/49 (16.3%) *P*=NS
Ko 2008 III-3	RAH 16 OH 32	290 (199 – 364) 219 (113 – 308) *P*=0.0002	81.9 (20 – 400) 665.6 (200 – 3500) *P*<0.0001	1.7 (1 – 4) 4.9 (3 – 8) *P*<0.0001	0/16 (0%)	1/16 (6.1%) 10/32 (31.2%) *P*=NS	1/16 (6%) 1/32 (3%) *P*=NR	15.6 (4 – 34) 17.1 (4 – 38) *P*=NS	1/16 (0/16 nodes) 4/32 (1/32 nodes) *P*=NS	3/16 (18.8%) 8/32 (25%) *P*=NS
Sert 2007 III-3	RAH 7 LH 8 (results only reported for 7 as 1 was excluded due to conversion)	241(160 – 445) 300 (225 – 375) *P*=NS	71† 160† *P*=0.038	4† 8† *P*=0.004	0/7 (0%) 1/8 (12.5%) *P*=NR	NR	0/7 (0%) 0/7 (0%)	13† 15† *P*=NS	NR	4/7 (57%) 6/7 (86%) *P*=NR
Advanced stage cervical cancer										
Lambaudie 2008 III-3	RAH 12 OH 20	190† 210† *P*=NS	NR NR	3† 7† *P*=0.00007	NR	0/12 (0%) 0/20 (0%) *P*=NR	NR	Med: 7 Med: 12 *P*=NS	NR	4/12 (33%) 5/20 (25%) *P*=NS

NOTE: LH – laparoscopic hysterectomy; Med – median; NR – not reported; NS – not significant; OH open hysterectomy; RAH – robotic assisted hysterectomy; v – versus; * figures presented as mean and [standard deviation] or (range) unless otherwise stated;
† not specified whether mean or median.

Safety

Data describing numbers and overall incidence of complications was provided for all studies (Table 18). Magrina et al (2008) did not report data on rate or type of complications but simply reported 'no difference' between cohorts. No studies reported statistically significant differences between the RAH and comparative cohorts in terms of overall rates of complications (Table 18). Two studies reported no significant difference between the rate of intraoperative complications in RAH and comparative cohorts (Ko et al 2008; Nezhat et al 2008a,b), and three studies reported no significant difference between postoperative complications in RAH and comparative cohorts (Boggess et al 2008; Ko et al 2008; Nezhat et al 2008a,b).

Table 19 compares the incidence of reported complications for each cohort using data from all relevant studies. While no statistical analysis was undertaken, this data shows higher incidence of overall complications in the LH cohort (51.4% across 2 studies) compared with RAH (21.2% across 5 studies), and OH cohorts (19.8% across 3 studies).

Overall, it was noted that the most common adverse events in the RAH cohort tended to be cystotomy, lymphatic-related events and vaginal cuff abscess/dehiscence, but these were similar to the incidences reported in the LH cohort. These particular adverse events were either less frequent or not reported in the OH cohort. A higher incidence of major pulmonary events, wound complications and ureteral stenosis was observed in OH cohorts compared with RAH and LH cohorts. It is recognised that the data are not conclusive because no attempt has been made to control for differences between study reporting, and statistical assessment was not possible.

Table 19 Adverse events for robotic-assisted or conventional hysterectomy for cervical cancer

Outcome	Technique		
	Robotic n/N	Standard laparoscopic n/N	Open n/N
Mortality	0/16 (0.0%) (1 study)	NR	0/32 (0.0%) (1 study)
Complications			
Abdominal pain requiring readmission	1/64 (2 studies)	1/30 (1 study)	0/49 (1 study)
Compartment syndrome	0/7 (1 study)	1/7 (1 study)	NR
Cystotomy	3/20 (2 studies)	3/37 (2 studies)	NR
Deep vein thrombosis	0/13 (1 study)	2/30 (1 study)	NR
Femoral nerve injury	0/51 (1 study)	NR	2/49 (1 study)
Fever	0/13 (1 study)	2/30 (1 study)	NR
GI injury/ complication (including bowel obstruction, ileus, *c. difficile* colitis)	2/92 (4 studies)	4/30 (1 study)	4/101 (3 studies)
Parietal abscess	0/12 (1 study)	NR	1/20 (1 study)
Postoperative haemorrhage	0/51 (1 study)	NR	0/49 (1 study)
Lymphatic related complication (lymphocyst/ lymphocele/ lymphoedema/ vaginal lymph drainage)	9/99 (5 studies)	3/37 (2 studies)	1/101 (3 studies)
Pulmonary embolus	0/16 (1 study)	NR	2/32 (1 study)
Ureteral transection (intraoperative)	0/16 (1 study)	NR	1/32 (1 study)
Urinary retention	1/13 (1 study)	1/30 (1 study)	NR
Ureteral stenosis	0/12 (1 study)	NR	2/20 (1 study)
Ureterovaginal fistula	1/16 (1 study)	NR	0/32 (1 study)
Urinary tract infection	1/19 (2 studies)	1/7 (1 study)	1/20 (1 study)
Vaginal cuff abscess/ dehiscence	3/67 (2 studies)	NR	1/81 (2 studies)
Vaginal bleeding	0/13 (1 study)	1/30 (1 study)	NR
Wound complications (infection, dehiscence)	0/67 (2 studies)	NR	5/81 (2 studies)
Total incidence of complications	21/99 (21.2%) (5 studies)	19/37 (51.4%) (2 studies)	20/101 (19.8%) (3 studies)

NOTE: NR - not reported; Table includes data from the following studies: Sert 2007, Ko 2008, Boggess 2008b, Nezhat 2008b and Lambaudie 2008.

Hysterectomy for mixed benign conditions

Nonrandomised comparative studies

Appraisal of study quality

One study compared RAH to LH for benign gynaecological indications (Payne et al 2008) (Table 15). In both groups, indications for surgery were diverse ranging from myomas (46%–50%), endometriosis, presence of ovarian cysts, dysmenorrhoea and dyspareunia, but differences between cohorts were not statistically assessed. This study consisted of level III-3 evidence. A retrospective systematic chart review was conducted for all patients. The robotic-assisted sample was compared to historical controls that received laparoscopic surgery prior to implementation of the robotic program. All cases were performed by two surgeons at two institutions.

An intention to treat analysis of the RAH versus LH group was described but no statistical analysis was provided. This study reported no significant difference for preoperative characteristics between cohorts including age, BMI, mean uterine weight and ethnic origin. Operative time, EBL, LOS, conversion rates and complication rates were reported uniformly for each cohort. It was noted that the study included data from converted cases in the LH group with the reported LOS data. It was unclear whether this method was used for operative time and EBL also.

Efficacy

Operative time

This study reported a significantly longer mean operative time for the RAH group compared with the LH group (Table 20). However, after controlling for learning curve, operative time was reported to be 13.7 minutes faster in the RAH compared with the LH group (P=0.03).

Estimated blood loss and length of hospital stay

Both the EBL and LOS were significantly lower in the RAH cohort compared with the LH cohort (P<0.0001 for both) (Table 20).

Conversions

The conversion rate was significantly lower for the RAH group compared with the LH group (P=0.0008) (Table 20).

Safety

This study reported no significant difference in complication rates between the RAH and LH group (Table 20). Complications included cystotomy (1 patient) and cuff infection (1 patient) in the RAH group, and enterotomy (1 patient) and vaginal tear (1 patient) in the LH group.

Table 20 Comparison of key efficacy and safety outcomes for robotic-assisted or conventional hysterectomy for benign gynaecological conditions

Study	Number of patients	Operative time (mins)*	Estimated blood loss (mL)*	Length of hospital stay (days)*	Conversions n/N (%)	Transfusions n/N (%)	Complications n/N (%)
Payne 2008 III-3	RAH 100 LH 100	119.4 [59.3] 92.4 [92.4] *P*<0.0001	61 [60.9] 113 [85.9] *P*<0.0001	1 [0.7] 1.6 [1.4] *P*<0.007	4/100 (4%) 20/100 (20%) *P*=0.0008	NR NR	2/100 (2%) 2/100 (2%) *P*=NS

NOTE: NR – not reported; NS – not significant; RAH – robotic assisted hysterectomy; LH – laparoscopic hysterectomy; * figures presented as mean and [standard deviation].

Myomectomy

Nonrandomised comparative studies

Appraisal of study quality

Two studies compared robotic-assisted myomectomy (RAM) to laparoscopic (LM) (Nezhat et al 2008c), and open (OM) approaches (Advincula et al 2007) (Table 15). These studies consisted of level III-2 evidence. Nezhat et al (2008c) stated one surgeon performed all procedures in a single-centre. Advincula et al (2007) stated that one surgeon was used to perform all RAM procedures, while six surgeons performed the OM procedures.

Basic inclusion criteria were reported in the two studies. In both studies, RAH patients were selected retrospectively (chart analysis) and compared with a matched control group that underwent LM or OM procedures during the same study period. Patients suitable for the RAM procedure were those with symptomatic leiomyomata thought to be approachable with conventional LM because of size, number and/or location (Advincula et al 2007). This study stipulated leiomyomata thought to be too large for laparoscopic entry as an exclusion criterion for RAM.

Both studies matched treatment groups for patient characteristics including age, BMI, weight or size of leiomyomata, and Nezhat et al (2008c) also matched groups for previous abdominal surgeries and gravidity. All preoperative characteristics between groups were reported to be statistically insignificant. It was noted that leiomyomata size and weight appeared substantially different between the two studies, with mean weight in the RAM group being 116 grams (range 25–350 grams) in Nezhat et al (2008c) compared with 227.86 grams (SD 247.54 grams) in Advincula et al (2007).

The main outcomes of interest were reported uniformly with the exception of complication rates in Nezhat et al (2008c) and pregnancy rate in Advincula et al (2007).

Both of these studies had relatively small sample sizes; particularly notable was the RAM cohort in Nezhat et al (2008c) that was disproportionately smaller compared with the LM cohort.

Efficacy

Operative time

Significantly longer mean operative times were reported for the RAM cohorts compared with the LM (Nezhat et al 2008c) or OM cohorts (Advincula et al 2007) (Table 21).

Estimated blood loss

Advincula et al (2007) reported that EBL was significantly lower in the RAM compared with the OM group, while Nezhat et al (2008c) reported no significant difference between the RAM and LM cohorts (Table 21).

Length of hospital stay

LOS for the RAM group was significantly lower compared with the OM group (Advincula et al 2007), but was not significantly different compared with the LM group (Nezhat et al 2008c) (Table 21).

Conversions

Advincula et al (2007) reported two conversions in the RAM group, while Nezhat et al (2008c) reported no conversions in the RAM or LM group (Table 21).

Transfusions

Advincula et al (2007) reported that transfusions were only required in the OM group, but statistical significance was not reported, while Nezhat et al (2008c) reported that no transfusions were required in the RAM or LM group (Table 21).

Pregnancy rates

The pregnancy rate was slightly higher in the LM group compared with the RAM group, however this was not statistically significant (Nezhat et al 2008c) (Table 21).

Safety

Complication rates reported by Advincula et al (2007) were lower in the RAM compared with the OM group, but this was not statistically assessed (Table 21). There was a higher incidence of major complications in the OM group (blood loss and anaemia requiring transfusion (2 patients), respiratory arrest (1 patient), DVT (1 patient), acute renal failure (1 patient), hypertension (2 patients), haematoma (2 patients) and wound dehiscence (1 patient)), compared with the RAM group (cardiogenic shock caused by vasopressin (1 patient), aspiration (1 patient), port site cellulitis (1 patient) and chest pain (1 patient)). Nezhat et al (2008c) reported no major complications necessitating transfusion, readmission to hospital, or the use of further antibiotics in either the RAM or LM group.

Table 21 Comparison of key efficacy and safety outcomes for robotic-assisted or conventional myomectomy

Study	Number of patients	Operative time (mins)*	Estimated blood loss (mL)*	Length of hospital stay (days)*	Conversions n/N (%)	Transfusions n/N (%)	Pregnancy rate n/N (%)	Complications n/N (%)
Nezhat 2008c III-2	RAM 15 LM 35	234 (140 – 445) 203 (95 – 330) *P*=0.03	370 (150 – 500) 420 (110 – 750) *P*=NS	1.0 (1 – 1) 1.05 (1 – 3) *P*=NS	0/15 (0%) 0/35 (0%) *P*=NR	0/15 (0%) 0/35 (0%) *P*=NR	1/15 (6.7%) 3/35 (8.6%) *P*=NS	NR
Advincula 2007 III-2	RAM 29 OM 29	231.4 [85.1] 154.4 [43.1] *P*<0.0001	195.7 [228.6] 364.7 [473.3] *P*=0.0112	1.5 [1.0] 3.6 [1.5] *P*<0.0001	2/29 (6.9%)	0/29 (0%) 2/29 (6.9%) *P*=NR	NR	4/29 (14%) 14/29 (48.3%) *P*=NR

NOTE: LM – laparoscopic myomectomy; NR – Not reported; NS – not significant; OM – open myomectomy; RAM – robotic-assisted myomectomy; * figures presented as mean and [standard deviation] or (range).

