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Computer-Assisted Surgery Using Telemanipulators

An Evidence-Based Analysis

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The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

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ABBREVIATIONS AND ACRONYMS

CABG	Coronary arterial bypass graft
CCOHTA	Canadian Coordinating Office for Health Technology Assessment
CEDIT	Comité d'Evaluation et de Diffusion des Innovations Technologiques
USFDA	United States Food and Drug Administration
IMA	Internal mammary artery
ITA	Internal thoracic artery
MIDCAB	Minimally invasive CABG
NICE	National Institute for Clinical Excellence
PDA	Patent ductus arteriosus
RRP	Radical retropubic prostatectomy
VIP	Vattikuti Institute prostatectomy

EXECUTIVE SUMMARY

Objective

The objective of this health technology policy assessment was to determine the effectiveness and cost-effectiveness of computer-assisted surgery with telemanipulators.

The Technology

The technology for computer-assisted surgery with telemanipulators is a robotic arm that carries an endoscope while two other manipulator arms carry interchangeable tools, such as scissors and grippers. In a master-slave telemanipulator system, the master may consist of a joystick input system, or for surgery, may mimic the motion of the slave robot, such as the da Vinci and ZEUS surgical systems. These systems are capable of telerobotic surgery, or surgery from remote locations.

Review Strategy

The Cochrane and INAHTA databases yielded 4 health technology assessments or systematic reviews on computer-assisted surgery using telemanipulators. A search of MEDLINE and EMBASE January 1, 2001 to November 24, 2003 was conducted. This search produced 448 studies, of which 19 met the inclusion criteria.

Summary of Findings

Published health technology assessments indicate that there are limited data from studies, although there is initial evidence of the safety and efficacy of telemanipulators in some procedures when they are used at large academic centres for surgery on selected patients.
Most studies are Level 3 and 4 observational studies and assess a wide variety of surgical procedures.
Limited studies indicate the promise of telemanipulators, but their efficacy is not fully established. In some procedures, the advantages that telemanipulators may offer may also be achieved by non-robotic minimally invasive/laparoscopic techniques.
To date, cost-effectiveness has not been demonstrated.
Patients who have undergone robotic surgery must be followed to further define outcomes (e.g., long-term quality of the graft after coronary arterial bypass graft [CABG] surgery).
The exact role of computer-assisted surgery with telemanipulators has not been fully defined.
Telemanipulators should be used in procedures for which their performance offers the greatest advantage over non-computer-enhanced surgical procedures.

OBJECTIVE

The objective of this health technology policy assessment was to determine the effectiveness and cost-effectiveness of computer-assisted surgery with telemanipulators.

BACKGROUND

Clinical Need

Computer-assisted surgery with telemanipulators has been developed largely for procedures that require great precision. Currently, computer-assisted surgery has been used in a range of procedures that require surgeons to operate through multiple, small incisions. The most common applications are for laparoscopic and minimally invasive techniques, such as the following:

Urology for radical laparoscopic prostatectomy
General surgery for laparoscopic cholecystectomy (gall bladder removal), Nissen fundoplication (gastrointestinal antireflux surgery)
Cardiac and thoracic surgery for mitral valve repair, atrial septal defect repair, internal mammary artery (IMA) mobilization for coronary artery bypass grafting (CABG)

The main objective of the telemanipulator technologies is to overcome some of the reported[1] limitations of laparoscopic and other microsurgical techniques, such as an unstable camera platform, the limited motion (degrees of freedom) of straight laparoscopic instruments, 2-dimensional (as opposed to 3-dimensional) imaging, and poor ergonomics for the surgeon.

In addition, long-distance telerobotic surgery may offer specific advantages for remote novice surgeons during their early experiences with minimally invasive approaches to surgery. For example, few urologists have substantial experience with laparoscopy, and laparoscopic radical prostatectomy is a very difficult operation to perform.[2] Similarly, laparoscopic gastrointestinal operations are difficult operations to learn, master, and perform routinely.[1]

Davies[3] suggested that telemanipulator systems may be of benefit in soft tissue surgery, particularly in minimally invasive "keyhole" procedures. The use of a telemanipulator may overcome many problems of visualizing where the tips of the tools are located. On the other hand, the tendency for soft tissue to move when pressed or cut and to change shape may make robotic soft tissue interventions difficult.[3]

The Technology

In surgery using telemanipulators, also referred to as a master-slave telemanipulator system, surgeons operate programmable machines using computer-assisted technology.[3]

The master of telemanipulator systems mimics the motion of the slave robot. A robotic arm carries an endoscope while two other manipulator arms carry interchangeable tools, such as scissors and grippers. The surgeon has control over the field of view through voice, foot, or hand commands that move the camera arm of the telemanipulator. Another feature of telemanipulator systems is the "wrist" inside the body, which can angle tools and may be of value in tying knots for sutures inside the body.

The two main telemanipulator systems available are the da Vinci and ZEUS systems (Intuitive Surgical, Sunnyvale, CA). With the da Vinci surgical system, the surgeon steps on a foot switch that allows the control handles to move the camera arm. Two cameras that view through side-by-side lenses in the single endoscope provide 3-dimensional tissue discrimination. Although the picture is stable, it is limited in scope, and the surgeon must be sure to move the robotic arms only when they are in sight.[4] In the ZEUS system, the surgeon moves the camera arm with voice, foot, or hand commands. Both systems are capable of telerobotic surgery, that is, facilitating surgery from remote locations.

Limitations of the Technology

Limited Tensile Feedback

Davies[3] points out that, at this time, there is no sense of feel fed back from the master to the slave. The surgeon must use the endoscopic vision for monitoring the process, relying on visual clues to estimate the tension placed on tissues. Similarly, the surgeon cannot judge how tightly the instruments are grasping the tissues. Davies[3] considers this sense of feel or haptics a complex issue at the forefront of research and thinks that force-sensing systems at the slave are required to apply appropriate feedback forces to the master or surgeon. Furthermore, a realistic sense of feel requires more than simple force information. Rates of change in force and motion, as well as their interaction, are equally important in determining such aspects as tissue texture.[3]

Restricted Visual Field

The master controls develop considerable resistance to movement only when movement of an instrument is obstructed completely. Therefore, any motion of the instruments outside the robot's field of view risks visceral injury.[4] Additionally, serious lateral forces at the insertion site may develop if the remote pivot point is not positioned correctly.[4]

Guyton[4] stated that operations that are confined to a small field of view, such as cholecystectomy, may be accomplished more easily than are long, linear dissections such as internal mammary artery (IMA) mobilization during CABG procedures. Since movement from one end of a long field to another may cause serious interference between surgical arms and the camera arm, an additional surgeon is recommended to be near the patient to ensure patient safety.[4] The surgeon at the patient's side can adjust the position of the robotic arms during the operation to minimize interference.[4]

Need for Training

The experience and judgment of the surgeon are likely the most important factors that ensure a safe robotic procedure. [4] Surgical teams must complete mandatory safety training before using a telemanipulator. Deliberate, stepwise training maximizes the safety of successful applications.[4] The surgeon must master each individual action independently, combining actions into all or part of the procedure only after demonstrating proficiency. Guyton suggested that during this period of developing skills and procedures, robotic work should be protocol-driven and subject to careful ongoing scrutiny with prospective data collection.[4]

Space and Set-up Requirements

Telemanipulator systems need dedicated, specifically designed and wired operating rooms with more space than conventional operating rooms.[4] For storage outside the operating room, a small room is required. The video signal from da Vinci is generally broadcast on several slave monitors in the operating room.[4]

Rapid surveys with the camera are restricted through use of the controls, but are accomplished easily by manually detaching the endoscope from the robotic camera arm. Set-up flexibility can be limited because moving the camera from one port to another is time consuming.[4]

The set-up of the operating room varies with the procedure. Changing the set-up of the operating room from that needed for cholecystectomy to the set-up needed for fundoplication may be time consuming when the device is in the same operating room.

