Horizon Scanning in Surgery: Application to Surgical Education and Practice

Robotic colorectal surgery

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Disclaimer

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

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

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

Objective

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

Introduction

Indications for colorectal surgery

Colorectal surgery encompasses a broad range of procedures, undertaken to treat a variety of conditions/diseases of the colon, rectum and anus. These may be of either benign or malignant etiology and include conditions such as colorectal cancer, diverticulitis, polyps/adenoma, rectal prolapse and ulcerative colitis.

Colorectal surgery may be undertaken either laparoscopically or as an open procedure. The choice of operation modality will be influenced by the precise indication for surgery, feasibility, capacity and patient/surgeon preference.

Burden of disease

It is difficult to precisely enumerate a burden of disease for this procedure, as use of robot-assisted colorectal surgery is dependent on a number of variables that cannot be assessed from available prevalence data. Additionally, benign conditions that may be treated with robot-assisted surgery are poorly represented in incidence and prevalence data.

Centres for Disease Control and Prevention (CDC) data indicate that colorectal cancer had an incidence rate in the United States (US) of 49.5 per 100,000 in 2004 (US Cancer Statistics Working Group 2007). Further, the 2005 National Hospital Discharge Survey (DeFrances and Hall 2007) showed that 148,000 discharges from short-stay hospitals in the US in 2005 carried a diagnosis of malignant neoplasm of the large intestine and rectum. A further 5,580,000 discharges had an operation on the digestive system while admitted (DeFrances and Hall 2007).

Technology

The da Vinci® surgical robotic system (Intuitive Surgical, Inc., Sunnyvale CA, USA) will be the only system considered by this report, as earlier competitors such as the AESOP and ZEUS systems (Computer Motion) are no longer on the market due to a merger between Intuitive Surgical and Computer Motion in June 2003 (Tooher and Pham 2004).

The da Vinci is a master-slave telemanipulation system. The surgeon is seated at a remote console and is able to direct the robotic surgical arms via a telerobotic videoscopic link. There are three main components of the da Vinci system: the surgical cart, the vision tower and the surgeon console.

Surgical cart

The robotic arm cart is placed beside the operating table. It holds up to four interactive robotic arms. Two arms are attached to the instrument adaptors which are connected to robotic instrumentation through reusable trocars. The third arm positions the endoscope, allowing the surgeon to alter the field of vision from the console. An optional fourth arm enables the addition of another instrument to allow for tasks such as applying countertraction.

The surgical instrumentation (EndoWrist®) is fully articulated, imitating the function of both an elbow joint and a wrist. This enables seven degrees of freedom and two degrees of axial rotation, designed to mimic the natural motions of open surgery.

Vision tower

The vision tower houses a high-definition three-dimensional vision system. The components of the system enhance and refine the images using synchronizers, high-intensity illuminators and camera control units.

Surgeon console

The surgeon 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, located in a natural position below the visual display. The surgeon's hand movements are digitized and transmitted to the robotic arms which perform identical, real-time movements in the operative field, scaling motion and filtering fine tremor. 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, with the robotic surgical arms deactivated whenever the surgeon's eyes are removed from the display.

Stage of development

The da Vinci robotic system is widely diffused within the United States healthcare system. As of March 31, 2008, there were 647 da Vinci surgical systems placed in US hospitals. A further 148 systems had been sold within Europe and 72 in the rest of the world (Intuitive Surgical 2008). This includes major centres in Australia, Canada, France, Germany, India, Romania, Saudi Arabia and the United Kingdom, amongst others.

Regulatory approval
The U.S. Food and Drug Administration (FDA) granted 510(k) approval to the da Vinci Surgical System for a wide range of adult and pediatric surgery, including urologic procedures, general laparoscopic procedures, general non-cardiovascular thoracoscopic procedures, and thoracoscopically-assisted cardiotomy procedures. It may also be used with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The FDA has not yet cleared the da Vinci for use in colorectal surgical procedures.

Current clinical trials
The only current collection of data from robotic colorectal surgery is the Minimally Invasive Surgery (MIS) Database for the Purpose of Research (NCT00535990). This is being created at the University of California in San Diego and will record standardized data from a variety of MIS procedures, including robotic colorectal surgery. It is anticipated that 1000 participants will be enrolled across a variety of indications, with recruitment completed in July 2010.

