Early results after robot-assisted colorectal surgery

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ABSTRACT

INTRODUCTION: Implementation of robotic technology in surgery is challenging in many ways. The aim of this study was to present the implementation process and results of the first two years of consecutive robot-assisted laparoscopic (RAL) colorectal procedures.

MATERIAL AND METHODS: The study was a retrospective study of a consecutive, unselected patient population. All outcome parameters were predefined and all patients completed 30-day follow-up. All parameters were reported, including complication rate, reoperation rate and mortality.

RESULTS: From April 2010 to April 2012, a total of 223 elective RAL colorectal procedures were performed. The procedures were grouped as follows: left colectomy/sigmoid resection (n = 65), low anterior resection (n = 50), abdominoperineal resection (n = 10), right colectomy (n = 56), rectopexia (n = 21), colectomy (n = 8), palliative procedure (n = 8) and stoma reversal (n = 8). The overall mortality rate was 0.4%; intra- and post-operative complication rates were 5.4% and 16%, respectively; and the reoperation rate was 9%. Conversion to open surgery was necessary in 9% of cases. A positive learning curve was found for low anterior resections with a significant decrease in duration of surgery over the course of the study period.

CONCLUSION: RAL colorectal surgery can be performed as a standard procedure for most colorectal procedures. Appropriate staff education, surgical plan and quality assessment are necessary and we recommend a credentialing system for robotic surgery certification. Future randomized clinical trials should be performed to evaluate the short- and long-term results in these patients.

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Technical developments in surgery have caused remarkable changes for patients as well as surgeons over the past 20 years. The safety and superiority of laparoscopy compared with open surgery for colorectal resections is well documented. Procedure costs have increased, but at the same time, morbidity has decreased with shorter hospital stay and less pain for the patient [1, 2].

The introduction of robotic technology in laparoscopy has added new dimensions to surgery and the robotic systems can potentially overcome many of the inherent problems in conventional laparoscopy. The da Vinci Surgical System (Surgical Intuitive) has been introduced in many surgical specialities and procedures [3], but implementation of new technology is challenging with respect to surgical strategy, safety and education in the department.

We report a single institution experience with implementation of robot-assisted laparoscopic (RAL) colorectal surgery including the 30-day outcome data for all procedures performed during the first two years.

MATERIAL AND METHODS

Design

This was a retrospective study. The department is a high-volume acute surgical department with a colorectal unit managing all aspects of colorectal and anal malignancies. From April 2010, all patients suitable for laparoscopic surgery were considered candidates for a RAL procedure. Patients with recurrent cancer, preoperative stage T4 cancer or anal cancer were not considered candidates for RAL surgery.

Surgical set-up and credentialing system

Patients were scheduled for RAL if surgeons and operating rooms (OR) were available, as our da Vinci OR capacity was limited to two days per week in the study period (increasing to 2.5 days per week in 2012). The RAL technique was implemented by three experienced laparoscopic colorectal surgeons (> 500 laparoscopic colorectal resections each). After 100 procedures in September 2011, two additional colorectal surgeons were included in the team. All surgeons in the robotic team were double board-certified surgeons (general and colorectal) with considerable laparoscopic experience. Each surgeon passed the credentialing process for robotic surgical certification at the Robotic Surgical Centre at Herlev Hospital which included a web-based education programme, dry-lab training and surgical simulator training at the local hospital and a two-day course with theoretical and practical training on cadavers or pigs. Operating room nurses also participated in the two-day course.

The centre incorporates specialists from the department of surgery, gynaecology and urology, and administers three da Vinci systems (one S and two Si systems), see **Figure 1**. We used both systems with a total of five ports with 12 mm ports for the camera and assistant and 8 mm ports for the robotic instruments. Dissection was performed with a medial and "vessel first" approach in all cancer procedures. In all rectal and left-sided resec-

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FIGURE 1

The patient-site cart of the da Vinci surgical system with four interactive robotic arms holding three laparoscopic instruments and a 3D camera. The camera and all instruments are controlled real-time by the surgeon from the surgeon console (not shown).

tions, the specimen was extracted through a small phannenstiel incision and anastomoses were routinely stapled transanally. Specimens after right colectomies were extracted through a transverse incision above the umbilicus and an extracorporeal stapled anastomosis was performed.

All rectopexies were performed as posterior Well's procedures. All procedures were performed by two specialists working together.

Data collection and analysis

Post-operative follow-up was not routinely planned, although all patients with cancer were seen in the out-patient clinic 2-4 weeks post-operatively to receive the histological diagnosis. A complete follow-up of all patients was obtained from the electronic patient journal system. All patient and perioperative data were registered continuously and collected retrospectively.

Demographic data, co-morbidity and risk factors were registered. Operative data were registered such as type of procedure, set-up time (time from patient in OR/induction of anaesthesia to first incision), duration of surgery (time from first incision to last suture, including port placement and docking time), intraoperative complications and others. All outcome parameters were predefined and reported, including complications, re-operation and mortality within 30 days. All predefined post-operative complications are listed in **Table 1**.