For mitral valve procedures, a 4 cm working port is still required for placement of an atrial retractor, as is patient-side assistance for needle, tissue, and suture retrieval.[5]

Potential Intraoperative Hazards

During surgery the instruments held by the robotic arms may collide inside a patient's chest or abdomen or there may be interference between the robotic arms moving over the patient.[6] Time latency, the time delay of milliseconds between the telerobotic surgeon moving and the remote robotic arms mimicking it, needs to be resolved.[6]

Alternative Technologies

Alternative technologies to telemanipulators are laparoscopic surgery, endoscopic minimally invasive surgery (e.g., minimally invasive coronary artery bypass grafting), and conventional procedures (e.g., coronary artery bypass grafting).

Ontario Facilities Where the Technology is Used

Centre for Minimal Access Surgery, (CMAS) St. Joseph's Healthcare and McMaster University. The Centre has 3 partner sites: North Bay General Hospital, Complexe Hospitalier de la Sagamie in Chicoutimi, Quebec and the Stanton Regional Health Board in Yellowknife, Northwest Territories. Canadian Surgical Technologies and Advanced Robotics (CSTAR), London Health Sciences Centre and Lawson Health Research Institute.

Regulatory Status

The United States Food and Drug Administration (USFDA)[7] stated that the ZEUS MicroWrist Surgical System, or ZEUS system, and accessories are intended to be used to

… assist a surgeon during procedures such as laparoscopic cholecystectomy and Nissen fundoplication, to hold and position an endoscope, and to control laparoscopic instruments in performance of the surgical tasks of grasping, sharp cutting, blunt dissection, electrocautery and suturing with knot placement. The ZEUS system is intended to be used by surgeons who are trained in minimally invasive surgery, have successfully completed a ZEUS system training program, and are certified in accordance with their respective hospital's customary practice for ZEUS system use. The ZEUS MicroWrist surgical system is intended to be used in an operating room environment in which the ZEUS system, the operating surgeon and patient are in the same room.[7]

The ZEUS MicroWrist Surgical System is licensed by Health Canada (License # 39262, Class 4). Health Canada categorizes all medical devices based on the risk associated with their use. All medical devices are grouped into four classes with Class I devices presenting the lowest potential risk (e.g., a thermometer) and Class IV devices presenting the greatest potential risk (e.g., pacemakers).[8] Health Canada stated that the ZEUS system "is intended to be used as a platform for holding/positioning an endoscope and accurately controlling endoscopic instruments and accessories during cardiac and other surgical procedures. The endoscopic instruments are intended for endoscopic manipulation of tissue, including retraction and exposure, dissection, cutting, grasping, suturing, ligation, approximation, and controlling coagulation".[9]

The USFDA[10] stated that the da Vinci system is intended to

…assist in the accurate control of Intuitive Surgical endoscopic instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders and endoscopic retractors, stabilizers, electrocautery and accessories during laparoscopic surgical procedures such as cholecystectomy, Nissen fundoplication, radical prostatectomy, and general noncardiac thoracoscopic surgical procedures such as internal mammary artery mobilization. It is intended to be used by trained physicians in an operating room environment.

The da Vinci system is licensed by Health Canada (License # 27856, Class 4). Health Canada stated that the da Vinci system is "intended to assist in the accurate control of Intuitive Surgical endoscopic instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories during laparoscopic surgical procedures such as cholecystectomy or Nissen fundoplication and thoracoscopic surgical procedures such as internal mammary artery mobilization."[9]

According to the USFDA[11;12], the SOCRATES System (Intuitive Surgical, Sunnyvale, CA) is indicated for use in

…general thoracoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy for which a rigid laparoscope or endoscope is indicated for use. A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic and thorascopic anterior spinal fusion, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass grafting where endoscopic visualization is indicated and examination of the evacuated cardiac chamber during performance of valve replacement. Use of the SOCRATES system enables a remote surgeon to telecommunicate with any AESOP HR local controller through HERMES. This communication link allows the remote surgeon to assist the local surgeon with field of view positioning.

The SOCRATES System is not currently licensed by Health Canada.

LITERATURE REVIEW ON EFFECTIVENESS

Objective

To assess the effectiveness and cost-effectiveness of computer-assisted surgery with telemanipulators

Methods

Inclusion criteria

English language articles (January 1 2001–November 24, 2003)
Journal articles that report primary data on the effectiveness or cost-effectiveness of computer-assisted surgery using telemanipulators obtained in a clinical setting, or analysis of primary data maintained in registries or databases
Study design and methods must be clearly described
Systematic reviews, randomized controlled trials (RCTs), non-randomized controlled trials and/or cohort studies that have $\geq$20 patients, cost-effectiveness studies

Exclusion criteria

Duplicate publications (superseded by another publication by the same investigator group, with the same objective and data)
Non-English articles
Non-systematic reviews, letters and editorials
Animal and in-vitro studies
Case reports
Studies that do not examine the outcomes of interest

Intervention

Computer-assisted surgery with a telemanipulator
Controls do not undergo computer-assisted surgery with telemanipulators but receive optimal conventional medical management

Literature Search

Cochrane database of systematic reviews
ACP Journal Club
DARE
INAHTA
EMBASE
MEDLINE
Reference section from reviews and extracted articles

Outcomes of Interest

Mortality
Adverse effects

Length of operation
Length of hospitalization
Graft patency
Economic analysis data

RESULTS OF LITERATURE REVIEW

The Cochrane and INAHTA databases yielded 4 health technology assessments or systematic reviews on robotic surgery. A search of MEDLINE and EMBASE January 2001 to November 2003 was conducted. This search produced 448 studies of which 19 met the inclusion criteria. The quality of the included articles is presented below.

Quality of Evidence

Study Design	Level of Evidence	Number of Eligible Studies
Large RCT, systematic reviews of RCTs	1	
Large RCT unpublished but reported to an international scientific meeting	1(g)	
Small RCT	2	
Small RCT unpublished but reported to an international scientific meeting	2(g)	
Nonrandomized study with contemporaneous controls	3a	2
Nonrandomized study with historical controls	3b	2
Nonrandomized study presented at international conference	3(g)	
Surveillance (database or register)	4a	
Case series (multi-site)	4b	1
Case series (single site)	4c	14
Retrospective review, modelling	4d	
Case series presented at international conference	4(g)	

g=grey literature
Assessment of Evidence

Comité d'Evaluation et de Diffusion des Innovations Technologiques (CEDIT)

Created in 1982, the CEDIT is a hospital-based agency for the assessment of medical technology. The CEDIT is responsible for providing advice to the Director General of the Assistance Publique-Hôpitaux de Paris (APHP) on the "technical performance, efficacy, efficiency, and safety of innovative technologies" in APHP hospitals as well as their "economic, organizational, social and ethical consequences."[13]

In 1999, CEDIT[14]studied telemanipulators as aids to cardiac surgery. At that time the technology was considered to be at the research and development stage. The recommendation issued then was that an invitation to tender for a partnership between the APHP and the manufacturers be organized under stringent research protocols. Furthermore, the APHP sought advice from CEDIT regarding the opportunity of purchasing telemanipulator systems and on taking over maintenance costs for 2 da Vinci surgical systems that APHP had already purchased and installed with private funds.

Since 1999, 2 more hospitals have approached CEDIT regarding the potential purchase of a telemanipulator system.

In an update to the 1999 recommendation, CEDIT[15] in October 2002 stated that the literature on telemanipulators contained either descriptive data or feasibility reports.. For cardiac surgery, CEDIT stated that several teams have used a telemanipulator system to partially or fully perform CABG on a closed chest with the heart beating or arrested. For digestive, urologic and gynecologic procedures, telemanipulator systems have been used to study case series of patients undergoing cholecystectomy, prostatectomy, nephrectomy, and restoration of tubal patency.