Current treatment and alternatives

The current gold standard colorectal surgery may be either an open or laparoscopic procedure, dependent on both the precise indication for surgery and key patient characteristics. Robotic colorectal surgery may not be appropriate for some patients, such as those with hostile abdominal anatomy; the use of this technique demands expert clinical judgement as part of its determination.

However, the majority of patients suitable for a laparoscopic colorectal procedure will also be eligible for a robotic procedure. Thus, the most appropriate clinical comparator in this instance is laparoscopic colorectal surgery.

Laparoscopic surgery offers a number of benefits over open surgery, including reduction in pain, more rapid recovery of bowel function, shorter hospital stay and better cosmetic results; however, laparoscopic surgery takes longer than open surgery and results in similar complication rates and long-term outcomes (Reza et al 2006).

Laparoscopy also carries some inherent technical limitations, including an unstable camera platform, the limited range of motion of straight laparoscopic instruments, two-dimensional imaging and poor ergonomics for the surgeon (Ballantyne 2002).

Robotic surgery theoretically may overcome these pitfalls by allowing tridimensional imaging under the surgeon's direct control, utilising instrumentation with seven degrees of freedom which mimic natural hand dexterity (Spinoglio et al 2008). It also filters hand tremor, facilitates fine dexterity and allows motion scaling, thus supporting the complex and precise dissection frequently required by the narrow surgical field associated with colorectal surgery (Baik 2008a).

Literature review

Search criteria

Keyword/MeSH terms utilized:
Robotics*, Colon/surgery*, Rectum/surgery*, Robotic colorectal surgery
Databases utilized:
PubMed, OVID

Inclusion criteria

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Randomized controlled trials; non-randomized comparative studies
Patient	Adult male and female patients with benign or malignant colorectal dizease requiring surgical treatment
Intervention	Robot-assisted colorectal surgery
Comparator	Laparoscopic colorectal surgery
Outcome	Efficacy: operative time; length of hospital stay; conversion; time to defecation; pathology outcomes (malignant indications) Safety: Blood loss; complications; robot-specific morbidity Cost-effectiveness: surgical costs
Language	English only

Included studies

A total of nine comparative studies were identified for inclusion in this review (Table 2). These studies considered robotic colorectal surgery for a variety of indications and procedures.

Table 2 Characteristics of included studies

Study/Location	Level of Evidence	No. of patients	Duration of follow-up	Indication			Procedure
				Ca	Ben	Mix	
Baik et al 2008 Korea	II	RA: 18 LP: 18	Peri-operative + LOS	●			Low anterior resection
D'Annibale et al 2004 Italy	III-2	RA: 53 LP: 53	Peri-operative + LOS			●	Mixed
Heemskerk et al 2007 Netherlands	III-2	RA: 14 LP: 19	Peri-operative + LOS		●		Rectopexy
Pigazzi et al 2006 USA	III-2	RA: 6 LP: 6	Peri-operative + LOS	●			Low anterior resection
Spinoglio et al 2008 Italy	III-2*	RA: 50 LP:161	Peri-operative + LOS			●	Mixed
Woeste et al 2005 Germany	III-2	RA: 4 LP: 23	Up to 10 weeks		●		Sigmoid resection
Delaney et al 2003	III-2/3	RA: 6	Peri-operative + LOS			●	Mixed

USA		LP: 6					
Rawlings et al 2007 USA	III-2/3	RA: 30 LP: 27	Peri-operative & LOS			●	Right & sigmoid colectomies

NOTES: Ca malignant disease; Ben benign disease; mix mixed indications reported; RA robot-assisted; LP laparoscopic procedure; *comparative for efficacy outcomes only; LOS length of stay

An examination of key patient characteristics (Table 3) indicated that distribution of co-morbidities did not favour one group over another, although this was not statistically examined.