Linear regression was used to investigate any positive learning curve for specific procedures. Statistical analyses were performed using the Statistical Analysis System 9.2 for Windows. $p < 0.05$ was considered to be statistically significant. All values are presented as medians (range) if not stated otherwise.

Trial registration: not relevant.

Results

From 20 April 2010 to 27 April 2012, a total of 223 elective colorectal procedures were performed in 222 patients. Demographic and co-morbidity data of the study population are listed in **Table 2**. The type and distribution of all procedures including outcomes are illustrated in Table 1.

The number of procedures performed per month increased during the study period (**Figure 2**). The set-up time did not change significantly ($p = 0.35$, linear regression model), but a significant decrease in the duration of surgery for low anterior resections (LAR) was found during the study period ($p = 0.02$, linear regression, **Figure 3**).

All procedures (223 procedures)

All perioperative complications are listed in Table 1. Two procedures were converted to laparoscopy, one due to difficult robotic mobilisation of the splenic flexure (left colectomy) and the other due to localisation and fixation of the sigmoid colon near the hepatic flexure (sigmoid resection). Specific indications for reoperation are shown in Table 1.

Four patients (1.8%) were transferred to the intensive care unit post-operatively (anastomotic leak = 2, small bowel obstruction = 1, aspiration pneumonia = 1) and one patient died in the follow-up period (mortality rate 0.4%). Blood transfusion was necessary in 18 patients (8.1%), with a median of two (1-8) units per patient, most frequently after LAR (n = 6) and right colectomy (n = 7).

Left colectomy/sigmoid resection (65 procedures)

Seven patients (11%) had an end colostomy caused by reoperation for anastomotic leak in four cases, and in the remaining three cases primary anastomosis was avoided due to patient co-morbidity. Four patients (6.2%) had an intraoperative complication, including lesions of bladder, spleen, ureter and uterus, respectively.

Low anterior resection (50 procedures)

A diverting loop ileostomy was created in 68% of the patients, whereas 32% ended up with a colostomy, includ-

TABLE 1

Outcome for specific procedures in 222 patients.

	Left colectomy, sigmoid resection	LAR	APR	Right colectomy	Rectopexia	Colectomy	Palliation	Stoma reversal	Total
Procedures, n	65	50	10	56	21	8	8	5	223
Stoma formation, n (%)	7 (11)	16 (32)	10 (100)	2 (3.6)	0	8 (100)	6 (75)	0	49 (22)
Conversion to laparoscopy, n (%)	2 (3.1)	0	0	0	0	0	0	0	2 (0.9)
Conversion to open surgery, n (%)	7 (11)	4 (8)	0	5 (8.9)	1 (5)	1 (12.5)	1 (12.5)	1 (20)	20 (9)
Mobilization of splenic flexure, n (%)	17 (26)	0	0	0	0	8 (100)	1 (12.5)	0	26 (12)
Set-up time, h:min., median (range)	1:15 (0:45-2:15)	1:19 (0:40-2:45)	1:25 (0:57-1:45)	1:16 (0:45-2:15)	1:08 (0:40-1:40)	1:16 (1:00-1:55)	1:15 (0:35-1:38)	1:29 (1:06-1:40)	1:15 (0:35-2:45)
Duration of surgery, h:min., median (range)	2:34 (1:15-6:09)	3:34 (1:50-7:33)	5:18 (3:35-8:31)	2:13 (1:11-5:10)	1:58 (1:20-4:05)	4:48 (3:25-6:30)	1:22 (0:35-2:45)	2:30 (1:58-2:43)	2:41 (0:35-8:31)
Intraoperative complications, n/N (%)	4/65 (6.2)	2/50 (4)	0/10	2/56 (3.6)	2/21 (9.5)	1/8 (12.5)	1/8 (12.5)	0/5	12/223 (5.4)
Post-operative complications[a]*, n/N (%)*	8/65 (12)	19/50 (38)	1/10 (10)	6/56 (11)	2/21 (9.5)	0	0	0	36/223 (16)
Anastomotic leak	4/62 (6.5)	6/39 (15)	0	1/55 (1.8)	-	-	0/1	0/5	11/162 (6.8)
Urinary retention	2/65 (3.1)	6/50 (12)	0	0	0	0	0	0	8/223 (3.6)
Wound infection	2/65 (3.1)	3/50 (6)	0	1/55 (1.8)	0	0	0	0	6/223 (2.7)
Pneumonia	1/65 (1.5)	1/50 (2)	0	3/56 (5.4)	1/21 (4.8)	0	0	0	6/223 (2.7)
Sepsis	1/65 (1.5)	2/50 (4)	0	0	0	0	0	0	3/223 (1.3)
Urinary tract infection	0	2/50 (4)	1/10 (10)	0	0	0	0	0	3/223 (1.3)
Intraabdominal abscess without anastomotic leak	0	2/50 (4)	0	0	0	0	0	0	2/223 (0.9)
MI	0	0	0	1/55 (1.8)	0	0	0	0	1/223 (0.4)
ATN	0	1/50 (2)	0	0	0	0	0	0	1/223 (0.4)
Aspiration pneumonia with reoperation (cause)	0	0	0	1/55 (1.8)	0	0	0	0	1/223 (0.4)
Anastomotic leak	4/62 (6.5)	5/39 (13)	0	1/55 (1.8)	-	-	0	0	10/162 (6.2)
SBO	2/65 (3.1)	3/50 (6)	0	0	1/21 (4.8)	0	0	0	6/223 (2.7)
Bleeding	1/65 (1.5)	2/50 (4)	0	0	0	0	0	0	3/223 (1.3)
Wound rupture	0	0	0	1/56 (1.8)	0	0	0	0	1/223 (0.4)
Reoperation rate, overall, n/N (%)	7/65 (11)	10/50 (20)	0	2/56 (3.6)	1/21 (4.8)	0	0	0	20/223 (9)
Stay in hospital, days, median (range)	4 (1-26)	8 (3-100)	8 (5-10)	4 (1-22)	4 (1-15)	6 (4-13)	7 (2-13)	4 (2-6)	5 (1-100)
30-day mortality, n/N (%)	0	0	0	1/56 (1.8)	0	0	0	0	1/223 (0.4)