Tubal re-anastomosis

Nonrandomised comparative studies

Appraisal of study quality

Two primary studies compared the feasibility of robotic-assisted microsurgical tubal anastomosis (RATA) to open tubal anastomosis (OTA) (Rodgers et al 2007; Dharia Patel et al 2008) (Table 15). The studies consisted of level III-2 and III-3 evidence. Both studies appeared to involve a single-centre with one surgeon performing all surgeries with the exception of Rodgers et al (2007), in which the OTA procedures were performed by three different surgeons.

Explicit inclusion criteria were reported in both studies. One study reported RATA prospective patient selection (Dharia Patel et al 2008); whereas the second study reported retrospective patient selection (procedural terminology codes were used) (Rodgers et al 2007). These patients were compared with OTA patients who underwent surgery in the same study period (Rodgers et al 2007) or during a historical period (Dharia Patel et al 2008). Rodgers et al (2007) specified that patients received a particular procedure depending upon which surgeon they presented to. Cases performed using the Zeus Robotic System, or laparoscopy without aid of robot were excluded (Rodgers et al 2007).

Both studies reported comparable patient characteristics including age, BMI and parity, with no significant differences between groups. Dharia Patel et al (2008) also reported previous method of tubal ligation in each group, and reported no significant difference in the mean time from sterilisation to reversal between the groups. This data was not reported by Rodgers et al (2007).

Operative time, LOS and pregnancy rates were reported in both studies. Patient recovery time was measured by the Instrumental Activities of Daily Living (IADL) scale by Dharia Patel et al (2008), or time to return to work by Rodgers et al (2007). Other key outcomes reported by only one of the studies included tubal patency, complication rates and management of postoperative pain (Dharia Patel et al 2008).

Efficacy

Operative time

The studies by Rodgers et al (2007) and Dharia Patel et al (2008) reported significantly longer mean or median operative times for the RATA groups compared with the OTA groups (Table 22).

Estimated blood loss

EBL was only reported by Rodgers et al (2007) who found no significant difference between the RATA and OTA groups in terms of the number of patients with EBL less than 100 mL (RATA 19 patients (73%), OTA 31 patients (80%); P=0.48).

Length of hospital stay

LOS was significantly lower in the RATA cohort compared with the OTA cohort in the study by Dharia Patel et al (2008), while Rodgers et al (2007) reported no significant difference between the two groups (Table 22).

Conversions and transfusions

Conversion and transfusion rates were not reported by either study.

Pregnancy rates

Tubal patency success was ≥ 1 in each patient in both the RATA and OTA cohorts in the study by Dharia Patel et al (2008) (Table 22). Viable pregnancy rates were either not statistically different or not statistically assessed between cohorts. Dharia Patel et al (2008) reported a shorter range of follow-up time with a maximum of 11 months (RATA) and 14 (OTA) months, compared with Rodgers et al (2007) who reported up to 5 years follow-up (cohort not specified). Given that pregnancy outcomes are generally long-term, it is likely that the pregnancy rate in the former study was underreported.

Analgesic requirement

Dharia Patel et al (2008) measured postoperative pain by comparing the mean number of Ibuprofen and Hydrocodone/Acetaminophen tablets consumed postoperatively. Significantly less postoperative pain management was required in the RATA group compared with the OTA group (Ibuprofen consumption 29.3 (range 2-90) versus 90 (range 88-90) (P=0.0001); Hydrocodone/Acetaminophen consumption 16.6 (range 0-40) versus 36 (range 0-40) (P=0.003)).

Return to normal activity

Dharia Patel et al (2008) reported that using the IADL scale, patient recovery was quicker in the RATA group (mean 11.1 days, range 2–28) compared with the OTA group (mean 28.1 days, range 21-42) (P=0.0001). Similarly, Rodgers et al (2007) reported that the return to work was quicker following RATA (median 0.8 weeks, range 0.5–2.9) compared with OTA (median 2.8 weeks, range 1.0-3.4) (P=0.013).

Safety

Dharia Patel et al (2008) reported one complication in the RATA group (an intraoperative trocar injury to the inferior epigastric artery) and no complications in the OTA group (Table 22), however statistical significance was not reported. Rodgers et al (2007) reported one complication in the RATA group (readmission for tachycardia) and six complications in the OTA group (postoperative fever, cellulitis, wound separation, readmission for abdominal pain, reoperation for an incisional hernia and excessive nausea and vomiting), however there was no significant difference in overall complication rates between the two groups (Table 22).

Table 22 Comparison of key efficacy and safety outcomes for robotic-assisted or conventional tubal re-anastomosis for reversal of tubal ligation

Study	Number of patients	Operative time (mins)*	Length of hospital stay (hours)*	Viable pregnancy rate† n/N (%)	Tubal patency‡ (n per patient)	Complications n/N (%)
Rodgers 2007 III-2	RATA 26 OTA 41	Med: 229 (205 – 252) Med: 181 (154 – 202) *P*=0.001	Med: 1.65 (1.2 – 2.65) Med: 2.4 (1.4 – 5.8) *P*=NS	14/23 (61%) 23/33 (70%) *P*=NS	NR	1/26 (3.8%) 6/41 (14.6%) *P*=NS
Dharia Patel 2008 III-3	RATA 18 OTA 10	201 (140 – 263) 155.3 (120 – 183) *P*=0.001	4 34.7 (26 – 84) *P*=0.0001	5/18 (28%) 3/10 (30%) *P*=NR	≥1 ≥1	1/18 (5.6%) 0/10 (0%) *P*=NR

NOTE: Med – median; NR – not reported; NS – not significant; OTA – open tubal anastomosis; RATA – robotic-assisted tubal anastomosis; * figures presented as mean and [standard deviation] or (range) unless otherwise stated; † Pregnancy rate comprised the number of viable pregnancies; ‡ Tubal patency was established in at least one tube by hysterosalpingogram or subsequent pregnancy.

Sacrocolpopexy

Nonrandomised comparative studies

Appraisal of study quality

A single study compared short-term outcomes of robotic-assisted sacrocolpopexy (RAS) with those of open sacrocolpopexy (OS) (Geller et al 2008) (Table 15). This study involved two centres with one primary surgeon performing all RAS procedures, and was classified as III-3 evidence.

Basic exclusion criteria were explicit. The sample size and study period for each surgical procedure were described. The study described retrospective data collection, with OS as the historical control. Patient characteristics including age, race and BMI were not significantly different between groups. There was a significant difference in preoperative pelvic organ prolapse quantitative (POP-Q) assessment between the RAS and OS groups. The RAS group showed significantly more prolapse of the uterine or vaginal cuff ('C'), the anterior vaginal wall ('Aa' and 'Ba'), and posterior vaginal wall ('Bp' only).

The primary outcome reported by this study was quantification of vaginal vault prolapse (POP-Q instrument) 6-weeks postoperatively; secondary outcomes were standard perioperative measures (operative time, EBL, LOS and complication rates).

The major data limitation in this study was the significant differences between groups for preoperative POP-Q measures. The RAS group had significantly greater prolapse compared to the OS group at baseline. This study reported a number of possible confounding factors, as patients who had prior prolapse surgery or concomitant prolapse or incontinence surgery were not excluded. Geller et al (2008) attempted to control for several of these factors by performing two linear regressions controlling for covariates including BMI and concomitant surgeries (hysterectomy, anti-incontinence surgery, lysis of adhesions, other concurrent prolapse repair), with operative time and EBL as the dependent variables. Concurrent hysterectomy rate was higher in the RAS compared with OS group (P=0.02), whereas concurrent prolapse repair rate was significantly lower in the RAS compared with OS group (P<0.001). No significant difference in the rate of concurrent anti-incontinence surgery was reported between groups. Data on effectiveness were limited due to the short-term follow-up (6 weeks following surgery).

Efficacy

Operative time

This study reported a significantly longer mean operative time for the RAS compared with the OS cohort (Table 23). When Geller et al (2008) controlled for covariates (BMI, hysterectomy, other concomitant prolapse surgery, anti-incontinence surgery, and lysis of adhesions) through linear regression, the operative time for the RAS cohort was still found to be significantly longer than that of the OS cohort.

Concomitant hysterectomy was found to be a positive predictor of operative time (*P*=0.03).

Estimated blood loss and length of hospital stay

Significantly less blood loss and shorter LOS were reported for the RAS cohort compared with the OS cohort (Table 23). In another regression model controlling for similar covariates to those listed above, EBL remained significantly lower in the RAS group. Concomitant hysterectomy (*P*=0.02) and anti-incontinence surgery (*P*=0.003) were found to be positive predictors of EBL.

Conversions

Conversion rate was not reported.

Transfusions

Rate of transfusion was not significantly different between the RAS and OS cohorts (Table 23).

Postoperative pelvic organ prolapse quantification

This study demonstrated only one significant difference between groups for postoperative pelvic organ prolapse quantification (POP-Q), in 'C' (uterine or vaginal cuff support) where the RAS cohort showed slight improvement compared with the OS cohort (Table 23). In all other POP-Q categories no significant differences between the groups were reported. The authors also compared preoperative POP-Q values with postoperative POP-Q values for the RAS group, reporting significant improvement in all values (data not shown). Similar data was not reported for the OS group.

Safety

Overall complication rates appeared higher in the RAS compared to the OS cohort but this measure was not statistically analysed (Table 23). Specific complications were described (transfusion, pulmonary embolus, genitourinary tract injury or cystotomy, gastrointestinal tract injury, ileus, bowel obstruction, postoperative fever, pneumonia, wound infection and urinary retention) and these were statistically analysed between groups. The rates of specific complications were similar between the RAS and OS groups with only one significant difference noted for postoperative fever (RAS 3/73 patients (4.1%) versus OS 0/105 patients (0.0%); *P*=0.04).

Table 23 Comparison of key efficacy and safety outcomes for robotic-assisted or conventional sacrocolpopexy for the treatment of vaginal vault prolapse

Study	Number of patients	Operative time (mins)*	Estimated blood loss (mL)*	Length of hospital stay (days)*	Transfusions n/N	Complications n/N	Preoperative POP-Q†				Postoperative POP-Q†			
								Robotic	Open	P values		Robotic	Open	*P* values
Geller 2008	RAS 73	328 [55]	103 [96]	1.3 [0.8]	1/73 (1.4%)	14/73 (19.2%)	C	3 (0 – 5)	1 (-3 – 4)	0.002	C	-9 (-10 – -8)	-8 (-9 – -8)	0.008
III-3	OS 105	225 [61]	255 [155]	2.7 [1.4]	4/105 (3.8%)	16/105 (15.2%)	Aa	3 (1 – 3)	1 (-1 – 2)	<0.001	Aa	-3 (-3 – -3)	3 (-3 – -3)	0.38
		P<0.001	*P*<0.001	*P*<0.001	*P*=NS	*P*=NR	Ba	4 (3 – 6)	0 (0 – 4)	<0.001	Ba	-3 (-3 – -3)	-3 (-3 – -3)	0.29
							Ap	-2 (-3 – 0)	-2 (-2 – 0)	0.11	Ap	-3 (-3 – -2)	-3 (-3 – -2))	0.67
							Bp	2.5 (-1 – 5)	0 (-2 – 3)	0.005	Bp	-3 (-3 – -2)	-3 (-3 – -2)	0.55

NOTE: NR - Not reported; NS - not significant; OS – open sacrocolpopexy; POP-Q – Pelvic Organ Prolapse Quantification (C – either uterine or vaginal cuff support; Aa and Ba – support of the anterior vaginal wall; Ap and Bp – support of the posterior vaginal wall. Positive values signify prolapse that protrudes beyond the introitus, whereas negative values signify less severe prolapse that remains within the vagina. "0" signifies prolapse that that comes to the introitus but does not protrude externally.); RAS – robotic-assisted sacrocolpopexy; * figures presented as mean and [standard deviation]; † figures presented as median (interquartile range).

Ongoing and unpublished trials

Searches of the Clinical Trials Database, NHS CRD, NHS HTA, Current Controlled Trials, and the Australian New Zealand Clinical Trials Registry identified a number of unpublished studies. The details for each are provided in Table 24.