Table 3 Key patient characteristics

Study	Level of Evidence	Mean patient age	ASA Score		TNM staging	
			RA	LP	RA	LP
Baik et al 2008	II	RA: 57.3±6.3 LP: 62.0±9.0	I: 12/18 II: 6/18 III: 0/18 IV: 0/18	I: 9/18 II: 6/18 III: 1/18 IV: 1/18	I: 5/18 II: 4/18 III: 9/18	I: 5/18 II: 4/18 III: 9/18
D'Annibale et al 2004	III-2	RA: 64±13 LP: 65±9	…	…	0: 4/22 I: 2/22 II: 11/22 III: 5/22 IV: 0/22	0: 4/42 I: 10/42 II: 12/42 III:14/42 IV: 2/42
Heemskerk et al 2007	III-2	RA: 55 LP: 47	1.6 (mean)	1.6 (mean)	…	…
Pigazzi et al 2006	III-2	RA: 60 (42-78) LP: 70 (57-88)	II: 2/6 III: 4/6	II: 2/6 III: 4/6	…	…
Spinoglio et al 2008	III-2	RA: 66.7 LP: 68.8	I: 13/50 II: 24/50 III: 12/50 IV: 1/50	I: 30/161 II: 59/161 III: 57/161 IV: 14/161	…	…
Woeste et al 2005	III-2	…	…	…	…	…
Delaney et al 2003	III-2/3	RA*: 49.5 (43.5-85) LP*: 50 (43-89)	I: 0/6 II: 3/6 III: 1/6 IV: 2/6	I: 1/6 II: 2/6 III: 3/6 IV: 0/6	…	…
Rawlings et al 2007	III-2/3	RA: 64.6±11.7 LP: 63.1±17.5	…	…	…	…

Critical appraisal

Only one randomized controlled trial was identified for inclusion (Baik et al 2008). Randomization, concealment and implementation were well executed and clearly described. Patient characteristics were comparable at baseline and the interventions, primary outcomes and statistical analysis were well described. Follow-up was limited to peri-operative outcomes and length of stay, and it was not reported if there were any losses to follow-up.

Five National Health and Medical Research Council (NHMRC) Level III-2 studies were identified for inclusion. These comparative studies were not randomized, but utilized a concurrent comparator group of patients undergoing laparoscopic surgery. Rationale for patient selection was not always explicit. One study (Woeste et al 2005) did not describe the baseline characteristics of either treatment group. D'Annibale et al (2004) and Spinoglio et al (2008) reported no significant differences in age and gender between the two groups. Pigazzi et al (2006) and Heemskerk et al (2007) both reported a younger patient group for robotic surgery. Authors described the interventions clearly, but frequently failed to predefine outcome measures and statistical tests. Follow-up was limited to the immediate postoperative period, apart from one study (Woeste et al 2005) that considered delayed complications up to ten weeks postoperative.

Finally, two NHMRC Level III-2/3 studies were considered. It was not clear from the methodology described whether the comparator laparoscopic groups were concurrent or historical; hence, a lower level of evidence was assigned to the studies. Again, the underlying indications for surgery were a mix of benign and malignant disease, with patient groups comparable at baseline with regard to age, body mass index and gender, although only Rawlings et al tested this statistically. Both of these studies focussed on cost as a key outcome, with other safety and efficacy parameters also considered.

Given the limited sample sizes of a number of these studies, and the poor reporting of power calculations, it is unlikely that many of these studies were adequately powered to detect a statistically significant difference in treatment effect between the two groups. This, along with a frequent lack of allocation details, the mixing of indications and procedures, short-follow-up and non-statistical comparison of safety outcomes, limits the conclusions that can be drawn from the available evidence base.

Safety and efficacy

Safety

Inconsistent safety outcomes reporting made it difficult to compare safety outcomes between the two groups. This was further hampered by the fact that no study reported undertaking any significance testing.

Mortality and overall complication rates
There was no robot-specific morbidity reported in the four studies that explicitly discussed this outcome (Baik et al 2008; Delaney et al 2003; Rawlings et al 2007; Woeste et al 2005). No mortality was attributed to complications related to the robotic system.

It appears that the rates of complications are generally comparable between the two treatment modalities; however, it is difficult to directly compare the severity of complications between the two surgical modalities (see Table 4).