CEDIT[15] stated that the indications for which the greatest benefits can be derived from these systems in terms of length of hospital stays and postoperative morbidity have not yet been defined. Similarly, the proportion of patients that could benefit from telemanipulator surgery is not known.[15] Furthermore, CEDIT stated that reports published by other evaluation agencies (ECRI, Canadian Coordinating Office for Health Technology Assessment and the National Horizon Scanning Centre) concluded that the role of robotic surgery systems is still undefined.

According to experts contacted by CEDIT, the first step to be taken before purchasing additional robotic systems is to use those currently installed.[15] In addition, the experts did not consider robotic systems appropriate for routine use.[15]

According to CEDIT in 2002, robotic systems need an evaluation of their clinical utility, setting aside the small-scale studies conducted in centres where teams go through the learning curve in isolation.[15] CEDIT recommended that a phased approach to the introduction of the technology must be adopted starting with studies on animals, cadavers, and then simulations.[15] It was recommended that only one primary surgical team is required per project working in a specific area. These specialized should pass on knowledge to other teams. Furthermore, CEDIT stated that randomized controlled multicentre trials including hundreds of patients are required to determine the benefit of robotic surgery compared with conventional minimally invasive surgery.[15]

In 2002, CEDIT considered that its 1999 recommendation concerning the use of telemanipulator robots as an aid to cardiac surgery was not implemented and that there was no change in the situation at Assistance Publique Hôpitaux de Paris.[15] CEDIT stated that APHP should be involved in evaluating the technology and provide funding for one or two carefully conducted projects.[15]

CEDIT[15] recommended that the 4 centres concerned should present a multidisciplinary project that should specify a 3-year program comprising the following:
A full description of the number and type of surgical procedures targeted to make optimal use of the telemanipulator system
The methods and evaluation criteria used for each of the series
The planned clinical research protocols
The organizational method used for the surgical unit and the teams, as validated by each of the wards concerned
The hygiene procedures as validated by the hospital's nosocomial disease control committee
If applicable, a detailed description of co-financing schemes and partnerships. Such partnerships may involve other surgical teams that are working on the same technique.

Canadian Coordinating Office for Health Technology Assessment

The following is a commentary from the February 2002 CCOHTA health technology assessment.[16]

Patient Group
CCOHTA stated that computer-assisted systems have the potential to replace other approaches to surgery for a range of surgical procedures. To date, the most common applications appear to have been laparoscopic techniques and microsurgery. Some computer-assisted systems have been used in cardiac surgery; however, the USFDA considers this application investigational.

Current Practice
Current practice includes a variety of conventional and minimally invasive surgical techniques. The disadvantages of current methods include adverse effects associated with surgeon fatigue and limits to the precision of surgical technique (e.g., hand tremor). However, fatigue associated with viewing a console may be an issue in use of computer-enhanced surgical systems during lengthy procedures.

The Evidence
CCOHTA stated that there is a lack of controlled clinical trials of this technology. In a study[17] associated with the USFDA approval of the da Vinci system, 113 cholecystectomies and fundoplications were compared with results for 132 patients who had conventional laparoscopic surgery. The computer-aided approach was comparable in safety and effectiveness to standard surgery, though it took 40 to 50 minutes longer to perform.

Several groups of investigators described large clinical case series. Overall findings were that computer-assisted procedures were successfully and safely completed. These include the following:

Chitwood et al.[18] 52 cases of mitral valve repair, cholecystectomy and fundoplication.
Chitwood et al.[19] 110 mitral valve repairs.
Mohr et al.[20] 131 CABG procedures and 17 mitral valve repairs
Kappert et al.[21] 61 CABG procedures
Prasad et al.[22] 19 CABG cases with favourable short term outcomes and no adverse events at 1 year follow-up

Smaller pilot studies included use of computer-assisted approaches for laparoscopic tubal anastamosis,[23] prostatectomy,[24] and pelvic lymph node dissection.[25]

Conclusion
CCOHTA concluded that computer-assisted surgical systems show promise as a means of improving the quality of certain surgical procedures. There are only limited data from clinical trials with these systems, though there is initial evidence of their safety and efficacy in some applications, when they are used in centres of excellence, for procedures on carefully selected patients. Neither their efficacy in terms of comparative patient outcomes nor their cost-effectiveness has been established. Advantages from quicker recovery and shorter hospital stays have already been achieved through the introduction of less invasive nonrobotic procedures. The benefit of computer-assisted surgery over the nonrobotic techniques is not clear.

National Horizon Scanning Centre

In January 2002, the National Horizon Scanning Centre[26] briefly summarized the indication, stage and research of the da Vinci and ZEUS system.

da Vinci
Indication: laparoscopy and minimally invasive procedures for general, digestive, thoracic, cardiac, urology, and vascular indications.

Stage: Conformité Européenne marked (or commonly referred to as CE marked, the European regulatory approval) and USFDA approved. There is one system in the United Kingdom at St. Mary's Hospital, London. There are more than 70 systems worldwide.
Research: Cardiac, digestive, and urology studies are ongoing in the United Kingdom. Published data consists of case series and small case studies. A series of 146 patients undergoing various laparoscopic surgeries including gastroplasties, cholecystectomies, and antireflux procedures reported the feasibility of robotic procedures.

ZEUS
Indication: Laparoscopic and thoracic procedures.
Stage: CE marked, USUSFDA approved. One system in the Royal Brompton Hospital, London. Forty-nine systems worldwide.
Research: No research of ZEUS was reported.

Alberta Heritage Foundation for Medical Research

The brief Alberta Heritage Foundation for Medical Research Tech Scan[27] prepared in July 2000 stated that marketing approval for the device represents a further step in the diffusion of computer aided surgical technology and that the scope of the da Vinci system is likely to widen to additional applications that have not yet been cleared by the USFDA. The introduction of such technology will raise a number of issues related to capital and recurrent costs of the system, theatre time, selection of patients and effects on health outcomes.

Studies Published Since the Review by the Canadian Coordinating Office of Health Technology Assessment

An updated literature search of the years January 2001-November 2003 produced 19 studies listed in Table 1. Details of each study are presented in Table 1. All studies used either the da Vinci or ZEUS surgical system. Most of the studies are case series. The studies that included a comparison group of patients are briefly discussed below.

■ Tewari et al.[28] conducted a single-centre study in the United States comparing patient outcomes after robot-assisted laparoscopic prostatectomy, (VIP, n=200) to the reference standard radical retropubic prostatectomy (RRP) with the "anatomical technique" (n=100). Inclusion criteria consisted of surgical candidates for prostatectomy. The choice between RRP and VIP was offered to all patients who had a 10-year life expectancy and had prostate cancer of Gleason score $\geq$6. Patients were assigned on the basis of their personal preferences. Follow-up was for 556 days in the RRP group and 236 days in the VIP group. No explicit explanation was provided regarding this difference in follow-up.

No intraoperative or postoperative deaths occurred in either treatment arm. The postoperative percentage cancer in the specimen, Gleason scores and pathological states were comparable between treatment groups. There were more complications after RRP than VIP (20% vs. 5%, $p<0.05$). The mean operative duration was comparable and not significantly different between the groups. Hospital stay was longer for patients who received RRP compared to VIP (3.5 vs. 1.2 days, $p<0.05$). The number of patients discharged within 24 hours was significantly different between patients who received VIP (93%) and RRP (0%), $p<0.001$.

The 50% return of continence occurred in 160 days (RRP) vs. 44 days (VIP), $p<0.05$. The 50% return of erection occurred in 180 days (VIP) vs. 440 days (RRP), $p<0.05$.

Limitations to this study included the following:
One team performed VIP; however, 8 different surgeons undertook the RRP procedures.
Different lengths of follow-up between arms.
Non-robotic laparoscopic radical prostatectomy is an alternative to open RRP.