Table 24 Ongoing and unpublished studies

Study	Indication	Details	Outcomes
Laparoscopic Hysterectomy: a Clinical Randomised Trial Comparing Conventional and Robot-Assisted (da Vinci®)Techniques ClinicalTrials.gov Identifier: NCT00683293	Laparoscopic hysterectomy	Design: open label, parallel assignment, randomised, treatment Estimated enrolment: 100 Start/end date: May 2008/ December 2010 Sponsors and collaborators: Kantonsspital Aarau Location: Switzerland	Duration of surgery, complications, costs
A Pilot Study Assessing Transoral Robotic Surgery (TORS) For Oral And Laryngopharyngeal Benign And Malignant Lesions Using The da Vinci® Robotic Surgical System ClinicalTrials.gov Identifier: NCT00721539	Oral and laryngopharyngeal benign and malignant lesions	Design: historical control, nonrandomised, open label, safety/efficacy study, single group assignment Estimated enrolment: 75 Start/end date: July 2008/ NR Sponsors and collaborators: Stanford University Location: USA	Complication rate, feasibility defined as ability to perform the planned diagnostic or therapeutic procedure, blood loss, intraoperative time
Robotic Assisted Surgery in Upper Aerodigestive Tract Surgery ClinicalTrials.gov Identifier: NCT00473564	Hypopharyngeal, oral cavity or oropharyngeal lesions	Design: nonrandomised, open label, safety/efficacy study, single group assignment, treatment, uncontrolled Estimated enrolment: 40 Start/end date: February 2007/ February 1010 Sponsors and collaborators: University of Alabama at Birmingham Location: USA	Assessment of exposure and access to lesions, patient safety, surgical time and set-up
Same Procedure Cardiac Hybrid Surgery in a Specialty Built OR-- A Pilot Study ClinicalTrials.gov Identifier: NCT00366015	Coronary artery disease	Design: nonrandomised, open label, safety/efficacy study, single group assignment, treatment, uncontrolled Estimated enrolment: 50 Start/end date: August 2003/ January 2009 Sponsors and collaborators: Lawson Health Research Institute, Canada Foundation for Innovation, Ontario Innovative Trust, Ontario Research and Development Challenge Fund Location: Canada	Safety and efficacy of integrated myocardial revascularisation performed in a single stage using da Vinci, 1-year postoperative stenosis rate, success rate (reduction in stenosis to <50%, myocardial infarction, death, inability to revascularise, in-hospital complications, repeat revascularisation

Table 24 continued Ongoing and unpublished studies

Study	Indication	Details	Outcomes
Robotic Assisted Versus Laparoscopic Cholecystectomy - Outcome and Cost Analyses of a Case-Matched Control Study ClinicalTrials.gov Identifier: NCT00562900	Cholecystolithiasis	Design: active control, nonrandomised, open label, parallel assignment, safety/efficacy study, treatment Estimated enrolment: 50 Start/end date: December 2004/ February 2007 Sponsors and collaborators: University of Zurich Location: Switzerland	Complications, conversion rates, operative time, hospital costs
Conventional Laparoscopic Versus Robotic Assisted Laparoscopic Sacrocolpopexy: a Randomised Controlled Trial ClinicalTrials.gov Identifier: NCT00551993	Pelvic organ prolapse	Design: active control, double blind (subject, outcomes assessor), efficacy study, parallel assignment, randomised, treatment Estimated enrolment: 64 Start/end date: September 2006/ November 2009 Sponsors and collaborators: The Cleveland Clinic Location: USA	Operative time from incision to closure, perioperative complications, hospital costs and postoperative patient outcomes (anatomic outcomes on physical examination and patient satisfaction using validated condition specific quality of life measures)
Prospective Evaluation of Robot-Assisted Surgery in Gynecologic Oncology ClinicalTrials.gov Identifier: NCT00671827	Gynaecologic cancer	Design: case-only Estimated enrolment: 500 Start/end date: April 2008/ April 2013 Sponsors and collaborators: M.D. Anderson Cancer Center Location: USA	Length of surgery, the procedures performed during surgery, side effects of robot-assisted gynaecologic cancer surgeries, complications during recovery
A Pilot Study of the Use of the da Vinci Robotic System for Otorhinolaryngology-Head and Neck Surgery ClinicalTrials.gov Identifier: NCT00627562	Head and neck neoplasms	Design: historical control, open label, single group assignment, treatment Estimated enrolment: 30 Start/end date: July 2007/ March 2015 Sponsors and collaborators: Montefiore Medical Centre Location: USA	Ability to adequately visualise the operative field and complete planned surgery, complication rate, blood loss, operative time, quality of life
Recovery After Robotic Urogynecological Surgery: The Patient's Perspective ClinicalTrials.gov Identifier: NCT00757432	Urogynaecology	Design: cohort, retrospective Estimated enrolment: 30 Start/end date: September 2008/ NR Sponsors and collaborators: University of Rochester Location: USA	Patient experience, including pain scores, use of pain medications, resumption of usual activities, and bowel function in the postoperative period following robotic urogynaecologic surgery

Table 24 continued Ongoing and unpublished studies

Study	Indication	Details	Outcomes
A Prospective Randomised Trial Comparing Conventional vs. Robotic Assisted Laparoscopic Hysterectomy ClinicalTrials.gov Identifier: NCT00485355	Hysterectomy	Design: active control, double blind (subject, outcomes assessor), parallel assignment, randomised, safety/efficacy study, treatment Estimated enrolment: 52 Start/end date: June 2007/ February 2010 Sponsors and collaborators: The Cleveland Clinic Location: USA	Operative time, perioperative complications; comparison of costs; qualify of life issues; postoperative pain and narcotic use; return to normal activity
Prospective Assessment of Clinical and Quality of Life Outcomes After Open or Laparoscopic Radical Prostatectomy ClinicalTrials.gov Identifier: NCT00578123	Prostate cancer	Design: open label, randomised, single group assignment, supportive care Estimated enrolment: 450 Start/end date: July 2005/ July 2010 Sponsors and collaborators: Memorial Sloan-Kettering Cancer Center, The Cleveland Clinic Location: USA	Potency function, recovery of continence
A Phase III Randomised Clinical Trial of Laparoscopic or Robotic Radical Hysterectomy Versus Abdominal Radical Hysterectomy in Patients With Early Stage Cervical Cancer ClinicalTrials.gov Identifier: NCT00614211	Cervical cancer	Design: open label, parallel assignment, randomised, treatment Estimated enrolment: 740 Start/end date: January 2008/ July 2017 Sponsors and collaborators: Queensland Centre for Gynaecological Cancer, M.D. Anderson Cancer Center Location: USA, Australia	Disease free survival, patterns of recurrence, intra-operative, perioperative, postoperative and long term treatment related morbidity, costs, feasibility of sentinel lymph node biopsy, pelvic floor distress inventory, overall survival, quality of life
Robotic versus conventional Laparoscopic Fundoplication: a randomised controlled double-blind assessment of quality of life ISRCTN03806561	Gastro-oesophageal reflux disease	Design: pilot randomised controlled single centre trial Estimated enrolment: 40 Start/end date: April 2004/ August 2006 Sponsors and collaborators: University of Heidelberg Location: Germany	Quality of life, functional outcomes, operating time, intraoperative blood loss, complications, conversions, morbidity, postoperative length of hospital stay, costs
A study to determine the feasibility of randomisation to open versus minimal access cystectomy in patients with muscle invasive bladder cancer ISRCTN38528926	Invasive bladder cancer	Design: late phase II randomised multi-centre feasibility trial Estimated enrolment: 72 Start/end date: January 2009/ December 2010 Sponsors and collaborators: Cardiff University Location: UK	Feasibility of randomisation, safety and efficacy of minimal versus open cystectomy (extent of lymph node dissection, short term morbidity, complications), potential barriers to randomisation, potential factors relating to non-registration of patients

Table 24 continued Ongoing and unpublished studies

Study	Indication	Details	Outcomes
LAPPRO: Laparoscopic Prostatectomy Robot Open - A randomised, open trial of radical prostatectomy with or without lymph node dissection as part of a prospective, nonrandomised, open trial comparing robot-assisted laparoscopic and open radical prostatectomy ISRCTN06393679	Prostate cancer	Design: multicentre, prospective, nonrandomised trial, with a randomised trial in a sub population concerning one specific aspect Estimated enrolment: 1400 Start/end date: February 2008/ August 2010 Sponsors and collaborators: Sahlgrenska University Hospital Location: Sweden	Erectile dysfunction, urinary leakage, radicality, oncological result judged by PSA relapse, operating time, blood transfusions, re-operations, length of hospital stay, re-admittance, length of sick leave, length of catheter treatment, continued urinary leakage and erectile dysfunction, inguinal hernia, short term complications, mortality and complications, self evaluated health related quality of life, health economy analyses

Results – Australian experience of robotic-assisted surgery

Clinical perspectives

Interviews were conducted with seven surgeons from six of the seven Australian hospitals that are currently using the da Vinci Surgical System, and took on average 30 minutes each. These surgeons represented two public and four private hospitals. An eighth surgeon however, declined to participate.

Five of the seven participating surgeons were urologists, four of whom currently use the da Vinci Surgical System exclusively for robotic-assisted radical laparoscopic prostatectomy. The remaining urologist does not currently use robotic technology in his practice, but suggested that he would most likely be using this technology to perform robotic-assisted laparoscopic pyeloplasty and partial nephrectomy in the future.

The cardiothoracic surgeon interviewed for this report uses robotic-assisted surgery primarily for mitral valve repair and replacement, as well as for CABG, repair of atrial septal defects and removal of atrial tumours. This surgeon was able to refer us to a theatre nurse experienced in the set-up and maintenance of the da Vinci Surgical System, who was also interviewed for this report.

The gynaecological oncologist interviewed for this report currently uses this technology exclusively for robotic-assisted radical hysterectomy for the treatment of endometrial cancer.

Training and learning curve issues

All of the surgeons currently using the da Vinci Surgical System reported undergoing a similar training regimen. The initial training stage involved travelling to the United States to participate in a mandatory short course run by the manufacturer of the robot, Intuitive Surgical. The training course consisted of a mixture of lectures on the principles/engineering of the robot, learning stitching and tying principles using plastic models, in vivo work on cadavers and pigs, as well as observing experienced surgeons. Following this, all surgeons were expected to complete three cases which were proctored by another surgeon who had completed a minimum of 20 cases on the robot.

Other members of the surgical team have also undertaken structured training programs in the use of the da Vinci Surgical System. We spoke with one theatre nurse who, as part of a multidisciplinary team consisting of another nurse, an anaesthetist, a bedside surgeon and an operating surgeon, travelled to the United States for a 6-day training course run by Intuitive Surgical. A major focus of this training was to learn how to set-up the robot for cardiac surgery. Upon their return

to Australia they were then able to train theatre technicians in their department in the set-up of the machine.

The training requirements for the da Vinci Surgical System involve a significant commitment not just from those receiving training, but also from those surgeons acting as mentors. A surgeon's first few cases can take between 6 and 8 hours each, and two senior urologists that were interviewed suggested that training in robotic-assisted surgery should be taking place in public hospitals to enable graded mentorship. This would mean that rather than having to perform a whole surgery early on in their training, surgeons would be able to perform parts of a procedure and then sit back and observe for other parts, similar to open surgical procedures. Recently, one Australian public hospital has established a dedicated robotic department that has been funded to enable 200 radical prostatectomies to be performed each year, which will occupy the robot for 2 days a week. This will enable other specialties to use the robot 3 days a week. The facility will serve as a training centre for Australian urologists, who will be mentored by a highly experienced surgeon who has performed 600 robotic-assisted radical laparoscopic prostatectomies himself, and has been involved in over 1500 procedures. This department has been provided with AUD$1.25 million in funding to conduct a randomised controlled trial evaluating the safety and efficacy of robotic-assisted laparoscopic radical prostatectomy in the Australian healthcare context.

Of the six surgeons interviewed for this report that are currently using the da Vinci Surgical System, length of experience with the technology ranged from 6 months to over 4 years, while the number of cases performed to date ranged from 20 to just over 500. One urologist explained that the way in which surgeons are currently trained to use the robot may place their initial cohort of patients at risk of poorer outcomes compared to what they would have achieved with conventional surgical approaches. He suggested that based on published data it takes approximately 200 cases before a surgeon's skill with robotic-assisted surgery is equivalent to that with conventional surgery. One urologist explained that not all surgeons will want, or be able, to take up this technology. He explained that three of his colleagues who underwent training on the robot have decided not to pursue it in their clinical practice. This may have been due to the fact that they could not work quickly enough with the technology; they felt that their accuracy of dissection was not as good as what they could achieve with open surgery; or they found it too stressful.

Technical issues

While all of the surgeons interviewed agreed that there is a loss of tactile sensation with robotic-assisted surgery, none of them viewed this as an issue of concern. Most surgeons reported that the loss of tactile sensation is something that is quickly accommodated for by other sensory input, including the quality of the 3D vision

afforded by the robot. As one surgeon explained, there are many visual cues, such as blanching of the skin, which give a sense of the force being applied.

With regard to the set-up of the da Vinci Surgical System prior to surgery, the theatre nurse that was interviewed explained that for cardiac procedures set-up of the robot is done while the patient is in the operating theatre, whereas for urological procedures, set-up is usually complete before the patient arrives. The set-up for cardiac procedures is more complex because of the large amount of equipment that is required, necessitating a great deal of coordination and teamwork. The nurse reported that because of this highly coordinated team effort which has developed over four years, the set-up time for cardiac surgery at their hospital was now approximately one hour, while the changeover time between cardiac patients was 10 minutes.