Table 4 Complications

Study	Level of Evidence	# patients	RA procedure	Laparoscopic procedure
Malignant disease				
Baik 2008	II	RA: 18 LP: 18	1 postoperative intraluminal bleeding 2 back pain 1 scrotal swelling	1 postoperative intraabdominal bleeding
Pigazzi 2006	III-2	RA: 6 LP: 6	1 prolonged ileus	1 pelvic abscess
Benign disease				
Heemskerk 2007	III-2	RA: 19 LP: 14	…	…
Woeste 2005	III-2	RA: 4 LP: 23	1 inflamed colon*	3 local wound infection 1 postoperative bleed 1 insufficient anastomosis
Mixed indications				
D'Annibale 2004	III-2	RA: 53 LP: 53	1 bowel obstruction (adhesions) 1 bowel injury 1 cerebrovascular accident 1 wound infection	1 anastomotic fistula 1 acute anemia 1 wound infection 1 jugular thrombosis 2 pneumonia 1 hypoesthesia of leg 1 acute renal failure
Spinoglio 2008	III-2	RA: 50 LP: 161	1 incisional hernia 1 lung atelectasia 1 wound infection 1 arm phlebitis 1 brain stroke 1 anastomotic leak	…
Delaney 2003	III-2/3	RA: 6 LP: 6	1 atelectasis	1 incisional hernia
Rawlings 2007 *right colectomy*	III-2/3	RA: 17 LP: 15	1 anastomotic leak	1 prolonged ileus 1 postoperative bleed

Rawlings 2007 *sigmoid colectomy*		RA: 13 LP: 12	1 left hip paresthesia 1 cecal injury 1 transverse colon injury 1 urinary retention	1 anastomotic leak 1 wound infection

NOTES: …not reported; RA robot-assisted; * 10 weeks post-operative

Intra-operative blood loss

There was no significant difference in the volume of intraoperative blood loss between the robotic and laparoscopic groups in the seven patient groups reported in six studies (see Table 5). Further, it was not possible to identify a consistent trend favouring one technique over the other for this outcome; this may be a result of the variety in the procedures being undertaken.

Table 5 Intraoperative blood loss (millilitres)

Study	**Level of Evidence**	**# patients**	**RA procedure Mean loss ± SD [median] (range)**	**Laparoscopic procedure Mean loss ± SD [median] (range)**	***P* value**
Malignant disease					
Baik 2008	II	RA: 18 LP: 18	0.6±0.6*	0.8±1.0*	0.511
Pigazzi 2006	III-2	RA: 6 LP: 6	104 (50-200)	150 (50-300)	NS
Benign disease					
Woeste 2005	III-2	RA: 4 LP: 23	60.0±17.3	59.8±55.5	0.97
Mixed indications					
D'Annibale 2004	III-2	RA: 53 LP: 53	21±80	37±102	NS
Delaney 2003	III-2/3	RA: 6 LP: 6	[100] (50-350)	[87.5] (50-200)	NS
Rawlings 2007 *right colectomy*	III-2/3	RA: 17 LP: 15	40.0±24.9 [30] (15-100)	66.3±50.7 [50] (20-200)	0.067
Rawlings 2007 *sigmoid colect.*		RA: 13 LP: 12	90.4±60.0 [75] (20-200)	65.4±52.1 [50] (20-200)	0.280

NOTES: RA robot-assisted; SD standard deviation; NS not significant; … not reported; statistically significant values bolded; *reported as hemoglobin change (g/dl)

Efficacy

Table 6 provides a summary of the mean duration of the robotic and comparator laparoscopic procedures.

Both Baik et al (2008) and Pigazzi et al (2006) reported on the duration of low anterior resections. Heemskerk et at (2007) undertook rectopexies and Woeste et al (2005), sigmoid resections. Rawlings et al (2007) reported their patient population as having undergone either right or sigmoid colectomies. The other three studes (D'Annibale et al (2004); Spinoglio et al (2008) and Delaney et al (2003)) undertook a variety of operative procedures across the patient population and did not report duration of operation separately for each different procedure.

All studies reported a shorter operative time in the laparoscopic group; this was statistically significant in five of the nine patient groups. There was no significant difference in operation duration in the studies undertaking low anterior resections and sigmoid colectomies.