The National Institute for Clinical Excellence[29] (NICE) in the United Kingdom issued an interventional procedure guidance in October 2003 stating that current evidence on the safety and efficacy of non-robotic laparoscopic radical prostatectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. NICE stated that the evidence relating to this procedure was based largely on case series from a few specialized centres. No data on the clinical recurrence of cancer were available.

CCOHTA conducted an emerging technology review[30] for laparoscopic radical prostatectomy and stated that no randomized trial has been conducted to evaluate its clinical efficacy. The amount of published data is relatively small and most results are taken from case series. Long-term follow-up data regarding survival rates and erectile function are still lacking. Evidence comparing nonrobotic versus robotic laparoscopic radical prostatectomy is lacking.

■ Le Bret et al.[31] studied the surgical closure of patent ductus arteriosus (PDA) in 60 French pediatric patients. Fifty-six patients, including premature infants, were considered for the videothoracoscopic approach. Children were excluded from the study if they had any of the following:
Previous thoracotomies
Ductus greater than 9 mm in diameter (determined by transthoracic echocardiographic evaluation)
PDA complicated by endocarditis

Twenty-eight patients underwent the videothorascopic procedure and 28 patients underwent a robotically assisted procedure.[31] Details of how the patients were allotted were not reported. The robotically assisted PDA closure was completed in 27 patients. One patient was converted to classical thoracoscopy due to poor exposition caused by insufficient lung retraction. No intraoperative accident or incident was observed in either group. The total operating time and surgical procedure time was significantly higher in the robotically assisted PDA group ($p<0.01$).

There was no difference in the length of stay in either the intensive care unit (ICU) or the hospital between the two groups.[31] A persisting shunt was observed in 3 children (1 in the videothoracoscopic and 2 in the robotically assisted PDA procedure). The 3 patients were operated on the same day by the thoracoscopic approach. In all patients, the persisting shunt was related to an incomplete dissection of the ductus and misplacement of the clips. No further details were provided. No wound infection or hemorrhage were observed at discharge.

Le Bret et al.[31] concluded, "The robotic approach did not prove to be either superior or inferior to the videothoracoscopic technique in terms of safety, quality of outcome, and reduction of complication. It appears more complicated, demanding, and time-consuming and presently has no particular advantage over the regular technique."

Limitations to the Le Bret et al. study include the following:
Lack of detail of how patients were allotted to the treatment groups
Children ranged in age from 3 weeks to 15 years; robotic PDA surgery may have an advantage in very young or small infants compared with older, larger children.

■ In a German study, Bucerius et al.[32] evaluated the postoperative pain levels of patients after telemanipulator-assisted internal thoracic artery (ITA) dissection (n=24) versus the pain levels of patients who underwent ITA dissection by minimally invasive direct vision CABG (MIDCAB) (n=73). The MIDCAB procedure ITA takedown was performed under direct vision with rib retractors. The results were also compared with pain levels experienced by patients who had conventional CABG with a median

sternotomy (n=93). All patients received morphine-like analgesics (piritramid and tramadol) or nonsteroidal anti-inflammatory drugs (ibuprofen).

There were no significant differences between the groups for duration of intubation, chest tube drainage and time in the intensive care unit.

There was a significant difference between total hospital stay between the telemanipulator-assisted MIDCAB group and the a) direct vision MIDCAB group ($p<0.05$) and b) the conventional CABG group ($p<0.05$).

Overall pain levels were significantly lower in the telemanipulator-assisted MIDCAB group compared with those of patients in the direct visionMIDCAB group ($p<0.001$) and the conventional CABG group ($p<0.001$).[32] Overall pain levels among patients in the direct vision MIDCAB group were lower than those of patients in the CABG group, but the differences were not statistically significant ($p=0.138$). The only statistically significant difference in pain medication between the groups was for ibuprofen: patients who received telemanipulator-assisted MIDCAB required less ibuprofen postoperatively compared with those who received direct vision MIDCAB and CABG ($p=0.001$ and $p=0.018$ respectively).

Bucerius et al.[32] concluded that the higher pain levels among patients in the MIDCAB group might be explained by the traumatic spreading of the chest required for ITA dissection under direct vision.
Limitations to the study by Bucerius et al.[32] included the following:
Takedown of the ITA can also be performed by conventional endoscopic techniques. There was no discussion regarding the use of non–telemanipulator-assisted MIDCAB using endoscopic techniques compared with the telemanipulator- assisted MIDCAB.
The authors stated that 48 of the patients receiving MIDCAB had been randomly assigned to either telemanipulator-assisted ITA takedown (n=24) or MIDCAB (n=24). In addition, another 142 patients received routine surgical treatment, either MIDCAB (n=49) or conventional CABG (n=93) "as indicated by medical demands."[32] These 142 patients were combined with the previous 48 prospectively allotted patients in order to obtain the 3 treatment groups of interest. Therefore, the study groups are "unclean" since the MIDCAB group contains a mixture of patients from different sources. It is not clear when the 142 patients were enrolled, if they were historical controls, or how they were selected.

■ In the United States, Melvin et al.[33] assessed the efficacy and safety of computer-assisted versus standard laparoscopic antireflux surgery. All patients who were referred to a single surgeon's practice with the diagnosis of gastroesophageal reflux disease and selected for surgery were entered into a database. Referrals were from a variety of sources including gastroenterologists, primary care physicians and other surgeons. The indications for an operative intervention were continued symptoms of reflux including regurgitation, heartburn, and in some cases, extraesophageal manifestations. All patients required medical therapy and had had symptoms of gastroesophageal reflux disease for at least 6 months. Patients with previous surgery of the gastroesophageal junction, morbid obesity, and paraesophageal hernia were excluded from the study.

The control group consisted of 20 patients entered into the antireflux database beginning 3 months before USFDA approval of the da Vinci surgical system and initiation of the study.[33] The treatment group consisted of 20 patients who presented to the office after the da Vinci surgical system was approved.

Melvin et al.[33] reported that the patient demographics (age, sex, weight, and antireflux medication) were similar in the 2 groups. There were no intraoperative or device-related complications. The operative time was shorter for patients in the laparoscopic group compared with those in the telemanipulator-assisted group ($p<0.001$). This difference was decreased by eliminating the recorded operative times for the first

10 robotic procedures, but still remained significantly longer ($p<0.006$). No complications were reported during the hospital stay.

All patients were seen at least once within the first month after the surgical procedure.[33] Two patients in each group were lost to follow-up. All 4 of these patients were relatively symptom- free at the time of the first postoperative visits. The follow-up period was longer for the control group (11.2 months vs. 6.7 months, $p<0.001$). There was a significant difference between the 2 groups in the number of patients taking daily antisecretory medication (6/18 laparoscopic patients vs. 0/18 telemanipulator-assisted patients). None of the 6 patients taking daily medications reported symptoms of heartburn while on medication. One of the patients in the control group required reoperation for persistent reflux.

Melvin et al.[33] concluded that the study demonstrated the effectiveness of computer-assisted surgery; however, it failed to demonstrate a significant superiority in the performance and outcome of the computer-assisted procedure. Melvin et al.[33] stated that symptom relief, specifically from heartburn and regurgitation, may correlate with reduction of acid reflux and therefore, was used as an outcome measure. On the other hand, Melvin et al.[33] argued that the use of antisecretory medicine, although often recorded, does not seem to correlate well with reflux and may be overutilized.[34]

Limitations to the study by Melvin et al.[33] included the following:
There was a difference in the length of follow-up between the patient groups. Explanation for the difference was not reported.
The patient groups were recruited at different times. The control group consisted of patients entered into the antireflux database beginning 3 months before USFDA approval of the da Vinci system and initiation of the study. The treatment group consisted of patients who presented to the office after the da Vinci surgical system was approved.