None of the interviewed surgeons had experienced a mechanical breakdown of the da Vinci Surgical System during an operation, although most agreed that if this were to occur they would continue with the procedure laproscopically or convert to an open operation. One surgeon reported that of the over 500 cases he has performed, there was just one case where the machine would not turn on, and the operation had to be rescheduled for the following week. The theatre nurse that was interviewed explained that in four years working with the robot, there have been many instances when members of the surgical team have had to troubleshoot minor problems with the machine; however, there have been no major breakdowns.

Most of the interviewed surgeons reported that they had not yet performed a follow-up operation after robotic-assisted surgery because of complications, but explained that the surgical approach taken for such an operation would largely depend on the type of complication. One urologist reported that less than 5% of his robotic patients required follow-up surgery. Minor wound complications could be addressed using open surgery, while a stricture of the urethra could be handled by endoscopic surgery. Therefore, follow-up operations do not always require the robot. The cardiothoracic surgeon reported that only 2.5% of his patients have required follow-up operations, and while feasible to do robotically, most are done as an open procedure with sternotomy.

Advantages of robotic-assisted surgery

All of the surgeons interviewed agreed that there are a number of key advantages to using robotic-assisted surgery over conventional laparoscopic or open approaches, including:

- Reduced blood loss
- Reduced postoperative pain
- Shorter length of hospital stay

- Quicker return to normal daily activities

In addition to these general benefits of robotic-assisted technology, individual surgeons were also able to identify specific advantages related to their own specialties.

Urological procedures

One surgeon explained that because of the reduction in physical stress, as well as improved vision, it was easier to concentrate during robotic-assisted surgery, which in turn facilitated nerve sparing. As a result, his experience with over 500 patients has shown that in men aged between 45 and 75 years who had bilateral nerve sparing, and who were sexually active prior to surgery, over 66% had a good return to sexual function following surgery. This is an improvement over what he achieved previously with open surgery. Further, over 97% of these patients were continent within 6 months of surgery. One surgeon reported that certain complications seen during laparoscopic surgery, such as rectal injuries, strictures at the anastomosis and the requirement to convert to an open procedure, have been largely absent in his series of robotic-assisted patients. Interestingly, two other surgeons suggested that with regard to cancer control, sexual function and continence, it is likely that a good robotic surgeon will achieve similar outcomes to a good open surgeon, and that the success of the procedure is surgeon, rather than technology dependent.

Cardiac procedures

The advantages of using robotic technology for cardiac surgery are similar to those for other minimally invasive cardiac techniques such as video-assisted endoscopic surgery. These advantages include a much smaller incision, and thus better cosmesis, as well as less trauma to the patient due to the fact that a sternotomy is not required.

One of the major advantages of robotic-assisted surgery over other minimally invasive techniques for cardiac procedures is that there is little need to alter surgical protocols/procedures from what is normally done in open procedures. In addition, with robotic-assisted surgery the size of the patient is no longer an issue. In non-robotic minimally invasive procedures, the operating plane is determined by the size of the patient. This is not really an issue when the patient is slim in build; however this is not often the case. With robotic-assisted surgery, placement of the robotic arms inside the patient changes the plane at which the surgeon is operating, and as a result, patients as large as 165 kilograms have been successfully operated on using this technology.

It was the opinion of the surgeon we spoke with that once the initial learning curve has been overcome, the use of robotic technology can in fact simplify the performance of certain cardiac surgical procedures.

Gynaecological procedures

One of the key advantages of using robotic technology for gynaecological procedures is the reduction in surgeon fatigue. Advanced gynaecological laparoscopic surgery is

ergonomically challenging for surgeons, with many taking time off work and even retiring early due to workplace injuries. The use of robotic-assisted surgery enables surgeons to overcome many of these physical stresses.

The use of robotic technology in gynaecological surgery may enable complex cases, which otherwise could not have been treated using conventional surgical approaches, to be undertaken. Robotic technology may not have a particular advantage in simple cases which can just as easily be done using conventional approaches. However, the more obese the patient, or the more complex the surgery, the more benefits such as the manoeuvrability afforded by the 7 jointed wrist which can mimic the human hand, the 3D vision and the intuitive motion of the robotic technology come into play.

Disadvantages and limitations of robotic-assisted surgery

The disadvantage of robotic-assisted surgery as identified by all participating surgeons is the cost of the technology. In addition, both the gynaecological oncologist and cardiothoracic surgeon highlighted increased set-up times as a potential drawback of the technology. In robotic-assisted surgery the time taken to set-up the operating theatre and position the patient for surgery is longer when compared with conventional surgical approaches.

In relation to cardiac surgery, one of the biggest challenges associated with the use of robotic technology is that it requires much more of a team-based approach, and is optimally performed with two surgeons. Successful performance of these procedures requires that each member of the multidisciplinary surgical team including nurses, anaesthetists and technicians, have been appropriately trained in the use of robotic technology. This may explain why many of the cardiothoracic surgeons who originally trained in the use of this technology have not pursued it further.

On a broader scale, one surgeon suggested that the limited access to this technology had the potential to create tensions within professional groups and fuel professional jealousy.

Patient issues

All of the surgeons interviewed who are currently using robotic-assisted surgery in their clinical practice agreed that the response of patients, when told of the option of this technology, is overwhelmingly positive. In fact, many patients have already done their own research on robotic-assisted surgery prior to meeting with their surgeon and are often well-informed about the potential benefits and drawbacks of this treatment option. In addition, testimonials from celebrities such as Sam Newman and David Parkin have increased the profile of robotic technology in the wider community, particularly in relation to the treatment of prostate cancer.

Most surgeons reported that in their experience, the overwhelming majority of patients (80-99%) choose robotic-assisted surgery over conventional open or

laparoscopic approaches, despite the fact that it is often a significantly more costly option. However, one urologist reported that in his current practice approximately 50% of patients still choose open surgery as their mode of treatment. Another surgeon explained that after conducting their own background research, some patients have expressed that they would prefer a surgeon who has performed a few hundred cases using the robot, and thus have chosen to have their surgery performed at centres with more experience.

Most of the urologists interviewed agreed that generally if a patient is a suitable candidate for either laparoscopic or open radical prostatectomy, then they are also a suitable candidate for robotic-assisted laparoscopic radical prostatectomy. However, two urologists explained that they would not perform robotic-assisted surgery on patients who were grossly obese, or who had very large prostates or previous dramatic pelvic colonic surgery. Interestingly, one senior urologist who had performed over 200 robotic-assisted procedures suggested that experienced surgeons may find performing a radical prostatectomy in an obese patient to be easier using robotic technology compared with an open approach due to the 3D vision afforded by the robot.

According to the gynaecological oncologist interviewed, there are no absolute contraindications for robotic-assisted gynaecological surgery. He did explain that at his stage of experience with robotic technology, at just over 20 cases, he limits its use to treatment of patients with endometrial cancer and certain other benign surgeries. In addition, while he hoped to treat cervical cancer patients using this technology in the future, this surgery required a more advanced skill level that he had not yet attained. It was suggested that robotic technology is unlikely to be suited to the treatment of patients with ovarian cancer, due to the nature of the surgery which requires access not only to the pelvis, but to the upper abdomen as well. While the robot is very good when limited to one surgical field such as the pelvis, it can be quite cumbersome to move around and re-dock once you have to move outside the field.

With regard to cardiac surgery, the vast majority of patients who are suitable for open surgery or other minimally invasive procedures will also be suitable for robotic-assisted surgery; however, there are a few exceptions. For example if a patient requires two procedures to be performed at the same time, such as mitral valve surgery and CABG, they would not be a candidate for robotic-assisted surgery. This is because the operation would then become too lengthy and would necessitate two separate incisions (mitral valve surgery would require an incision on the right hand side of the chest, while CABG would require an incision on the left hand side of the chest). Similarly, patients would not be eligible for robotic-assisted surgery if they had issues with their peripheral circulation (such as peripheral vascular disease) and also required a CABG which would involve cannulation of the femoral artery, or if they had heavy calcification in the mitral annulus. In addition, robotic-assisted surgery is

best for planned operations, thus if a patient is very ill and the operation is being performed in an emergency situation, it is unlikely that robotic technology would be used.

Cost and resource issues

Of the surgeons who we spoke with regarding the expense of robotic-assisted surgery within Australian private hospitals, many suggested that it would be difficult to obtain standardised cost data as different hospitals have used different business models for this technology. This was clearly reflected by the large variation in out of pocket costs for individuals undergoing robotic-assisted laparoscopic radical prostatectomy within different private hospitals, which ranged from AUD$5,000 to over AUD$10,000. In one private hospital, it was decided that the da Vinci Surgical System would be a loss leader and the hospital was willing to accept a loss on this technology in the hope that it would attract more surgeons. That is, the cost of the robot would be offset by the fact that these surgeons were filling up more of their operating lists and thus generating more income. In this hospital, the robotic technology was available at a relatively low cost to the surgeon, thus the volume of procedures performed was high, and in the last 12 months more robotic-assisted procedures were performed in this hospital than in any other institution in the world. Simply due to the economies of scale, the robot at this hospital is now running at a modest profit, after many years of running at a loss. Importantly, all of the urologists interviewed reported that private health insurers would only reimburse patients undergoing robotic-assisted laparoscopic radical prostatectomy the same amount as an open procedure, leaving patients with significant out of pocket costs. The other specialist surgeons were of the opinion that robotic-assisted procedures for gynaecological and cardiac indications were generally covered by most of the major private health insurers; however, some of the smaller insurers did not cover these procedures. Private insurers cover the cost of one surgeon and one assistant which is the normal requirement during open or non-robotic minimally invasive cardiac procedures. However, as robotic-assisted cardiac procedures ideally require two surgeons to be present, the cost of the additional surgeon is usually borne as an out of pocket expense by the patient.

Two urologists were able to provide a perspective on the costs associated with performing robotic-assisted laparoscopic radical prostatectomy in the public hospital system. While both surgeons agreed that this technology represented a significant expense for the public system, the consensus was that the benefits incurred in terms of reduced length of hospital stay meant that it did provide a good return on investment. One surgeon explained that in his state, if the initial cost of the machine was taken out of the equation, when the expense of an open radical prostatectomy was compared to that of a robotic-assisted procedure, the cost to the public purse was AUD$3000 less if the procedure was performed robotically. He reported that last year, 250 conventional radical prostatectomy procedures were performed within

the public system in his state. It was suggested that given the shorter hospital stay that is associated with robotic-assisted surgery, had these operations been performed robotically, this would have resulted in a gain of approximately 1200 bed days for the public system. He explained that as the cost of building a new bed into a public hospital structure was approximately AUD$750,000, utilising robotic technology within public hospitals would facilitate the treatment of more patients and would be a cheaper option than creating new hospital beds.

One of the interviewed surgeons explained that he had tried to obtain specific cost data regarding the use of the da Vinci Surgical System in his own hospital. He had hoped to use this information for the purposes of a research study aimed at determining the cost effectiveness of this technology. However, he was unable to obtain this data from the hospital due to its confidential nature. This may explain, at least in part, the lack of published information on the cost of the da Vinci Surgical System in the Australian healthcare context.

Jurisdictional health perspectives

Interviews were conducted with two jurisdictional health representatives from one Australian state and one territory, and took on average 20 minutes each. Both representatives stated that the da Vinci Surgical System was not currently in use in public hospitals within their jurisdictions. One representative was aware of two hospitals in his jurisdiction that were using this technology. Two other representatives responded to our request for assistance with this report, but felt that they would be unable to provide significant input and declined to participate.

One representative reported that a few surgeons, primarily urologists, had expressed interest in using the robotic technology, including one surgeon who had used it previously in another jurisdiction. Similarly, another representative explained that his department was regularly approached by public health services within his jurisdiction to support the purchase of a robot. To date none of these requests have involved a collaboration between health services, or between different specialty areas within the same health service. Neither representative was aware of any requests from individual patients.

Both representatives were aware that the da Vinci Surgical System is currently used primarily for urological and some cardiac procedures, and recognised that based on evidence from the peer-reviewed literature this technology may offer some benefits to patients. One representative identified a reduced length of stay in hospital as one of the major benefits of robotic-assisted surgery, but also noted that most of the procedures performed using this technology appeared to require longer theatre times when compared with conventional surgical approaches.

The current cost of the technology was an area of major concern to both representatives. One representative explained that the da Vinci Surgical System may only have a 5 year life cycle attributed to it, which is short given that for other high cost equipment business case analyses generally look at a 10 year life cycle. Both representatives recognised that in addition to the initial purchase of the technology, there are also a number of ongoing costs. For example, the consumables for the robot could represent an additional annual cost of up to AUD$1 million over and above the reimbursement allocated to the hospital. In addition, there are likely to be significant costs associated with installing and maintaining the machine, as well as with any hardware and software upgrades that may be required. While it was acknowledged that some of these costs may be offset by the reduced length of hospital stay following robotic-assisted surgery, this has yet to be demonstrated in the Australian healthcare context.