Table 6 Operative time (minutes)

Study	Level of Evidence	# patients	RA procedure Mean duration ± SD [median] (range)	Laparoscopic procedure Mean duration ± SD [median] (range)	*P* value
Malignant disease					
Baik 2008	II	RA: 18 LP: 18	217.1±51.6 [202.5] (149-315)	204.3±51.9 [196.0] (114-297)	0.477
Pigazzi 2006	III-2	RA: 6 LP: 6	264 (192-318)	258 (198-312)	NS
Benign disease					
Heemskerk 2007	III-2	RA: 19 LP: 14	152	113	**0.04**
Woeste 2005	III-2	RA: 4 LP: 23	236.7±5.8	172.4±38	**<0.05**
Mixed indications					
D'Annibale 2004	III-2	RA: 53 LP: 53	240±61	222±77	NS
Spinoglio 2008	III-2	RA: 50 LP: 161	383.8	266.3	**<0.001**
Delaney 2003	III-2/3	RA: 6 LP: 6	[216.5] (170-274)	[150] (116-165)	**<0.05**
Rawlings 2007 *right colectomy*	III-2/3	RA: 17 LP: 15	218.9±44.6 [210] (167-340)	169.2±37.5 [160] (119-264)	**0.002**
Rawlings 2007 *sigmoid colect.*		RA: 13 LP: 12	225.2±37.1 [226] (147-283)	199.4±44.5 [198] (138-278)	0.128

NOTES: RA robot-assisted; SD standard deviation; NS not significant; statistically significant values bolded

Only four studies reported time to defecation as an outcome (Table 7). There was no statistically significant difference between the two groups reported by any of these studies. This outcome may be further influenced by the different bowel rest/feeding resumption protocols followed by individual hospitals.

Table 7 Time to defecation/resumption of flatus (days)

Study	Level of Evidence	# patients	RA procedure	Laparoscopic procedure	*P* value
Malignant disease					
Baik 2008	II	RA: 18 LP: 18	1.8±0.4 [2] (1-2)	2.4±1.3 [2] (1-6)	0.071
Benign disease					
Heemskerk 2007	III-2	RA: 19 LP: 14	1.8	1.9	0.857
Mixed indications					
D'Annibale 2004	III-2	RA: 53 LP: 53	4±2	4±2	NS
Spinoglio 2008	III-2	RA: 50 LP: 161	1.67	1.48	0.704

NOTES: RA robot-assisted; SD standard deviation; NS not significant; … not reported; statistically significant values bolded

Length of hospital stay was reported for eight patient groups across seven studies. The randomized controlled trial (Baik 2008) was the only study that reported a significant difference between the two groups for this outcome, in favour of the robotic procedures. Of the other seven patient groups, five reported a shorter mean length of stay for patients undergoing robotic colorectal procedures; however, these differences were not reported to be significant (Table 8).

Table 8 Length of stay (LOS)/hospital admission (days)

Study	Level of Evidence	n/n	RA procedure Mean LOS ± SD [median] (range)	Laparoscopic procedure Mean LOS ± SD [median] (range)	*P* value
Malignant disease					
Baik 2008	II	RA: 18 LP: 18	6.9±1.3 [7] (5-10)	8.7±1.3 [9] (6-12)	**<0.001**
Pigazzi 2006	III-2	RA: 6 LP: 6	4.5 (3-11)	3.6 (3-6)	NS
Benign disease					
Heemskerk 2007	III-2	RA: 19 LP: 14	3.5	4.3	0.527
Mixed indications					
D'Annibale 2004	III-2	RA: 53 LP: 53	10±4	10±6	NS
Spinoglio 2008	III-2	RA: 50 LP: 161	7.74	8.31	0.928
Delaney 2003	III-2/3	RA: 6 LP: 6	[3] (2-5)	[2.5] (2-7)	NS
Rawlings 2007 *right colectomy*	III-2/3	RA: 17 LP: 15	5.2±5.8 [4] (2-27)	5.5±3.4 [4] (3-15)	0.862
Rawlings 2007 *sigmoid colect.*		RA: 13 LP: 12	6.0±7.3 [4] (3-30)	6.6±8.3 [4.5] (4-33)	0.854

NOTES: RA robot-assisted; SD standard deviation; NS not significant; … not reported; statistically significant values bolded

Conversion of the initial procedure has been considered as an efficacy outcome, as it represents an operative failure. This outcome was reported for nine patient groups across the eight included studies (Table 9). The four studies that undertook significance testing on this outcome did not identify any significant difference in conversion rates between the robotic and laparoscopic groups.