SUMMARY OF FINDINGS ON EFFECTIVENESS

Published health technology assessments indicate that there are limited data from studies, although there is initial evidence of the safety and efficacy in some robotically assisted procedures when they are used at large academic centres for surgery on selected patients.
Most studies are Level 3 and 4 observational studies and assess a wide variety of surgical procedures.
Some authors stated that robotic surgery was neither superior or inferior to the conventional alternative.
Limited studies indicate the promise of telemanipulators, but efficacy is not fully established. In some procedures, the advantages that telemanipulators may offer may also be achieved by nonrobotic minimally invasive/laparoscopic techniques.
The cost of a telemanipulator is high. To date, cost-effectiveness has not been demonstrated.
Patients who have undergone robotic surgery must be followed to further define outcomes (e.g., long-term graft quality for CABG).
The diffusion of these systems can be expected to continue, but their place in surgical practice is not yet clear.

CONSULTATIONS WITH EXPERTS IN ONTARIO

Personal communication with experts in the field suggested that there are technical limitations to the use of the devices (e.g., limited flexibility, rotation and range of motion of device arms, limited flexibility of control knobs, durability of pins in instrument joints, lack of haptics).

Most experts stated that telemanipulator-assisted surgery is currently considered to be in the investigational stage of research.

One expert stated that long-distance robotic-assisted surgery can be used to 1) "decentralize healthcare"; 2) help "underdeveloped surgeons do better work"; 3) reduce costs associated with patient and physician travel for surgery; 4) recruit and retain surgeons in smaller communities; and 5) "connect smaller communities to larger academic centres."

Another expert considered long-distance surgery using telemanipulators to be highly experimental and "did not see where it is practical yet."

ECONOMIC ANALYSIS

Literature Review

No cost-effectiveness analysis and no economic analyses in general were identified that evaluated robotic surgery with telemanipulators.

CCOHTA reported that information on overall costs of these systems is scarce.[35] Capital costs are high and operating and maintenance costs must also be considered. There could be offsets to these costs through savings in operating room staff time, reduced length of hospital stay, and improved patient outcomes, but there are as yet no conclusive data.[35] The cost-effectiveness of the systems is likely to be affected by case selection and the organization of the service at individual centres.[35] For example, reduction in operating room staff time may not have an impact if salaried assistants are required for other types of surgery.

Centres that introduce this technology should be aware of the need for appropriate training and, given the substantial cost, consider use of these systems in procedures in which their performance offers the greatest advantage over assisted-assisted surgical approaches.[35]

Reported Costs

The initial cost of the ZEUS and da Vinci system is approximately $800,000 US and $1,000,000 US respectively.[4] It has been reported that the maintenance contracts, disposable draping materials, and specialized instruments that have only a limited number of uses increase the annual costs of the telemanipulators to approximately one quarter of the purchase price ($200,000-$250,000 US per year).[4]

Early in the surgeon's learning curve, longer operating times in robotic surgical cases increase the labour and facility costs. Although endoscopic positioners may allow the use of one fewer assistant, the ZEUS

and da Vinci systems require fully trained surgeons to be both at the bedside and at the control console.[4] Guyton[4] stated that therefore, more highly trained personnel are required for computer-assisted surgery than for conventional procedures.

Comité d'Evaluation et de Diffusion des Innovations Technologiques (CEDIT) assessed economic and financial aspects.[15] Telemanipulators are available under various purchase and leasing schemes.[15] The acquisition of a system (1-year warranty, shipment, installation, training included) involved an investment of approximately 1.1to 1.2 million euros.[15] Beyond the warranty period, a maintenance contract (preventive and corrective) can be purchased from the manufacturer at a price of more than 100,000 euros per year.

The procedure cost of instruments and consumables varies according to the surgical specialty, the particular surgery involved, and the surgeon's habits.[15] It is estimated to be 2500 euros on average.[15]

On the basis of an estimated rate of 50 operations per year and per telemanipulator at Assistance Publique Hôpitaux de Paris, CEDIT[15] gave 2 expenditure scenarios:

In the case of an already installed telemanipulator, total annual operating cost is 230,000 euros. When a system is purchased, the budget forecast for the first year of operation is of the order of 1.3 million euros (maintenance covered by the warranty).

Therefore, CEDIT estimated that the total annual additional cost incurred for the use of a telemanipulator in an Assistance Publique Hôpitaux de Paris ward (considering depreciation and operating costs including financial charges) was 365,000 euros.[15]

Thus far, any economic benefits expected from the use of telemanipulators (e.g., decreased mortality and morbidity, shortened hospital stays) have yet to be demonstrated.

CEDIT stated[15] that due to the high investment and operating costs, this technology will not generate productivity gains unless there is a true determination to pool expertise and share the system among specialties and among teams belonging to the same speciality.

EXISTING GUIDELINES REGARDING USE OF TECHNOLOGY

Currently, there are no guidelines specifically for the use of telemanipulators in surgery.

Ballantyne and Kelley[36] suggested that the introduction of telerobotics into clinical practice raises issues comparable to those generated by the rapid introduction of laparoscopic cholecystectomy in the late 1980s. Ballantyne and Kelley instituted processes in their hospitals (Hackensack University Medical Center, New Jersey and Henrico Doctors' Hospital, Richmond Virginia) for the granting of clinical privileges for telerobotic surgery derived from the Society of American Gastrointestinal Endoscopic Surgeons guidelines for granting clinical privileges for laparoscopic general surgery.[36] According to Ballantyne and Kelley[36], the following are requirements:

Board certification or eligibility for the appropriate surgical board
Clinical privileges for the open and laparoscopic operations that will be performed telerobotically
Satisfactory completion of the USFDA- mandated training course in the safe use of the robotic surgical system
Performance of telerobotic operations in animate models
Observation of clinical cases of telerobotic surgery by an expert surgeon
Acting as bedside assistant surgeon in telerobotic operations or supervision by a preceptor during the surgeon's initial operations
Observation by a proctor of the surgeon's initial clinical telerobotic operations
Ongoing monitoring of surgical outcomes of telerobotic operations

Ballantyne and Kelley[36] stated that, at their institutions, clinical privileges are granted for the performance of telerobotic surgery, not for individual telerobotic operations. Therefore, the surgeon undergoes the privileging process only once, rather than for each individual operation for which telerobotics may be used.[36]

In 2000, the Society of American Gastrointestinal Endoscopic Surgeons developed a guideline for telesurgery (remote surgery).[37]

Definition:
"Surgery, procedure or technique performed on any inanimate trainer, animate model, or patient in which the surgeon or operator is not at the immediate site of the model or patient being operated on. Visualization and manipulation of the tissues and equipment is performed with tele-electronic devices."[37]

Appropriate Use:
"Demonstration and/or teaching techniques or procedures with inanimate trainers as the objects of the procedure.
Demonstration and/or teaching techniques or procedures with animate model for purposes of testing technology under supervision of the Institutional Review Board (IRB).
Demonstration and teaching techniques or procedures on patients under strict guidance of an IRB and only when a qualified surgeon is present to intervene in a timely fashion if technical difficulties arise."[37]

Comments:

"Remote surgery, at this time, is highly investigational and should not be performed except under IRB approval and by persons thoroughly familiar with the technology. SAGES strongly urges surgeons and hospitals to defer clinical implementation of these modalities until the technology has been validated. It is our opinion that current clinical use of this technology should only be conducted under a protocol reviewed by an institutional committee for the protection of patients and should include the collection of quality assurance and outcomes data. The participants, facilities and telecommunication service vendors involved in these events should coordinate their efforts so that the visual fidelity and telecommunications interface is suitable for the planned activity."[37]

CONCLUSION

The exact role of computer-assisted surgery with telemanipulators has not been fully defined.
Telemanipulators should be used in procedures when their performance offers the greatest advantage over no computer-enhanced surgical procedures.
Evidence is incremental; true potential has not been fully explored
Deemed by experts and literature to be investigational

HEALTH SYSTEMS IMPLICATIONS

Medical

If it is decided to fund computer-assisted surgery with telemanipulators there is concern that this device may be considered in patients who do not require robotic surgery with a telemanipulator. However, to date the specific indications for surgery using telemanipulators are unknown.
An expert in the field suggested that the use telemanipulators for telerobotic surgery and telementoring may stimulate the acquisition and retention of specialist surgeons in remote locations in Ontario due to enhanced contact with physicians in large academic centres. However, any increased benefits over current modes of long distance communication (videoconferencing) as well as the supervision and mentoring of the most experienced cosurgeon already situated in the remote location are unclear.