The training requirements for robotic-assisted surgery remain another area for concern. If this technology were to be introduced into a public health service, this would raise a number of issues about the type of training required by surgeons and

other members of the surgical team who plan to use the robot, and how such a program would be resourced.

It was clear that both representatives were unconvinced as to the current utility of robotic technology, arguing that the resources required to provide one of these machines in the public system, particularly if it does only have a life cycle of 5 years, may be better allocated to other elective procedures that are known to be effective. However, one representative did explain that in her jurisdiction certain provisions were being made with regard to theatre size and design in order to be able to accommodate this technology in the future, should the case for its introduction strengthen.

Patient perspectives

Interviews were conducted with two representatives from patient advocacy organisations, and took on average 20 minutes each. One advocate represented a national organisation focused exclusively on patients with prostate cancer, and the other represented a national organisation focused on patients with all types of cancer.

Both advocates were aware of the use of the da Vinci Surgical System for the treatment of prostate cancer. Each advocate had heard about this technology in the media, as well as from speaking with urologists that are using it, and from prostate cancer patients themselves.

One advocate reported that in the last 12 months he had received one enquiry regarding the use of robotic-assisted surgery for prostate cancer. He explained that the real issues for patients with regard to this technology were cost and access. Patients with prostate cancer generally want to be treated as soon as possible, however with only seven Australian hospitals offering this technology currently, timely access to treatment is not always possible. Indeed, another patient advocate was aware of one patient, who after being diagnosed with moderately aggressive prostate cancer, and doing some research on potential treatment options, decided on robotic-assisted laparoscopic radical prostatectomy. Unfortunately, the private hospital in his home state that offered this procedure quoted a 4 month wait, and he elected to travel interstate to have the operation. This procedure cost the patient AUD$14,500, and this did not include travel or accommodation costs. The patient was not happy with the extent of financial support from his private health insurer, and received only AUD$1,700 in rebates.

Both advocates agreed that the reduced length of hospital stay and the faster return to work and normal activities are viewed by patients as the key advantages of robotic-assisted laparoscopic radical prostatectomy over conventional surgical approaches. This is particularly true for rural and remote men. Other outcomes that are of importance to both patients and their families include maintenance of urinary continence and sexual function. Each advocate was aware of the early postoperative experiences of at least one patient who had undergone robotic-assisted laparoscopic radical prostatectomy. The responses of these patients to the procedure have been overwhelmingly positive, with one patient reporting very little postoperative pain and normal sexual function, and both patients reporting near normal urinary continence.

Discussion

Question one – Literature review

Limitations of the evidence

The aim of this component of the review was to evaluate the safety and efficacy of robotic-assisted surgery compared with conventional surgical approaches for commonly performed urological, cardiac and gynaecological procedures. The conclusions that can be drawn from this review are limited by the quantity and quality of the available evidence. Despite a proliferation of new publications about robotic-assisted surgery in recent years, no RCTs could be identified for inclusion in this review. The available evidence was made up of nonrandomised comparative studies (either concurrently or historically controlled) that are more likely to be affected by biases inherent to such study designs. One recent systematic review of nonrandomised comparative studies comparing RALP to LRP and RRP was selected for inclusion.

The majority of studies were focused on the use of robotic-assisted surgery for urological procedures, particularly radical prostatectomy for clinically localised carcinoma of the prostate. This technology is increasingly being used in gynaecology, and a number of studies focused on the use of robotic-assisted surgery for radical hysterectomy for endometrial cancer staging or treatment of cervical cancer were also identified for inclusion. There is still a paucity of comparative evidence on the use of robotic-assisted surgery for cardiac applications, as well as for less common urological (radical and partial nephrectomy, radical cystectomy and pyeloplasty) and gynaecological (tubal re-anastomosis, myomectomy and sacrocolpopexy) procedures. Interestingly, only one of the included studies reported on outcomes from an Australian centre (Webb et al 2008).

The lack of randomisation in the studies included in this review may have introduced a number of biases. In particular in the selection of patients for inclusion in studies, as well as in the assignment of patients to treatment groups, limited the ability to draw firm conclusions. Importantly, in the majority of studies where the method of patient allocation was reported, patients were generally allocated to treatment groups based on either surgeon or patient preference. In addition, blinding of outcome assessors was not undertaken because of the nature of the surgery, and this may have introduced observation bias in the measurement of outcomes, particularly in the case of subjective measures.

The use of historical, rather than concurrent controls in many of the included studies may also have introduced certain biases. For example, the experience of each surgeon and his or her position on the learning curve may have varied over the course of time, which in turn could have affected outcomes in later versus earlier cases. It is

likely that experience with robotic-assisted surgery in most centres was much shorter than experience with conventional approaches.

None of the studies included in this review were able to thoroughly assess the long-term safety, efficacy or durability of robotic-assisted surgery, due to insufficient follow-up data. Follow-up times in most studies were not reported, however where they were reported, times were generally less than 2 years following robotic-assisted surgery. In order to assess patient survival following surgery, particularly in relation to cancer, a greater number of studies with longer follow-up times are required. Similarly, longer follow-up periods are required in order to assess key functional outcomes such as urinary continence and erectile function, as well as the incidence of rare complications, although these outcomes were generally poorly reported.

The majority of studies had small sample sizes, with only seven studies having 100 or more participants in each treatment arm. Therefore, many of the studies may not have been adequately powered to detect statistical differences in outcomes between treatment groups. In addition, the size of the evidence base for individual outcomes was further limited as not all outcomes were reported in all studies, and not all studies reported similar outcomes in a consistent manner. Further to this, there was a lack of standardisation with regard to the surgical protocols used, particularly in the case of radical hysterectomy, which added an extra dimension of heterogeneity to the outcomes reported. Patient-related outcomes such as pain, quality of life, satisfaction with procedure and cosmesis were generally poorly reported across all three surgical specialties.

Efficacy and safety

Urological procedures

Radical prostatectomy

In terms of efficacy, operative times for RALP were generally shorter than or not significantly different from LRP, but tended to be longer compared with RRP. Length of hospital stay for RALP was shorter than or not significantly different from both LRP and RRP. Other measures of postoperative recovery and convalescence including narcotic use, time to oral intake, ambulation and return to work were not reported in any studies. Both the estimated blood loss and need for transfusion following RALP was either less than, or not significantly different from, that observed following LRP or RRP. The conversion rate for RALP to an open procedure ranged from 0%-2.7%, while for LRP the conversion rate ranged from 0%-31.4%. Reported oncological outcomes were mainly limited to positive surgical margin rates, which were generally lower or not significantly different to those observed following LRP or RRP. Currently, insufficient follow-up data are available to determine long-term patient survival. Key patient-related outcomes such as urinary continence, erectile function and quality of life measures were poorly reported, and follow-up for these outcomes was generally limited to a maximum of 12 months

post-surgery. No significant differences in urinary continence or erectile function were observed between RALP and LRP patients; however, both urinary continence and erectile function were improved following RALP compared with RRP. Return to HRQoL was quicker following RALP compared with RRP during the first six postoperative weeks.

In terms of safety, the rate of complications for RALP was generally much lower compared with LRP or RRP; however, safety outcomes were poorly reported across studies. No deaths were reported with any of the procedures. Urinary tract infections were a common complication following all three procedures. Urinary retention was more common in RALP patients, while LRP and RRP patients were more likely to experience bladder neck contracture, fever and mictional syndrome.

Other urological procedures

The current evidence base for other urological procedures that employ robotic-assisted surgery, including radical or partial nephrectomy, radical cystectomy and pyeloplasty, is limited. For these procedures, as with radical prostatectomy, the robotic-assisted approach was generally associated with significantly better or equivalent outcomes for length of hospital stay, estimated blood loss and need for transfusion, when compared with conventional laparoscopic or open approaches. Operative times for robotic-assisted surgery were generally not significantly different to those for conventional approaches; however, a few studies did report a longer operative time for robotic-assisted patients, which may have reflected a learning curve effect. Reported oncological outcomes for radical or partial nephrectomy and radical cystectomy were mainly limited to positive surgical margin rates, which were not significantly different following robotic-assisted or conventional approaches. Few studies reported on patient-related outcomes; however, it was shown that postoperative pain and analgesic requirement, as well as the time taken to return to regular diet, were not significantly different following robotic-assisted or conventional surgery. It is difficult to assess the relative safety of robotic-assisted versus conventional approaches for these other urological procedures, due to the limited evidence base. In general, complications following these procedures were moderate to mild in nature. Across all studies, a total of three deaths were reported following robotic-assisted surgery, and two deaths were reported following open surgery. No deaths were reported following laparoscopic surgery.

Cardiac procedures

Mitral valve repair

In terms of efficacy, the limited evidence base revealed that operative times for RMVR were longer compared to OMVR. Length of hospital stay for RMVR was generally shorter than OMVR and VMVR. Both the estimated blood loss and need for transfusion following RMVR were not significantly different from that observed following OMVR. The need for reoperation appeared lower following RMVR compared with OMVR, but was not significantly different compared with VMVR.

Key patient-related outcomes such as pain and quality of life measures were not reported in any studies and insufficient follow-up data are available to determine long-term patient survival.

In terms of safety, the rate of complications for RMVR was higher compared with VMVR, but lower compared with OMVR. Mortality rates for all three procedures were generally low. Bleeding was a common complication following all three procedures, while patients undergoing OMVR were more likely to experience atrial fibrillation, pulmonary insufficiency and wound infection.

Gynaecological procedures

Radical hysterectomy for endometrial cancer staging and cervical cancer

RAH was generally associated with significantly better or equivalent outcomes for length of hospital stay, estimated blood loss and need for transfusion, when compared with conventional laparoscopic or open approaches. Operative times for RAH were generally shorter than, or not significantly different from, LH but tended to be longer when compared with OH. The conversion rate for RAH to an open procedure ranged from 0%-12.4%, while for LH the conversion rate ranged from 0%-26.3%. The total number of lymph nodes retrieved using RAH was generally higher than, or not significantly different from, LH or OH. Cancer recurrence was rare and was reported in only two patients, one following RAH and the other following OH. Insufficient follow-up data are available to determine long-term patient survival. Key patient-related outcomes such pain and quality of life measures were poorly reported.

In terms of safety, the rate of complications for RAH was generally lower or not significantly different compared with LH or OH; however, safety outcomes were poorly reported across studies. No deaths were reported with any of the procedures.

Other gynaecological procedures

The current evidence base for other gynaecological procedures that employ robotic-assisted surgery, including myomectomy, tubal re-anastomosis and sacrocolpopexy, is limited. For these procedures, the robotic-assisted approach was generally associated with significantly better or equivalent outcomes for length of hospital stay and estimated blood loss, when compared with conventional laparoscopic or open approaches. Operative times for robotic-assisted surgery were significantly longer when compared to conventional surgery, which may have reflected a learning curve effect. Measures of postoperative recovery and convalescence including return to work, activities of daily living scores and narcotic use were all significantly better following robotic-assisted surgery compared to the open approach. Reported functional outcomes such as pregnancy rates and tubal patency were not significantly different following robotic-assisted or conventional approaches.

It is difficult to assess the relative safety of robotic-assisted surgery for these other gynaecological procedures, due to the limited evidence base; however, in general

complication rates were not significantly different when compared to conventional surgical approaches. No deaths were reported with any of the procedures.

Question two – Australian experience of robotic-assisted surgery

The aim of this component of the review was to utilise qualitative data collection methods to evaluate the experiences of Australian surgeons using this technology, as well as the views of jurisdictional health representatives and patient advocates regarding this technology. Given the relatively small sample of people interviewed, the findings may not necessarily be representative of all individuals in each of the groups mentioned above. Additionally, it is important to note that as a qualitative method of data collection, interviewing can be influenced by researcher bias during the interview and reporting process.

All of the surgeons interviewed for this report agreed that robotic-assisted surgery offered a number of key advantages compared with conventional surgical approaches, including reduced blood loss and postoperative pain, shorter length of hospital stay and a quicker return to normal daily activities. In addition, some surgeons reported that this technology provided patients who would otherwise not have been eligible for surgery, with a surgical treatment option. It appears that this technology may also confer an advantage to surgeons, reducing the physical stress of surgery and thus surgeon fatigue. On the other hand the high cost of, and limited access to, robotic-assisted surgery in Australia at present has been identified by surgeons, jurisdictional health representatives and patient advocates as the main drawbacks of this technology.

Currently, the majority of centres offering robotic-assisted in Australia are privately run; although both of the jurisdictional health representatives interviewed for this report explained that there is a push from some surgeons to increase the uptake of this technology within public hospitals. Jurisdictional health representatives were concerned not only with the significant costs associated with the initial purchase of the technology, but also with the ongoing costs associated with maintenance and training. Both parties recognised that robotic-assisted surgery demands more sophisticated training to equip users with sufficient skills to competently handle the technology, as well as a level of multidisciplinary training that was not previously required. This in turn will have direct implications for the policies and future planning of training centres and accreditation bodies. While surgeons from each of the two Australian public hospitals currently offering robotic-assisted surgery explained that it did represent a significant expense for the public system, both agreed that the benefits of this technology, particularly in terms of reduced length of hospital stay, are such that it does provide a good return on investment. Due to the lack of cost data on the use of robotic-assisted surgery in the Australian healthcare

context however, determining the cost-effectiveness of this technology will be challenging.