Conversions to either a laparoscopic or open procedure after commencing a robotic procedure were undertaken for a variety of reasons, but were generally due to the discovery of unforseen disease complexities, such as dense adhesions to adjoining organs or tissue ischemia. No conversions were reported to be due to failure of the robot.

Table 9 Conversion of initial procedure

Study	Level of Evidence	n/n	RA procedure Number of conversions	Laparoscopic procedure Number of conversions	*P* value
Malignant disease					
Baik 2008	II	RA: 18 LP: 18	0/18	2/18 → open surgery	0.486
Pigazzi 2006	III-2	RA: 6 LP: 6	0/6	0/6	…
Benign disease					
Heemskerk 2007	III-2	RA: 19 LP: 14	1/14	0/19	0.383
Woeste 2005	III-2	RA: 4 LP: 23	1/4 → open surgery	3/23 → open surgery	NS
Mixed indications					
D'Annibale 2004	III-2	RA: 53 LP: 53	6/53* 2/6 → laparoscopy 4/6 → hand-assisted	3/53→ open laparotomy	…
Spinoglio 2008	III-2	RA: 50 LP: 161	2/50 1/2 → laparoscopy 1/2 → open laparotomy	4/161 → open laparotomy	0.603
Delaney 2003	III-2/3	RA: 6 LP: 6	1/6 → laparoscopy	0/6	…
Rawlings 2007 *right colectomy*	III-2/3	RA: 17 LP: 15	0/17	2/15 → open surgery	…
Rawlings 2007 *sigmoid colect.*		RA: 13 LP: 12	2/13 → open surgery	0/12	…

NOTES: RA robot-assisted; SD standard deviation; NS not significant; … not reported; statistically significant values bolded

Pathology outcomes did not reveal any significant difference between robotic and laparoscopic procedures (Table 10). Comparable numbers of lymph nodes were removed, and there were no significant differences in resection margins detected.

Table 10 Pathology outcomes (malignant indications)

Study	RA procedure	Laparoscopic procedure	*P* value
Mean±SD lymph nodes harvested/nodes in specimen (n=)[median] (range)			
Baik 2008	20.0±9.1 [18] (6-49)	17.4±10.6 [22] (9-42)	0.437
Pigazzi 2006	14 (9-28)	17 (9-39)	NS
Spinoglio 2008*	22.03	22.85	0.73
Mean±SD distal resection margin (cm) [median] (range)			
Baik 2008	4.0±1.1 [4.0] (1.0-5.5)	3.7±1.1 [3.5] (1.5-6.0)	0.467
Pigazzi 2006	3.8 (1.8-9)	3.5 (2.2-5)	NS
Spinoglio 2008*	7.3	7.872	0.886
Mean±SD proximal resection margin (cm) [median] (range)			
Baik 2008	10.9±1.7 [8.5] (7.5-20.0)	10.3±3.6 [7.5] (5.5-8.5)	0.549
Pigazzi 2006	…	…	…
Spinoglio 2008*	…	…	…
Macroscopic judgement of specimen			
Baik 2008	Complete: 17 Nearly complete: 1 Incomplete: 0	Complete: 13 Nearly complete: 3 Incomplete: 0	0.368 0.323 …
Pigazzi 2006	…	…	…
Spinoglio 2008	…	…	…

NOTES: *results from the 44/50 patients with colorectal cancer as indication for RA surgery and 128/161 patients with colorectal cancer as indication for laparoscopic procedure

Cost impact

The acquisition cost of the da Vinci surgical system is approximately US$1.5 million. There are further costs associated with the system, including $100,000 in annual maintenance and $2000 per case for disposable instrumentation (Whiteford and Swanstrom 2007).

The need for extra training and increased set-up and operative time also need to be taken into account when calculating the costs of robotic colorectal surgery.