Human Resources/Services/Regulatory

If it is decided to fund computer-assisted surgery with telemanipulators, to ensure that a sufficient number of treatments are conducted in order to maintain technical skills and expertise, this technology should be limited to a few centres that perform robotic surgery and also have appropriate medical support.
An expert in the field suggested that telerobotic surgery may have the potential to reduce transportation requirements and costs for physicians and patients (and their families) who live in remote locations in Ontario and might require specialized surgery available only at a large academic centre. However, to date, the specific indications for such surgery have not been established. In addition, any benefits over surgery performed by the most experienced surgeon already located in a remote location have not been demonstrated.
For telerobotic surgery, problems such as loss of communication between the surgeon and the operating theatre, telemanipulator system failure, or complications such as bleeding or cardiac arrest during an operation will require someone onsite to take charge and implement the correct procedures.
If it is decided to fund robotic surgery with telemanipulators, telerobotic or "cybersurgery" may have the ability to create a real-time audit trail.

Legal

If it is decided to fund robotic surgery with telemanipulators, it is unclear who is liable in the event of a surgical problem during telerobotic surgery. If a complication arises it may be difficult to establish whether this was a telesurgeon's mistake or a technical failing of the system.
Telesurgery may involve a number of specialists, hospitals, states or countries and jurisdiction conflicts may occur.

Guidelines

If MOHLTC decides to fund computer-assisted surgery with telemanipulators, guidelines and standards should be insisted upon.

GLOSSARY

Anastomosis: A natural, pathological or surgical join between 2 hollow or tubular organs.

Off pump coronary artery bypass (OPCAB): A bypass procedure that allows the surgeon to sew the bypass grafts into place in the chest without stopping the heart or using a heart-lung machine. Instead, heart stabilizers keep the heart motionless where the surgeon is working on a particular coronary artery.

On pump coronary artery bypass graft (On pump CABG): The use of a machine during a bypass procedure that allows the surgeon to stop the heart while the vital organs continue to receive blood and oxygen. Work can then be done without interference from bleeding or the heart's pumping motion.

Telemanipulator: A computer-enhanced surgical system that a surgeon operates while seated at a console. The surgeon views a 3-dimensional image of the surgical field. The monitor displays an image from a camera located in the robotic arm, allowing the surgeon to see the entire surgical field. The surgeon's hand movements are translated into real-time movements of the surgical instruments. Access of the instruments and camera to the surgical site is made through small incisions.

Telementoring: The process of an expert surgeon, who remains in his/her own hospital, instructing a novice in a remote location on how to perform a new operation or use a new surgical technology.

Telerobotic surgery: A surgical platform that permits surgeons to operate on patients from remote locations using robotic instruments.

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TABLES

Table 1. Studies Examining the Feasibility of Telemanipulators

Study	Type	Size	Results	Comment
Le Bret et al. France 2002	Surgical closure of patent ductus arteriosus. Observational prospective comparative.	Pediatric patients. Group 1: 28 videothoracoscopic technique, mean age 33 months Group 2: 28 robotically assisted (ZEUS), mean age 20 months	Total operating room time: 83.52 min vs. 162 min, p<0.01 Surgical procedure time: 24.24 min vs. 49.9 min, p<0.01 Conversion for technical failure or surgical problems: 0 vs. 1 conversion to classical thoracoscopy due to poor exposition caused by insufficient lung retraction. Accidents of dissection: 0 vs. 0 Postoperative There was no difference between the 2 groups in terms of ICU and hospital length of stay. ICU stay was less than 6 hours, and postoperative ventilation time was less than 2 hours. Reversible laryngeal nerve injury noted on one patient from each group. A persisting shunt was observed in 3 patients (1 in group 1 and 2 in group 2). The 3 children were reoperated on the same day by the thoracoscopic approach. In all patients, the persisting shunt was related to an incomplete dissection of the ductus and misplacement of the clips. No residual shunt noted at discharge. No wound infection. No hemorrhage observed. No midterm complications including recurrence of ductal shunting.	Operating room time and surgical procedure time significantly greater in the robotic group. "Robotic approach did not prove to be either superior or inferior to the videothoracoscopic technique in terms of safety, quality of outcome and reduction of complication. It appears more complicated, demanding and time consuming and presently has no particular advantage over the regular technique". Lack of detail of how patients were allotted to the treatment groups. Children ranged in age from 3 weeks to 15 years. Robotic PDA surgery may have an advantage in very young/small infants compared with older, larger children.
D'Attellis et al. France 2002	Robotic assisted cardiac surgery: CABG or valve surgery. Case series.	20 patients. Mean (±SD) age 53±5 years. da Vinci robot.	15 patients (75%) were extubated within 6 hours and discharged from the cardiac surgery ICU on postoperative day 1. 2 patients (10%) were reexplored in the immediate postoperative period (1 for postoperative bleeding and 1 for revision of the coronary artery anastomosis).	Patient positioning is important in decreasing patient robot conflicts.

Study	Type	Size	Results	Comment
			2 additional conversions to thoracotomy (both were valve patients). Conversions were due to video system malfunction (n=1) and patient robot conflict (n=1). One reoperation at 6 months (rerepair of mitral valve by conventional surgery for recurrent bacterial endocarditis that was also preoperative) and 1 late death at 6 months (75 year old woman with preoperative NYHA IV heart failure with persistent low cardiac output after mitral valve repair). At 1 year follow-up, good functional results in 18 cases observed. Intraoperative difficulties: Video system dysfunction n=1 Mammary artery bleeding n=1 Tool manipulation n=2 Patient robot conflict n=3 Conversion to thoracotomy n=2	
Marescaux et al. France 2001	Telerobotic laparoscopic cholecystectomies. Case series.	25 patients. Median age=59 years (range 28-81). ZEUS robot.	Cholecystectomies successfully performed on 24/25 patients. Median time for dissection =25 min (range 14-109). Median total time for set-up and takedown of the robotic arms was18 min (range 13-27). One conversion to conventional laparoscopic procedure in a patient with acute cholecystitis. In 3 cases, minor technical adjustments were made: 2 cases resulting from a nonfunctioning grasper and 1 case from a malfunctioning robotic arm sensor. Mean postoperative hospital stay was 3 days. Follow-up at 1 week and 1 month showed 1 patient with symptoms of reflux disease that had been present before surgery. Responded to medical treatment. One patient reported upper abdominal wall pain at a site distant from the port insertion site. Responded to conservative treatment.	Feasible.