Conclusions

Despite the shortcomings of the available published evidence, robotic-assisted surgery is emerging as an alternative to conventional open or laparoscopic approaches for a range of urological, cardiac and gynaecological procedures. After reviewing the relevant comparative evidence published in the last five years, it seems that robotic-assisted surgery is at least as efficacious as conventional open or laparoscopic surgery, and appears to offer the advantages of decreased blood loss and transfusions with resultant decreases in length of hospital stay without increasing the rate of severe complications. To date, operative times for robotic-assisted approaches have generally been equal to or longer than conventional approaches, although it is likely they have been influenced by the experience of the surgical team and are amenable to improvement with increased experience. These findings from the published literature seem to echo the experiences of the Australian surgeons using this technology who were interviewed for this report. Currently, it is difficult to compare robotic-assisted and conventional approaches with regard to cancer control due to a lack of sufficient follow-up, although positive surgical margin rates appear to be similar. Patient-related outcomes, such as urinary continence, erectile function, quality of life measures and pain appear to be similar but were also difficult to assess as they were generally poorly reported.

Many of the limitations of the published evidence used in this review would be overcome by the availability of concurrently-controlled trial evidence. Ideally, studies should randomly allocate patients to treatments and follow them up over a sufficient length of time to ensure that useful survival data can be obtained. A sufficient number of patients should be recruited so that planned subgroup analyses of factors thought to influence outcomes, such as prostate size in the case of radical prostatectomy, can be undertaken without compromising statistical validity. Well-validated functional outcome measures that measure outcomes of importance to patients should be used. It is likely that many of these issues are addressed in current ongoing trials of robotic-assisted surgery, the results of which should assist in more clearly defining its safety and efficacy compared to conventional approaches. Searches of the Clinical Trials Database, NHS CRD, NHS HTA, Current Controlled Trials and the Australian New Zealand Clinical Trials Registry identified 15 ongoing trials. While the majority of these trials are being conducted in the United States, trials are now also underway in Canada, the United Kingdom, Sweden, Germany and Switzerland. In addition, one trial is being conducted in Australia at the Queensland Centre for Gynaecological Cancer, in collaboration with a US centre. While the undertaking of multicentre RCTs of robotic-assisted surgery is desirable, the problems inherent in attempting to randomise patients who are actively seeking

treatment with this technology, which at present is primarily available in private hospitals in Australia, may mean that it is difficult.

Acknowledgements

The authors wish to acknowledge the following individuals for their valuable assistance during the preparation of this review:

- Dr Aubrey Almeida, Epworth Richmond Hospital, Victoria
- Ms Megan Cahill, ACT Department of Health, Australian Capital Territory
- Ms Jo De Garis, Epworth Richmond Hospital, Victoria
- Dr Nigel Dunglison, Royal Brisbane and Women's Hospital, Queensland
- Dr Paul Fennessy, Department of Human Services, Victoria
- Dr Thomas Manolitsas, Epworth Eastern Hospital, Victoria
- Mr William McHugh, Prostate Cancer Foundation of Australia
- Mr John Stubbs, Cancer Voices Australia
- Dr Peter Sutherland, Royal Adelaide Hospital, South Australia
- Dr Peter Swindle, Greenslopes Private Hospital, Queensland
- Associate Professor Justin Vivian, St John of God Hospital, Western Australia
- Associate Professor David Webb, Epworth Eastern Hospital, Victoria

References

Abraham JB, Young JL, Box GN, Lee HJ, Deane LA, Ornstein DK. Comparative analysis of laparoscopic and robot-assisted radical cystectomy with ileal conduit urinary diversion. *J Endourol* 2007; **21**(12): 1473-1480.

Advincula AP, Xu X, Goudeau S, Ransom SB. Robot-assisted laparoscopic myomectomy versus abdominal myomectomy: a comparison of short-term surgical outcomes and immediate costs. *J Minim Invasive Gynecol* 2007; **14**(6): 698-705.

Australian Institute of Health and Welfare (AIHW) and Australasian Association of Cancer Registries (AACR) 2008. Cancer in Australia: an overview, 2008. Cancer series no. 46. Cat. no. CAN 42.Canberra: AIHW.

Australian Institute of Health and Welfare (AIHW): Coronary heart disease in Australia. Available at: www.aihw.gov.au/cvd/coronary_disease.cfm [Accessed March 2009].

Bell MC, Torgerson J, Seshadri-Kreaden U, Suttle AW, Hunt S. Comparison of outcomes and cost for endometrial cancer staging via traditional laparotomy, standard laparoscopy and robotic techniques. *Gynecol Oncol* 2008; **111**(3): 407-411.

Bernie JE, Venkatesh R, Brown J, Gardner TA, Sundaram CP. Comparison of laparoscopic pyeloplasty with and without robotic assistance. *JSLS* 2005; **9**(3): 258-261.

Boggess JF, Gehrig PA, Cantrell L, Shafer A, Ridgway M, Skinner EN, Fowler WC. A comparative study of 3 surgical methods for hysterectomy with staging for endometrial cancer: robotic assistance, laparoscopy, laparotomy. *Am J Obstet Gynecol* 2008a; **199**(4): 360-369.

Boggess JF, Gehrig PA, Cantrell L, Shafer A, Ridgway M, Skinner EN, Fowler WC. A case-control study of robot-assisted type III radical hysterectomy with pelvic lymph node dissection compared with open radical hysterectomy. *Am J Obstet Gynecol* 2008b; **199**(4): 357.

Caballero Romeu JP, Palacios RJ, Pereira Arias JG, Gamarra QM, Astobieta OA, Ibarluzea GG. Radical prostatectomy: evaluation of learning curve outcomes laparoscopic and robotic-assisted laparoscopic techniques with radical retropubic prostatectomy. *Actas Urol Esp* 2008; **32**(10): 968-975.

Caruso RP, Phillips CK, Kau E, Taneja SS, Stifelman MD. Robot assisted laparoscopic partial nephrectomy: initial experience. *J Urol* 2006; **176**(1): 36-39.

Chan RC, Barocas DA, Chang SS, Herrell SD, Clark PE, Baumgartner R, Smith JA, Cookson MS. Effect of a large prostate gland on open and robotically assisted laparoscopic radical prostatectomy. *BJU Int* 2008; **101**(9): 1140-1144.

Chitwood WR, Jr. Current status of endoscopic and robotic mitral valve surgery. *Ann Thorac Surg* 2005; **79**(6): S2248-S2253.

Cook DJ, Mulrow CD, Haynes BR. Systematic reviews: synthesis of best evidence for clinical decisions. *Ann Intern Med* 1997; **126**(5): 376–380.

DeNardis SA, Holloway RW, Bigsby GE, Pikaart DP, Ahmad S, Finkler NJ. Robotically assisted laparoscopic hysterectomy versus total abdominal hysterectomy and lymphadenectomy for endometrial cancer. *Gynecol Oncol* 2008; **111**(3): 412-417.

Device Technologies Australia Pty Ltd, 2009. Available at: www.device.com.au [Accessed December 10 2008].

Dharia Patel SP, Steinkampf MP, Whitten SJ, Malizia BA. Robotic tubal anastomosis: surgical technique and cost effectiveness. *Fertil Steril* 2008; **90**(4): 1175-1179.

Food and Drug Administration (FDA). Computer-assisted surgery: An update. Last updated 2005. http://www.fda.gov/fdac/features/2005/405_computer.html [Accessed December 10 2008].

Ficarra V, Novara G, Artibani W, Cestari A, Galfano A, Graefen M, Guazzoni G, Guillonneau B, Menon M, Montorsi F, Patel V, Rassweiler J, van Poppel H. Retropubic, laparoscopic, and robot-assisted radical prostatectomy: a systematic review and cumulative analysis of comparative studies. *Eur Urol* 2009 Jan 25 (Epub ahead of print).

Folliguet T, Vanhuyse F, Constantino X, Realli M, Laborde F. Mitral valve repair robotic versus sternotomy. *Eur J Cardiothorac Surg* 2006; **29**(3): 362-366.

Gehrig PA, Cantrell LA, Shafer A, Abaid LN, Mendivil A, Boggess JF. What is the optimal minimally invasive surgical procedure for endometrial cancer staging in the obese and morbidly obese woman? *Gynecol Oncol* 2008; **111**(1): 41-45.

Geller EJ, Siddiqui NY, Wu JM, Visco AG. Short-term outcomes of robotic sacrocolpopexy compared with abdominal sacrocolpopexy. *Obstet Gynecol* 2008; **112**(6): 1201-1206.

Guru KA, Wilding GE, Piacente P, Thompson J, Deng W, Kim HL, Mohler J, O'Leary K. Robot-assisted radical cystectomy versus open radical cystectomy: assessment of postoperative pain. *Can J Urol* 2007; **14**(6): 3753-3756.

Hakimi AA, Blitstein J, Feder M, Shapiro E, Ghavamian R. Direct comparison of surgical and functional outcomes of robotic-assisted versus pure laparoscopic radical prostatectomy: single-surgeon experience. *Urology* 2009; **73**(1):119-23.

Hemal AK and Kumar A. A prospective comparison of laparoscopic and robotic radical nephrectomy for T1-2N0M0 renal cell carcinoma. *World J Urol* 2009; **27**(1): 89-94.

Higgins JPT, Green S. Cochrane handbook for systematic reviews of interventions 4.2.5 [updated May 2005]. *The Cochrane Library*, Issue 3, 2005. Chichester, UK: John Wiley and Sons, Ltd.

Intuitive Surgical Inc, 2009. Available at: www.intuitivesurgical.com [Accessed December 10 2008].

Ko EM, Muto MG, Berkowitz RS, Feltmate CM. Robotic versus open radical hysterectomy: a comparative study at a single institution. *Gynecol Oncol* 2008; **111**(3): 425-430.

Lambaudie E, Houvenaeghel G, Walz J, Bannier M, Buttarelli M, Gurriet B, De Laparrent T, Blache JL. Robot-assisted laparoscopy in gynecologic oncology. *Surg Endosc* 2008; **22**(12): 2743-2747.

Laurila TA, Huang W, Jarrard DF. Robotic-assisted laparoscopic and radical retropubic prostatectomy generate similar positive margin rates in low and intermediate risk patients. *Urol Oncol* 2008 Jul 18 (Epub ahead of print).

Link RE, Bhayani SB, Kavoussi LR. A prospective comparison of robotic and laparoscopic pyeloplasty. *Ann Surg* 2006; **243**(4): 486-491.

Magrina JF, Kho RM, Weaver AL, Montero RP, Magtibay PM. Robotic radical hysterectomy: comparison with laparoscopy and laparotomy. *Gynecol Oncol* 2008; **109**(1): 86-91.

Medicare Australia. 2009. Available at: www9.health.gov.au/mbs/ [Accessed March 2009].

Menon M. Robotic radical retropubic prostatectomy. *BJU Int* 2003; **91**(3): 175–176.

Murphy DG, Hall R, Tong R, Goel R, Costello AJ. Robotic technology in surgery: current status in 2008. *ANZ J Surg* 2008; **78**(5): 1076–1081.

Nezhat FR, Datta MS, Liu C, Chuang L, Zakashansky K. Robotic radical hysterectomy versus total laparoscopic radical hysterectomy with pelvic lymphadenectomy for treatment of early cervical cancer. *JSLS* 2008a; **12**(3): 227-237.

Nezhat F. Minimally invasive surgery in gynecologic oncology: laparoscopy versus robotics. *Gynecol Oncol* 2008b; **111**(2 Suppl): S29-S32.

Nezhat C, Lavie O, Hsu S, Watson J, Barnett O, Lemyre M. Robotic-assisted laparoscopic myomectomy compared with standard laparoscopic myomectomy-a retrospective matched control study. *Fertil Steril* 2008c Apr 18 (Epub ahead of print).

NHMRC, 2000. How to use the evidence: assessment and application of scientific evidence, National Health and Medical Research Council, Canberra, Australia.

Payne TN and Dauterive FR. A comparison of total laparoscopic hysterectomy to robotically assisted hysterectomy: surgical outcomes in a community practice. *J Minim Invasive Gynaecol* 2008; **15**(3): 286-91.

Rodgers A K, Goldberg J M, Hammel J P, Falcone T. Tubal anastomosis by robotic compared with outpatient minilaparotomy. *Obstet Gynecol* 2007; **109**(6): 1375-1380.

Schroeck FR, Sun L, Freedland SJ, Albala DM, Mouraviev V, Polascik TJ, Moul JW. Comparison of prostate-specific antigen recurrence-free survival in a contemporary cohort of patients undergoing either radical retropubic or robot-assisted laparoscopic radical prostatectomy. *BJU Int* 2008; **102**(1): 28-32.