Three studies undertook a cost analysis across four patient groups. Little detail was provided on these analyses, but they appeared to be simple cost-comparisons based on safety and efficacy outcomes; no author reported undertaking modelling. Further, it was not always clear which costs were assigned to each category.

While the total costs were higher for all of the robotic procedures, this was found to be statistically significant in only one study (Table 11). However, authors report different elements of the costs (such as operating room personnel and supply costs) to significantly favour laparoscopic procedures over robotic procedures. Both Delaney et al (2003) and Rawlings et al (2007) were undertaken in the US healthcare system; Heemskerk et al (2007) was costed under the healthcare system of The Netherlands.

Table 11 Total costs of surgery

Study	# patients	Cost category	RA procedure Mean cost±SD [median] (range)	Laparoscopic procedure Mean cost±SD [median] (range)	*P* value
Benign disease					
Heemskerk et al 2007	RA: 19 LP: 14	Total	$4910.55*	$4165.46*	**0.012**
		Salary	$695.06	$516.65	**0.04**
		Instruments	$1042.85	$1042.85	1
		Lab/x-ray etc.	$25.04	$24.12	0.7
		Outpatient	$63.91	$63.91	1
		Admittance	$1894.96	$2518.03	0.441
Mixed indications					
Delaney et al 2003	RA: 6 LP: 6	Total hospital	[US$3721.5] (2365-5201)[†]	[US$2946] (2228-4767)	NS[‡]
		OR & equipment	[US$1417] (1178-2227)	[US$1411] (718-1658)	NS[‡]
Rawlings et al 2007 *Right colectomies*	RA: 17 LP: 15	Total hospital	US$9255±5075 [8098] (6105-28304)	US$8073±2805 [7084] (5474-16280)	0.430
		Total OR	US$5823±907 [5716] (4435-8175)	US$4339±867 [4318] (3050-5826)	**<0.000**
		OR personnel	US$2048±309 [2008] (1560-2869)	US$1340±402 [1425] (621-1982)	**<0.000**
		OR supply	US$2950±475 [2844] (2317-4287)	US$1841±518 [1742] (1210-2851)	**<0.000**
		OR time	US$1521±321 [1466] (1164-2391)	US$990±300 [991] (588-1849)	**<0.000**

Rawlings et al 2007 *Sigmoid colectomies*	RA: 13 LP: 12	Total hospital	US$12335±12162 [8529] (6569-52042)	US$10697±11719 [7406] (5312-47651)	0.735
		Total OR	US$6059±1225 [5846] (4579-9147)	US$4974±1596 [4784] (3041-9368)	<0.068
		OR personnel	US$2134±432 [2061] (1614-3223)	US$1621±617 [1594] (754-3327)	**<0.024**
		OR supply	US$3159±637 [3056] (2392-4780)	US$2137±905 [1989] (966-4645)	**<0.003**
		OR time	US$1500±461 [1405] (979-2810)	US$1348±681 [1152] (760-1505)	<0.519

NOTES: RA robot-assisted; LP laparoscopic procedure; SD standard deviation; NS not significant; … not reported; statistically significant values bolded; *converted from Euros by the study authors, currency not specified; † specifically excluding capital cost of da Vinci purchase; ‡ power analysis revealed that with a *P* value of 0.05, there was only a 10% chance of distinguishing a significant difference in costs between groups

Clinical practice guidelines and consensus statements

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) produced a consensus document on robotic surgery in 2007 (Herron and Marohn 2007). They found potential advantages across many surgical subspecialties, including “selected colorectal procedures”. It is also stated that “in resections for neoplasm, robotic surgery may help to enhance the completeness of lymph node dissection” (Herron et al 2007). However, this consensus statement is not clear on the evidence underpinning these findings.

Training and education impact

Training and educational issues surrounding the use of robotic surgery were not addressed in any of the studies identified as part of this horizon scanning report. It may be that the increasing dissemination of this technology especially in the USA may warrant a formal training program to be developed for certain specialties. This may alleviate any learning curve associated with the use of these devices

Summary

Robotic colorectal surgery is an emerging technique, for which there is only limited clinical data available.