Study	Type	Size	Results	Comment
Detter et al. Munich Germany 2002	Robotically assisted coronary artery surgery with and without cardiopulmonary bypass. Case series.	41 patients. ZEUS robot introduced step by step: IMA harvest n=12 patients Coronary anastomoses on arrested heart n=13 patients Coronary anastomoses on beating heart after median sternotomy n=6 patients Endoscopic CABG on arrested heart n=2 patients Endoscopic CABG on beating heart n=8 patients	IMA harvest ranged from 48-110 minutes and completed in all cases. Robotic anastomosis time averaged 21 min on the arrested and 25 min on the beating heart respectively. Endoscopic anastomosis was 41 min on the arrested heart and 36.5 min on the beating heart with an overall duration of surgery between 4.0 and 8.0 hours. One endoscopic case was intraoperatively converted to a MIDCAB with manual anastomosis. Total patency rate of all graft anastomoses was 97%. One patient underwent a reoperation with an uneventful postoperative course.	Feasible. Time to perform anastomoses was shorter in the sternotomy group than in the endoscopic group.
Bucerius et al. Leipzig Germany 2002	To evaluate postoperative pain levels after endoscopic versus conventional internal thoracic artery (ITA) dissection for minimally invasive direct CABG (MIDCAB). Results compared with pain levels associated with conventional CABG via a median sternotomy. Observational, prospective, comparative.	24 patients robotic ITA takedown (robotic MIDCAB) using da Vinci robot. 73 patients direct vision MIDCAB. 93 patients conventional CABG via a median sternotomy (CABG). Standardized questionnaire used to assess pain.	Overall pain levels were significantly lower in the robotic MIDCAB group vs. direct vision MIDCAB and CABG groups respectively ($p<0.001$). No significant difference between pain levels in direct vision MIDCAB and CABG. The only statistically significant difference in pain medication between the groups was for ibuprofen: robotic MIDCAB required less ibuprofen postoperatively compared with direct vision MIDCAB and CABG ($p=0.001$ and $p=0.018$ respectively).	Robotic MIDCAB may lead to reduced postoperative pain levels possibly due to less rib retraction. Robotic takedown of the ITA can also be performed by conventional endoscopic techniques. There was no discussion regarding the use of endoscopic, nontelemanipulator assisted MIDCAB compared with telemanipulator assisted MIDCAB. The authors stated that 48 of the patients receiving MIDCAB had been randomly assigned to either robotic ITA takedown (n=24) or direct vision MIDCAB (n=24). In addition, another 142 patients received routine surgical treatment, either direct vision MIDCAB

Study	Type	Size	Results	Comment
				(n=49) or conventional CABG (n=93) "as indicated by medical demands".[32] These 142 patients were combined with the previous 48 prospectively allotted patients in order to obtain the three treatment groups of interest. Therefore, the study groups are "unclean" since the direct vision MIDCAB group contains a mixture of patients from different sources. It is not clear when the 142 patients were enrolled, if they were historical controls or how they were selected.
Bentas et al. Frankfurt Germany 2003	Laparoscopic radical prostatectomy Case series.	40 consecutive patients. da Vinci robot.	Procedure was completed laparoscopically in all but two patients. Mean procedure time was 8.3 hours. Patients recovered rapidly after surgery with early oncological and functional results that were similar to those obtained with standard radical prostatectomy technique. No intra or postoperative deaths. 4 (10%) intraoperative adverse events and 1 reoperation. Trocar injury to an epigastric artery necessitated open revision on postoperative day 1. An intraoperative partial injury of the obturator nerve. Two instances of hemostatic complications at the dorsal vein complex. Complications Pulmonary embolism n=2 (5%) Deep vein thrombosis n=1 (3%) Obturator nerve injury n=1 (3%) Trocar injury to epigastric artery n=1 (3%) Venous plexus bleeding n=2 (5%) Urinary tract infection n=2 (5%) Prolonged anastomotic leak n=4 (10%)	Feasible.

Study	Type	Size	Results	Comment
Dogan et al. Frankfurt Germany 2002	Robotically enhanced totally endoscopic CABG on the arrested heart. Case series.	45 patients. Mean (±SD) age 63±6 years old. Consecutive single (n=37) or double vessel (n=8) operations. da Vinci robot.	Morbidity and Complications Conversion to minithoracotomy n=7 Conversion to full sternotomy n=3 Bleeding from the anastomosis n=2 Prolonged crossclamp time n=4 ITA injury n=1 Port access failure n=3 Hypovolemic shock n=1 Myocardial infarction n=1 Hypoxic brain damage n=1 Moderate reperfusion injury n=1 Retrograde aortic dissection n=1 Operating time: single vessel 4.2±0.9 hours, double vessel 6.3±1.0 hours. ICU stay: single vessel 24±21 hours, double vessel 74±64 hours. Hospital stay: single vessel 8.6±2.7 days, double vessel 15.4±6.4 days.	Feasible.
Kappert et al. Dresden Germany 2001	Robotic enhanced CABG. Case series.	201 patients. Median age 64±10.5 years. Group A, n=156. robotic system used to harvest the left or right IMA or both. Manual anastomoses performed via chest incision (MIDCAB or by the "Dresden Technique" REDTCAB). Group B, n=37. Harvest of the IMA and anastomoses performed totally endoscopically (TECAB). Group C, n=8. Robotic enhanced CABG via median sternotomy already preoperatively planned (open CABG).	99.4% survival rate. One patient died due to pneumonia on postoperative day 16. (Which Group?) 9 patients had to undergo reexploration due to bleeding. (Which Groups?) In Group B, 3 patients had an explorative second look due to increased postoperative drainage. Delayed wound healing at the site of the chest incision found only in Group A: 10 patients. No patients in Group B revealed any signs of delayed wound healing. Of patients with intent to treat TECAB, 19 (33.9%) were actually converted to a MIDCAB procedure. This was due to: LAD identification not possible endoscopically n=5 Diffuse sclerosis of the LAD n=5 Difficulties with endoscopic stabilization n=3 Pleural adhesions n=2 Intramural LAD course n=2 Insufficient occlusion of the LAD n=2 No significant differences in ICU or hospital stay	Feasible.

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		da Vinci robot.	were noted. ICU stay: 25.6±18.8 and 24.9±6.4 hours, A and B respectively. Hospital stay: 7±1 and 6±1 days, A and B respectively.	
Bodner et al. Innsbruck Germany 2002	Robotic assisted cholecystectomies. Case series.	25 patients. Median age 48 (range 22-78). da Vinci robot.	Successful in 23 patients. Two procedures were converted to conventional laparoscopy due to system bread downs. Median operating time was 100 min (range 60 to 171). Median robot setup and dismantle time was 60 min (range 49 to 82). Operating room occupied for median of 160 min. "Intraoperative events" included: Serosal lesion of the colon n=1 Bleeding n=1 Perforation with leakage of bile into the abdominal cavity n=2 Gall bladder could not be clutched by the robotic instruments until 20 mL of bile removed by an assistant n=1 Diffuse nonsurgical bleeding from gall bladder bed or leakage of bile during gall bladder dissection caused a drain to be placed in subhepatic space via incision of accessory port at end of operation n=8 Redo operation due to bleeding at a port site on the second postoperative day n=1 No peri or postoperative mortality. Median hospital stay 4 days (range 2-15).	Feasible.
Isgro et al. Ludwigshafen Germany 2003	Internal mammary artery takedown. Case series.	56 patients. Mean (±SD) age 64.9±8.6 years. ZEUS robot.	One patient ITA takedown was completed conventionally. All harvesting performed without complications. Mean setup time 24±12 min. Mean IMA takedown time 58±17 min. IMA was patent in all 56 patients.	Feasible.

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Giulianotti et al. Italy 2003	Robotics in "general surgery". Case series.	193 patients underwent a minimally invasive robotic procedure. 207 robotic surgical operations performed (abdominal, thoracic and vascular). Mean age 55.9 years. da Vinci robot.	179 were single procedures. 14 were double procedures (2 operations on the same patient). 4 conversions to open surgery and 3 to conventional laparoscopy (conversion rate 3.6%; 7 of 193 patients). The 4 procedures requiring conversion to open surgery included: 1 Nissen fundoplication due to traumatic hepatic lesion caused by the retractor. 1 pulmonary lobectomy due to pleural adhesions 1 pancreatoduodenectomy due to neoplastic infiltration of the portal vein 1 total gastrectomy due to neoplastic infiltration of the pancreas. The 3 procedures converted to conventional laparoscopy included: A cholecystectomy and a splenic aneurysmectomy due to robotic technical problems. A Nissen fundoplication due to peritoneal adhesions. Perioperative morbidity rate was 9.3% (18 of 193 patients). 2 patients had iatrogenic lesions (1 hepatic tear due to blind retraction, and 1 splenic lesion due to tear by traction on adhesions). 6 patients (3.1%) required a reoperation. Postoperative mortality rate was 1.5% (3 of 193 patients). Two patients died due to septic complications caused by anastomotic leakage and mediastinitis after total esophagectomy, and Boerhaave syndrome after pancreatoduodenectomy respectively. The third patient who underwent subtotal gastrectomy died owing to respiratory failure after a reoperation for hemoperitoneum.	Feasible. "Best indications still have to be defined". "This report could serve as a future prospective randomized trial."