Seamon LG, Cohn DE, Henretta MS, Kim KH, Carlson MJ, Phillips GS, Fowler JM. Minimally invasive comprehensive surgical staging for endometrial cancer: Robotics or laparoscopy? *Gynecol Oncol* 2009; **113**(1): 36-41.

Sert B and Abeler V. Robotic radical hysterectomy in early-stage cervical carcinoma patients, comparing results with total laparoscopic radical hysterectomy cases. The future is now? *Int J Med Robot* 2007; **3**(3): 224-228.

Srinualnad S. Early experience of robotic assisted laparoscopic radical prostatectomy. *J Med Assoc Thai* 2008; **91**(3): 377-382.

Sterrett S, Mammen T, Nazemi T, Galich A, Peters G, Smith L, Balaji KC. Major urological oncological surgeries can be performed using minimally invasive robotic or laparoscopic methods with similar early perioperative outcomes compared to conventional open methods. *World J Urol* 2007; **25**(2): 193-198.

Tabata M and Cohn LH. Minimally invasive mitral valve repair with and without robotic technology in the elderly. *Am J Geriatr Cardiol* 2006; **15**(5): 306-310.

Trabulsi EJ, Linden RA, Gomella LG, McGinnis DE, Strup SE, Lallas CD. The addition of robotic surgery to an established laparoscopic radical prostatectomy program: effect on positive surgical margins. *Can J Urol* 2008; **15**(2): 3994-3999.

Veljovich DS, Paley PJ, Drescher CW, Everett EN, Shah C, Peters WA, III. Robotic surgery in gynecologic oncology: program initiation and outcomes after the first year with comparison with laparotomy for endometrial cancer staging. *Am J Obstet Gynecol* 2008; **198**(6): 679.

Wang AJ and Bhayani SB. Robotic partial nephrectomy versus laparoscopic partial nephrectomy for renal cell carcinoma: single-surgeon analysis of >100 consecutive procedures. *Urology* 2009; **73**(2): 306-310.

Wang GJ, Barocas DA, Raman JD, Scherr DS. Robotic vs open radical cystectomy: prospective comparison of perioperative outcomes and pathological measures of early oncological efficacy. *BJU Int* 2007; **101**(1): 89-93.

Webb DR, Sethi K, Gee K. An analysis of the causes of bladder neck contracture after open and robot-assisted laparoscopic radical prostatectomy. *BJU Int* 2008; **103**(7): 957-63.

White MA, De Haan AP, Stephens DD, Maatman TK, Maatman TJ. Comparative analysis of surgical margins between radical retropubic prostatectomy and RALP: are patients sacrificed during initiation of robotics program? *Urology* 2009; **73**(3): 567-71.

Weise ES and Winfield HN. Robotic computer-assisted pyeloplasty versus conventional laparoscopic pyeloplasty. *J Endourol* 2006; **20**(10): 813-819.

Woo YJ and Nacke EA. Robotic minimally invasive mitral valve reconstruction yields less blood product transfusion and shorter length of stay. *Surgery* 2006; **140**(2): 263-267.

Yanke BV, Lallas CD, Pagnani C, McGinnis DE, Bagley DH. The minimally invasive treatment of ureteropelvic junction obstruction: a review of our experience during the last decade. *J Urol* 2008; **180**(4): 1397-1402.

Appendix A Excluded studies

Urological procedures

Reviews/Health technology assessments deemed ineligible

Adams E. Bibliography: Robotic surgery -Update 2006. VA Technology Assessment Program (VATAP) 2006.

Australian Safety and Efficacy Register of New Interventional Procedures – Surgical. Laparoscopic radical prostatectomy: a systematic review. Report no 48. Stepney: Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S) 2005: 118.

Caceres F, Sanchez C, Martinez-Pineiro L, Tabernero A, Alonso S, Cisneros J, Cabrera Castillo P M, Alvarez Maestro M, Martin Hernandez M, Perez-Utrilla Perez M, de la Pena JJ. Laparoscopic radical prostatectomy versus robotic. *Arch Esp Urol* 2007; **60**(4): 430-438.

Dasgupta P and Kirby RS. Outcomes of robotic assisted radical prostatectomy. *Int J Urol* 2009; **16**(3): 244-248.

Delaney CP, Lynch AC, Senagore AJ, Fazio VW. Comparison of robotically performed and traditional laparoscopic colorectal surgery. *Dis Colon Rectum* 2003; **46**(12): 1633-1639.

El Hakim A and Tweari A. Robotic prostatectomy - a review. *Med Gen Med* 2004; **6**(4): 20.

El Hakim A, Leung RA, Tewari A. Robotic prostatectomy: a pooled analysis of published literature. *Expert Rev Anticancer Ther* 2006; **6**(1): 11-20.

Ficarra V, Cavalleri S, Novara G, Aragona M, Artibani W. Evidence from robot-assisted laparoscopic radical prostatectomy: a systematic review. *Eur Urol* 2007; **51**(1): 45-55.

FinOHTA. Robotic assisted prostatectomy (project). Helsinki: Finnish Office for Health Care Technology Assessment (FinOHTA).

Frota R, Turna B, Barros R, Gill IS. Comparison of radical prostatectomy techniques: open, laparoscopic and robotic assisted. *Int Braz J Urol* 2008; **34**(3): 259-268.

Hakimi AA, Feder M, Ghavamian R. Minimally invasive approaches to prostate cancer: a review of the current literature. *Urol J* 2007; **4**(3): 130-137.

HAYES, Inc. Robotically assisted prostatectomy. Lansdale, PA: HAYES, Inc 2004: 29.

Herrmann T R, Rabenalt R, Stolzenburg J U, Liatsikos E N, Imkamp F, Tezval H, Gross A J, Jonas U, Burchardt M. Oncological and functional results of open, robot-assisted and laparoscopic radical prostatectomy: does surgical approach and surgical experience matter? *World J Urol* 2007; **25**(2): 149-160.

Kaul S and Menon M. Robotics in laparoscopic urology. *Minim Invasive Ther Allied Technol* 2005; **14**(2): 62-70.

Lam TB, Simpson M, Pennet L, Nabi G, Shelly M, Gillatt D, Swami S, N'Dow J, BAUS Section of Oncology. Surgical management of localised prostate cancer. Cochrane review protocol.

Llanos Mendez A, Villegas Portero R. Robot-assisted surgery using da Vinci robot telemanipulation in prostatectomy. Andalusian Agency for Health Technology Assessment (AETSA) 2007.

Martinez-Salamanca JI, Allona Almagro A. Radical prostatectomy: open, laparoscopic and robotic - looking for a new gold standard? *Actas Urologicas Espanolas* 2007; **31**(4): 316-327.

Murphy DG, Hall R, Tong R, Goel R, Costello AJ. Robotic technology in surgery: current status in 2008. *ANZ J Surg* 2008; **78**(12): 1076-1081.

Parsons JK and Bennett JL. Outcomes of retropubic, laparoscopic, and robotic-assisted prostatectomy. *Urology* 2008; **72**(2): 412-416.

Rassweiler J, Hruza M, Teber D, Su LM. Laparoscopic and robotic assisted radical prostatectomy: critical analysis of the results. *Eur Urol* 2006; **49**(4): 612-624.

Shah KK, Louie M, Thaly RK, Patel VR. Robot assisted laparoscopic pyeloplasty: a review of the current status. *Int J Med Robot* 2007; **3**: 35-40.

Steinberg PL, Merguerian PA, Bihrle W, Heaney JA, Seigne JD. A da Vinci robot system can make sense for a mature laparoscopic prostatectomy program. *JSLS* 2008; **12**(1): 9-12.

Tooher R, Pham C. The da Vinci surgical robotic system: Technology overview. ASERNIP-S Report No. 45. Adelaide, South Australia, 2004.

Tooher R, Swindle P, Woo H, Miller J, Maddern G. Laparoscopic radical prostatectomy for localized prostate cancer: a systematic review of comparative studies. *J Urol* 2006; **175**(6): 2011-2017.

Tooher R, Swindle P, Woo H, Miller J, Maddern G. Laparoscopic radical prostatectomy: accelerated systematic review. North Adelaide, S. Australia, Australia: Royal Australasian College of Surgeons, Australian Safety and Efficacy Register of New Interventional Procedures (ASERNIP) - Surgical. ASERNIP-S Report; 48. 2005.

Wexner SD, Bergamaschi R, Lacy A, Udo J, Brolmann H, Kennedy RH, John H. The current status of robotic pelvic surgery: results of a multinational interdisciplinary consensus conference. *Surg Endosc* 2009; **23**(2): 438-443.

Wilt TJ, MacDonald R, Rutks I, Shamliyan TA, Taylor BC, Kane RL. Systematic review: comparative effectiveness and harms of treatments for clinically localized prostate cancer. *Ann Intern Med* 2008; **148**(6): 435-448.

Primary studies deemed ineligible

Ahlering TE. Robotic versus laparoscopic radical prostatectomy. *Nat Clin Pract Urol* 2004; **1** (2): 58-59.

Ball AJ, Gambill B, Fabrizio MD, Davis JW, Given RW, Lynch DF, Shaves M, Schellhammer PF. Prospective longitudinal comparative study of early health-related quality-of-life outcomes in patients undergoing surgical treatment for localized

prostate cancer: a short-term evaluation of five approaches from a single institution. *J Endourol* 2006; **20**(10): 723-731.

Bhayani SB, Link RE, Varkarakis JM, Kavoussi LR. Complete daVinci versus laparoscopic pyeloplasty: cost analysis. *J Endourol* 2005; **19**(3): 327-332.

Boris RS, Kaul SA, Sarle RC, Stricker HJ. Radical prostatectomy: a single surgeon comparison of retropubic, perineal, and robotic approaches. *Can J Urol* 2007; **14**(3): 3566-3570.

Burgess SV, Atug F, Castle EP, Davis R, Thomas R. Cost analysis of radical retropubic, perineal, and robotic prostatectomy. *J Endourol* 2006; **20**(10): 827-830.

Galich A, Sterrett S, Nazemi T, Pohlman G, Smith L, Balaji KC. Comparative analysis of early perioperative outcomes following radical cystectomy by either the robotic or open method. *JSLS* 2006; **10**(2): 145-150.

Guillonneau BD. Laparoscopic versus robotic radical prostatectomy. *Nat Clin Pract Urol* 2005; **2**(2): 60-61.

Ham WS. Comparison of open versus robotic radical prostatectomy in clinically advanced prostate cancer. *Korean J Urol* 2008; **49**(10): 886-892.

Hegarty NJ and Kaouk JH. Radical prostatectomy: a comparison of open, laparoscopic and robot-assisted laparoscopic techniques. *Can J Urol* 2006; **13** (Suppl 1): 56-61.

Kaufman MR, Smith JA, Jr., Baumgartner RG, Wells N, Chang SS, Herrell SD, Cookson MS. Positive influence of robotically assisted laparoscopic prostatectomy on the collaborative-care pathway for open radical prostatectomy. *BJU Int* 2006; **97**(3): 473-475.

Kohl SK, Balaji KC, Smith LM, Wilson NP, Johansson SL, Sterrett SP, Abrahams NA. Clinical significance of benign glands at surgical margins in robotic radical prostatectomy specimens. *Urology* 2007; **69**(6): 1112-1116.

Lepor H. Open versus robotic radical prostatectomy. *Urol Oncol* 2006; **24**(2): 91-93.

Lotan Y, Cadeddu JA, Gettman MT. The new economics of radical prostatectomy: cost comparison of open, laparoscopic and robot assisted techniques. *J Urol* 2004; **172**(4 Pt 1): 1431-1435.

Menon M, Shrivastava A, Kaul 5, Badani KK, Fumo M, Bhandari M, Peabody JO, Vattikuti Institute prostatectomy: contemporary technique and analysis of results. *Eur Urol* 2007; **51**(3): 648-57; discussion 657-8.

Menon M, Shrivastava A, Tewari A. Laparoscopic radical prostatectomy: conventional and robotic. *Urology* 2005; **66**(5 Suppl): 101-104.

Menon M, Tewari A, Peabody JO, Shrivastava A, Kaul S, Bhandari A, Hemal AK. Vattikuti Institute prostatectomy, a technique of robotic radical prostatectomy for management of localized carcinoma of the prostate: experience of over 1100 cases. *Urol Clin North Am* 2004; **31**(4): 701-717.

Mouraviev V, Nosnik I, Sun L, Robertson CN, Walther P, Albala D, Moul JW, Polascik TJ. Financial comparative analysis of minimally invasive surgery to open surgery for

localized prostate cancer: a single-institution experience. *Urology* 2007; **69**(2): 311-314.

Nazemi T, Galich A, Sterrett S, Klingler D, Smith L, Balaji KC. Radical nephrectomy performed by open, laparoscopy with or without hand-assistance or robotic methods by the same surgeon produces comparable perioperative results. *Int Braz J Urol* 2006; **32**(1): 15-22.