Examining the evidence available to date across a number of indications and procedures (including low anterior resections, colectomies, rectopexies and resections), robotic colorectal surgery appears to provide outcomes comparable, but not superior, to those achieved with laparoscopic colorectal surgery, including oncologic adequacy and vascular control.

While it may be that robotic assistance is of particular use in some parts of these procedures (e.g. splenic takedown and fine dissection), there is no evidence to support this. This is due to the fact that each of the procedures has been evaluated as a whole, and not as a series of individual procedural components.

However, robotic surgery is associated with an increased surgical time and higher costs. Robotic colorectal surgery also only allows intervention in one abdominal region at a time; to change a surgical field, the entire system must be repositioned.

Further studies involving larger patient numbers and considering long-term outcomes are required to more accurately determine the safety and efficacy of robotic colorectal surgery and quantify other purported benefits, such as improved surgeon ergonomics and reduced operative fatigue.

Recommendation

From the mixed data available, robotic colorectal surgery does not appear to confer notable safety or efficacy benefits over traditional laparoscopic colorectal surgery. It is associated with a large initial financial investment, a longer operative time and higher surgical costs.

Therefore, at this stage of development, the available evidence does not support the continued use or expansion of robotic assistance in colorectal surgery.

More directed research is required to determine specific elements of colorectal procedures that may benefit from robotic assistance (e.g. splenic takedown, fine dissection).

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Appendix A

Additional papers not included in this assessment

Article reference	N=	Conclusions	Reason for exclusion
Braumann C, Jacobi C, Menenakos C, Borchert U, Rueckert J, Mueller J. Computer-assisted laparoscopic colon resection with the Da Vinci system: our first experiences. *Diseases of the Colon and Rectum* 2005; 48(9): 1820-1827.	5	Can be performed safely Specific benefits during dissection Limited by lack of large operation field and costs	Case reports
Ng S, Lee J, Yiu R, Lee J, Hon S. Telerobotic-assisted laparoscopic abdominoperineal resection for low rectal cancer: report of the first case in Hong Kong and China with an updated literature review. *World Journal of Gastroenterology* 2007; 13(17): 2514-2518.	1	Safe and effective	Case report
Weber P, Merola S, Wasielewski A, Ballantyne G. Telerobotic-assisted laparoscopic right and sigmoid colectomies for benign disease. *Diseases of the Colon and Rectum* 2002; 45(12): 1689-1696.	3	Feasible; warrants further investigation	Case reports

Studies excluded from this assessment

Baik S, Lee W, Rha K, Kim N, Sohn S, Chi H, Cho C, Lee S, Cheon J, Ahn J, Kim W. Robotic total mesorectal excision for rectal cancer using four robotic arms. *Surgical Endoscopy* 2008; 22: 792-797.	Case series; duplicate patients (Baik et al 2008).
Giulianotti P, Coratti A, Angelini M, Sbrana F, Cecconi S, Balestracci T, Caravaglios G. Robotics in general surgery. *Archives of Surgery* 2003; 138: 777-784.	Not colorectal indications
Hashizume M, Shimada M, Tomikawa M, Ikeda Y, Takahashi I, Abe R, Koga F, Gotoh N, Konishi K, Maehara S, Sugimachi K. Early experiences of endoscopic procedures in general surgery assisted by a computer- enhanced surgical system. *Surgical Endoscopy* 2002; 16: 1187-1191.	Colorectal procedures could not be separated from mixed data
Rawlings A, Woodland J, Crawford D. Telerobotic surgery for right & sigmoid colectomies: 30 consecutive cases. *Surgical Endoscopy* 2006; 20: 1713-1718.	Duplicate patients (Rawlings et al 2007)
Talamini M, Chapman S, Horgan S, Melvin W. A prospective analysis of 211 robotic-assisted surgical procedures. *Surgical Endoscopy* 2003; 17: 1521-1524.	Not colorectal indications
Vibert E, Denet C, Gayet B. Major digestive surgery using a remote-controlled robot. *Archives of Surgery* 2003; 138: 1002-1006.	Not colorectal indications
Ziogas D, Roukos D. Robotic surgery for rectal cancer: may it improve also survival? *Surgical Endoscopy* 2008; 22: 1405-1406.	Discussion only; no clinical outcomes reported