Study	Type	Size	Results	Comment
Ruurda et al. Netherlands 2002	Robot assisted laparoscopic cholecystectomies Case series.	40 patients. Median age 45 years (range 22 to 72) da Vinci robot.	One conversion to open procedure due to surgeons' inability to expose the gall bladder sufficiently due to severe cholecystitis. Robot related technical problems occurred in 3 cases. The replaceable hook of the electrocautery instrument detached during the procedure. Hook removed laparoscopically in 2 of the 3 cases, but resulted in laparotomy in 1 case because the hook could not be seen in an obese patient. Median total hospitalization time was 2 days (range 1 to 10). No postoperative morbidity or mortality at the time of patient release and during short term follow-up (length of follow-up not stated).	Feasible.
Horgan and Vanuno USA 2001	Robotic laparoscopic surgery. (gastric bypass, Heller myotomies, nephrectomies, gastrojejunostomies adrenlaectomy, Nissen fundoplication, Toupet fundoplication, cholecystectomy) Case series.	34 patients. Gastric bypass for morbid obesity n=7 Heller myotomies for achalasia n=9 Donor nephrectomies n=11 Gastrojejunosteomies n=2 Adrenalectomy n=1 Nissen fundoplication n=1 Toupet fundoplication n=1 Cholecystectomy n=1 Pyloroplasty n=1 da Vinci robot.	"No robot related complications".	Feasible.
Nifong et al. USA 2003	Mitral valve repair. Case series	38 patients. da Vinci robot.	No intraoperative deaths, strokes or device related complications. All patients had successful valve repairs. One patient required valve replacement for hemolysis and one patient was reexplored for bleeding. No incisional conversions. Two adverse events – one resulted in death at 20	Feasible.

Study	Type	Size	Results	Comment
			days. One patient reexplored through the same incision 6 hours post surgery for pacing wire site bleeding and was discharged from the hospital 3 days later. One patient developed a leak that was directed against a prosthetic chord causing hemolysis. Had mechanical valve replacement 19 days post operatively through a median sternotomy. The patient had a fatal stroke 1 day after the valve replacement while on warfarin therapy.	
Talamini et al. USA 2002	Robotically assisted gastrointestinal surgical procedures. Anti reflux n=25 Bowel resection n=18 Cholecystectomy n=8 Heller myotomy n=5 Splenectomy n=5 Exploratory laparoscopy n=4 Case series	60 patients da Vinci robot.	The conversion rate (either to standard laparoscopy or to open procedures) for the following procedures were reported: Anti reflux 12% Bowel resection 11% Cholecystectomy 12% Heller myotomy 20% Splenectomy 60% Exploratory laparoscopy 25% No operative deaths. Postoperative complications attributable to the robot by the authors: Trocar slippage n=4 Arm positioning n=2 System positioning n=2 (conversion to standard laparoscopy in 1 case) System failure n=2 (conversion to standard laparoscopy in 1 case) Dropped cautery hook n=1 Postoperative complications attributable to the operation and not the robot by the authors: Misshapen Nissen n=1 Gastric Leak n=1	Feasible.
Tewari et al. USA 2003	Robot assisted prostatectomy compared with radical retropubic	100 consecutive patients retropubic prostatectomy (RRP) (reference standard). Mean age 63.1	No deaths in either treatment arm. The percentage cancer, Gleason scores and pathological states were comparable between either treatment arm.	One team performed VIP, however, 8 different surgeons in the same institution undertook the RRPs.

Study	Type	Size	Results	Comment
	prostatectomy. Prospective, observational, single centre.	years (range 42 to 72). 200 consecutive patients robotic assisted prostatectomy (VIP). Mean age 59.9 (range 40 to 72) da Vinci robot. Inclusion criteria: Surgical candidates. Choice between RRP and VIP was offered to all patients who had a 10 year life expectancy and had prostate cancer of Gleason score ≥6. Patients assigned on basis of their personal preferences. Follow-up was for 556 days in the RRP group and 236 days in the VIP group. No explicit explanation was provided regarding this difference.	Mean operative duration comparable and not significantly different. The number of catheterization days was significantly different between RRP and VIP groups. 15.5(7-28) vs. 7(1-18), p<0.05. Blood loss was 910 and 150 mL for RRP and VIP respectively and transfusion was greater after RRP (67% vs. none; both p<0.001). Four times as many complications after RRP (20% vs. 5%), p<0.05. Hospital stay longer for RRP 3.5 vs. 1.2 days, p<0.05. 93% of VIP and none of RRP patients were discharged within 24 hours, p<0.001. The 50% return of continence occurred in 160 days (RRP) vs. 44 days (VIP), p<0.05. The 50% return of erection occurred in 180 days (VIP) vs. 440 days (RRP), p<0.05. Complications RRP VIP Aborted 1 2 Conversion - 0 Rectal injuries 1 0 Postoperative ileus 3 3 Wound dehiscence/hernia 1 2 Postop. fever/pneumonia 4 0 p<0.05 Lymphocele 2 0 Obturator neuropathy 2 0 DVT 1 1 Postop. MI 1 0 Postop.bleeding/reexploration 4 1 Total 20 5 p<0.05	Different lengths of follow-up between treatment arms.

Study	Type	Size	Results	Comment
Perez et al. USA 2003	Robotically assisted laparoscopic cholecystectomy. Case series	20 patients. Mean age 47±4 years. da Vinci robot.	All patients had successful procedures without complications or need for conversion to conventional laparoscopic cholecystectomy. Mean procedure time was 152±8 min. The large proportion of operating time associated with the robotically assisted surgery was related to robotic positioning and adjustments rather than surgeon directed tissue manipulation.	Feasible.
Melvin et al. USA 2002	Antireflux surgery. Robotic enhanced fundoplication compared with standard laparoscopic control procedures. observational historical controls.	20 consecutive patients entered into each treatment group. da Vinci robot.	Operative times were significantly longer in the robot group (97 vs. 141 minutes. No complications and most patients went home the first postoperative day. Length of follow-up was 11.2 months for the laparoscopic group and 6.7 months for the robotic group ($p<0.001$). At follow-up, symptoms were similar in both groups; however, there was a significant difference in the number of patients taking antisecretory medication - none in the robotic group but 6 in the laparoscopic group reported regular usage ($p<0.001$). None of the 6 patients taking daily medication reported symptoms of heartburn while on medication.	At current level of development, robotic enhanced fundoplication appeared to offer no clear advantages in operative outcomes compared with standard laparoscopic approaches.
Damiano et al. USA 2001	Robotically assisted CABG Prospective, multicentre case series	32 consecutive patients. Mean age 63±9 years. ZEUS robot.	30/32 patients available for late follow-up. No intraoperative device related complications. 3 intraoperative graft revisions. 3 patients required a return to the operating room the evening of surgery for excessive mediastinal hemorrhage. 3 patients had postoperative atrial fibrillation. The average length of stay in the intensive care unit was 1.3±1.0 days. The average hospital stay was 5.5±2.7 days. 8-12 weeks after operation, 26/28 grafts were patient. At a mean follow-up of 16±4 months, 28/30 patients were doing well.	Feasible. "Further clinical trials are warranted to explore the potential of this new technology and establish its precise role in the treatment of patients with coronary artery disease".