Pruthi RS and Wallen EM. Robotic assisted laparoscopic radical cystoprostatectomy: operative and pathological outcomes. *J Urol* 2007; **178**(3 Pt 1): 814-818.

Renoult E, Hubert J, Ladriere M, Billaut N, Mourey E, Feuillu B, Kessler M. Robot-assisted laparoscopic and open live-donor nephrectomy: a comparison of donor morbidity and early renal allograft outcomes. *Nephrol Dial Transplant* 2006; **21**(2): 472-477.

Rozet F, Harmon J, Cathelineau X, Barret E, Vallancien G. Robot-assisted versus pure laparoscopic radical prostatectomy. *World J Urol* 2006; **24**(2): 171-179.

Scales CD, Jr., Jones PJ, Eisenstein EL, Preminger GM, Albala DM. Local cost structures and the economics of robot assisted radical prostatectomy. *J Urol* 2005; **174**(6): 2323-2329.

Sharma S, Kim HL, Mohler JL. Routine pelvic drainage not required after open or robotic radical prostatectomy. *Urology* 2007; **69**(2): 330-333.

Tewari AK, Jhaveri JK, Surasi K, Patel N, Tan GY. Benefit of robotic assistance in comparing outcomes of minimally invasive versus open radical prostatectomy. *J Clin Oncol* 2008; **26**(30): 4999-5000.

Tewari A, Kaul S, Menon M. Robotic radical prostatectomy: a minimally invasive therapy for prostate cancer. *Curr Urol Rep* 2005; **6**(1): 45-48.

Tseng TY, Cancel QV, Fesperman SF, Kuebler HR, Sun L, Robertson CN, Polascik TJ, Moul JW, Vieweg J, Albala DM, Dahm P. The role of early adopter bias for new technologies in robot assisted laparoscopic prostatectomy. *J Urol* 2007; **177**(4): 1318-1323.

Wood DP, Schulte R, Dunn RL, Hollenbeck BK, Saur R, Wolf JS, Jr., Montie JE. Short-term health outcome differences between robotic and conventional radical prostatectomy. *Urology* 2007; **70**(5): 945-949.

Eligible primary studies not included individually as covered in the systematic review by Ficarra et al 2009

Ahlering TE, Woo D, Eichel L, Lee DI, Edwards R, Skarecky DW. Robot-assisted versus open radical prostatectomy: a comparison of one surgeon's outcomes. *Urology* 2004; **63**(5): 819-822.

Farnham SB, Webster TM, Herrell SD, Smith JA, Jr. Intraoperative blood loss and transfusion requirements for robotic-assisted radical prostatectomy versus radical retropubic prostatectomy. *Urology* 2006; **67**(2): 360-363.

Fracalanza S, Ficarra V, Cavalleri S, Galfano A, Novara G, Mangano A, Plebani M, Artibani W. Is robotically assisted laparoscopic radical prostatectomy less invasive than retropubic radical prostatectomy? Results from a prospective, unrandomized, comparative study. *BJU Int* 2008; **101**(9): 1145-1149.

Hu JC, Nelson RA, Wilson TG, Kawachi MH, Ramin SA, Lau C, Crocitto LE. Perioperative complications of laparoscopic and robotic assisted laparoscopic radical prostatectomy. *J Urol* 2006; **175**(2): 541-546.

Joseph JV, Vicente I, Madeb R, Erturk E, Patel HR. Robot-assisted vs pure laparoscopic radical prostatectomy: are there any differences? *BJU Int* 2005; **96**(1): 39-42.

Krambeck AE, Dimarco DS, Rangel LJ, Bergstralh EJ, Myers RP, Blute ML, Gettman MT. Radical prostatectomy for prostatic adenocarcinoma: a matched comparison of open retropubic and robot-assisted techniques. *BJU Int* 2009; **103**(4): 448-453.

Miller J, Smith A, Kouba E, Wallen E, Pruthi RS. Prospective evaluation of short-term impact and recovery of health related quality of life in men undergoing robotic assisted laparoscopic radical prostatectomy versus open radical prostatectomy. *J Urol* 2007; **178**(3 Pt 1): 854-858.

Nelson B, Kaufman M, Broughton G, Cookson MS, Chang SS, Herrell SD, Baumgartner RG, Smith JA, Jr. Comparison of length of hospital stay between radical retropubic prostatectomy and robotic assisted laparoscopic prostatectomy. *J Urol* 2007; **177**(3): 929-931.

Rozet F, Jaffe J, Braud G, Harmon J, Cathelineau X, Barret E, Vallancien G. A direct comparison of robotic assisted versus pure laparoscopic radical prostatectomy: a single institution experience. *J Urol* 2007; **178**(2): 478-482.

Smith JA, Jr., Chan RC, Chang SS, Herrell SD, Clark PE, Baumgartner R, Cookson MS. A comparison of the incidence and location of positive surgical margins in robotic assisted laparoscopic radical prostatectomy and open retropubic radical prostatectomy. *J Urol* 2007; **178**(6): 2385-2390.

Webster TM, Herrell SD, Chang SS, Cookson MS, Baumgartner RG, Anderson LW, Smith JA, Jr. Robotic assisted laparoscopic radical prostatectomy versus retropubic radical prostatectomy: a prospective assessment of postoperative pain. *J Urol* 2005; **174**(3): 912-914.

Cardiac procedures

Reviews/Health technology assessments deemed ineligible

HAYES, Inc. Robotically assisted coronary artery bypass surgery. Lansdale, PA: HAYES, Inc 2004.

Modi P and W.R. Minimally invasive mitral valve surgery: a systematic review and meta-analysis. *European J Cardiothorac Surg* 2008; **34**(5): 943-952.

National Institute for Clinical Excellence. Totally endoscopic robotically assisted coronary artery bypass grafting. London: National Institute for Clinical Excellence (NICE). Interventional Procedure Guidance 128. 2005.

Nio D, Diks J, Bemelman WA, Wisselink W, Legemate DA. Laparoscopic vascular surgery: a systematic review. *Eur J Vasc Endovasc Surg* 2007; **33**(3): 263-271.

Primary studies deemed ineligible

Ak K, Aybek T, Wimmer-Greinecker G, Ozaslan F, Bakhtiary F, Moritz A, Dogan S. Evolution of surgical techniques for atrial septal defect repair in adults: a 10-year single-institution experience. *J Thorac Cardiovasc Surg* 2007; **134**(3): 757-764.

Chitwood WR, Jr., Kypson AP, Nifong LW. Robotic mitral valve surgery: a technologic and economic revolution for heart centers. *Am Heart Hosp J* 2003; **1**(1): 30-39.

Kakeji Y, Konishi K, Ieiri S, Yasunaga T, Nakamoto M, Tanoue K, Baba H, Maehara Y, Hashizume M. Robotic laparoscopic distal gastrectomy: a comparison of the da Vinci and Zeus systems. *Int J Med Robot* 2006; **2**(4): 299-304.

Kiaii B, McClure RS, Stitt L, Rayman R, Dobkowski WB, Jablonsky G, Novick RJ, Boyd WD. Prospective angiographic comparison of direct, endoscopic, and telesurgical approaches to harvesting the internal thoracic artery. *Ann Thorac Surg* 2006; **82**(2): 624-628.

Kypson AP, Nifong LW, Chitwood WR, Jr. Robotic cardiac surgery. *J Long Term Eff Med Implants* 2003; **13**(6): 451-464.

Mair H, Jansens JL, Lattouf OM, Reichart B, Dabritz S. Epicardial lead implantation techniques for biventricular pacing via left lateral mini-thoracotomy, video-assisted thoracoscopy, and robotic approach. *Heart Surg Forum* 2003; **6**(5): 412-417.

Mierdl S, Byhahn C, Lischke V, Aybek T, Wimmer-Greinecker G, Dogan S, Viehmeyer S, Kessler P, Westphal K. Segmental myocardial wall motion during minimally invasive coronary artery bypass grafting using open and endoscopic surgical techniques. *Anesth Analg* 2005; **100**(2): 306-314.

Morgan JA, Thornton BA, Peacock JC, Hollingsworth KW, Smith CR, Oz MC, Argenziano M. Does robotic technology make minimally invasive cardiac surgery too expensive? A hospital cost analysis of robotic and conventional techniques. *J Card Surg* 2005; **20**(3): 246-251.

Gynaecological procedures

Reviews/Health technology assessments deemed ineligible

Dharia Patel SP and Falcone T. Robotics in reproductive medicine. *Fertil Steril* 2005; **84**(1): 1-11.

Hockel M. New techniques in the surgical treatment of cervical carcinoma: A systematic review. *Geburtshilfe und Frauenheilkunde* 2007; **67**(11): Nov.

Sroga J, Patel SD, Falcone T. Robotics in reproductive medicine. *Front Biosci* 2008; **13**: 1308-1317.

Primary studies deemed ineligible

Goldberg JM and Falcone T. Laparoscopic microsurgical tubal anastomosis with and without robotic assistance. *Hum Reprod* 2003; **18**(1): 145-147.

Magrina JF and Zanagnolo VL. Robotic surgery for cervical cancer. *Yonsei Med J* 2008; **49**(6): 879-885.

Muffly T, McCormick TC, Dean J, Bonham A, Hill RF. An evaluation of knot integrity when tied robotically and conventionally. *Am J Obstet Gynecol* 2009; **200**(5): e18-20.

Obermair A, Gebski V, Frumovitz M, Soliman PT, Schmeler KM, Levenback C, Ramirez PT. A phase III randomized clinical trial comparing laparoscopic or robotic radical hysterectomy with abdominal radical hysterectomy in patients with early stage cervical cancer. *J Minim Invasive Gynecol* 2008; **15**(5): 584-588.

Appendix B Interview questions

Clinical perspectives

Introduction

1. Could you first give us some background information about your work?
2. How did you first become involved in robotic-assisted surgery and why did you choose it? For which procedures do you use it?

Experience/training issues

3. What training do surgeons need/receive to use the da Vinci Surgical System? How long does this take?
4. What training of multidisciplinary staff is required?
5. Do you prefer robotic-assisted surgery to conventional surgical methods for any specific procedure(s)?
6. What are the advantages associated with robotic-assisted surgery?
7. What are the disadvantages and limitations of robotic-assisted surgery? What are the risks associated with it?
8. Do you still perform non-robotic surgeries? In what cases?
9. Which departments in your hospital use the da Vinci Surgical System? Can you provide the names of colleagues in other departments who use this system?
10. In your department, how many operations are performed each year using the da Vinci Surgical System?
11. What is the percentage of surgeons in your department that use the da Vinci robotic surgical system? Is this on a regular basis?
12. Are younger surgeons using the system more than older surgeons?

Technical issues

13. How does the set-up for robotic-assisted surgery differ from conventional surgical approaches?
14. Is the change over time between patients different with robotic-assisted surgery compared with conventional surgical approaches?
15. Surgeons lose tactile sensation with robotic-assisted surgery. What is your experience of this?

16. What happens if the da Vinci robotic surgical system mechanically fails during surgery?
17. If the da Vinci robotic surgical system does break down, how easily and within what timeframe can it be repaired?
18. How long on average does each surgery take?
19. How does the recovery time compare for robotic-assisted surgery versus other forms of surgery?
20. How often do patients need a follow-up operation after robotic-assisted surgery because of complications?
21. If the patient needs follow-up surgery, is it usually done using the robot or conventional means?

Patient issues

22. Would you recommend robotic-assisted surgery to all eligible patients over traditional surgery? What are your criteria for patient selection?
23. What are the patients' initial impressions/concerns when they first hear about robotic-assisted surgery?
24. What percentages of patients choose robotic-assisted surgery when given the option?

Cost issues

25. Does robotic-assisted surgery cost more than open surgery? What's the price differential?
26. What are the costs of robotic-assisted surgery for the patient? Does private health insurance cover this?
27. What are the maintenance costs and what has to be maintained regularly?

Jurisdictional health perspectives

1. What are your opinions of the da Vinci robotic surgical system?
2. In your jurisdiction, do any hospitals (public or private) have the da Vinci robotic surgical system? If yes:
    (a) Do you know for which procedures the robot is used for?
    (b) How are the machine costs paid for?
3. Do you think this is an improvement over conventional surgical approaches?
4. Have you been contacted by any surgeons/hospital administrators/patients regarding the da Vinci robotic surgical system?

5. Do you have any other concerns/comments regarding the da Vinci robotic surgical system?

Patient perspectives

1. Have you heard of robotic-assisted surgery/the da Vinci robotic surgical system?
2. Did you know that this approach was possible for radical prostatectomy?
3. Have any patients contacted you regarding robotic-assisted surgery for radical prostatectomy? If so, what were their thoughts/issues?
4. Robotic-assisted surgery is often more expensive than other approaches. Are you concerned about the costs?
5. Do you think that patients would choose robotic-assisted surgery over other more conventional surgical approaches if it was recommended by their surgeon?
6. Do you have any other concerns/comments regarding robotic-assisted surgery/ the da Vinci robotic surgical system?