APR = abdominoperineal (rectal) resection; ATN = acute tubular necrosis; LAR = low anterior resection; MI = myocardial infarction; SBO = small bowel obstruction.
a) We did not observe any other complications, such as pulmonary insufficiency, apoplexy, deep venous thrombosis, pulmonary embolism or peripheral arterial embolism/extremity ischaemia within the first 30 post-operative days.

ing five patients with anastomotic leakage, nine patients with middle to low rectal cancers and significant co-morbidity and two with disseminated disease. Two patients (4%) had an intraoperative complication, including lesions of the bladder and vagina. Three patients were re-operated for small bowel obstruction, all caused by stoma-related problems. Two patients were reoperated for massive bleeding, one from the mesentery and another from the anastomotic line (managed endoscopically).

Abdominoperineal resection (conventional or intersphincteric resection) (ten procedures)

No intraoperative or major post-operative complications were observed.

Right colectomy (56 procedures)

Two patients (3.6%) had an ileostomy due to anastomotic leakage and disseminated disease, respectively.

Two patients (3.6%) had an intraoperative complication, including lesion of the small bowel and pancreas. One patient died on the ninth post-operative day of multi organ failure caused by aspiration pneumonia and myocardial infarction. A diagnostic laparoscopy revealed an intact anastomosis.

Rectopexy (21 procedures)

Two patients (9.5%) had intraoperative complications including a presacral venous bleeding and a rectal lesion.

TABLE 2

Demographic data, co-morbidity and risk factors for all patients undergoing a robot-assisted laparoscopic colorectal procedure.

Demographic data	
Sex, M:F, n	95:127
Age, years, median (range)	69 (29-93)
BMI, kg/m^2, median (range)	24.5 (16-44.1)
ASA score 1-2, n (%)	189 (86)
ASA score ≤ 3, n (%)	31 (14)
Co-morbidity, n (%)	
Malignancy	168 (76)
Hypertension	80 (36)
Hypercholesterolaemia	48 (22)
Heart disease	34 (15)
Lung disease	19 (9)
Diabetes	16 (7)
Cerebrovascular disease	11 (5)
Colitis ulcerosa	9 (4)
Liver disease	2 (1)
Crohn's disease	2 (1)
Risk factors	
Previous abdominal/pelvic surgery, n (%)	78/222 (35)
Preoperative chemoradiotherapy, n (%)	20/168 (12)

ASA = American Society Anesthesiologists; BMI = body mass index; F = female; M = male.

One patient was reoperated (4.8%) due to a small bowel obstruction caused by adherences to the prosthetic mesh and recovered uneventfully.

Colectomy (eight procedures)

The indications for colectomy were ulcerative colitis (n = 6) and colonic cancer (n = 2). In one patient with massive colonic inflammation and intraabdominal adherences, the operation was converted to open surgery due to an iatrogenic lesion of the colonic wall made during dissection of the sigmoid colon from the bladder. The patient recovered uneventfully.

Palliative procedure (eight procedures)

All palliative procedures were performed in patients with disseminated disease. Six patients with bowel obstruction had diverting stomas, one patient had a non-therapeutic laparoscopy and an 84-year-old patient had an intracorporeal stapled and hand-sewn colo-colic bypass between the transverse and sigmoid colon due to massive tumour obstruction.

A trocar lesion of the transverse colon during pneumoperitoneum required conversion to open surgery in another patient (12.5%).

Stoma reversal (five procedures)

Four patients with colostomy and one patient with a colostomy and a loop ileostomy had reversal surgery performed, of which the latter was converted to open surgery.

DISCUSSION

We evaluated both the implementation and the outcome of robot-assisted colorectal surgery in a large consecutive patient series from a single institution and show that several standard colorectal procedures can be performed as RAL procedures with results comparable to those of similar conventional laparoscopic procedures.

We observed no system malfunction or technical failures of the da Vinci system of consequence for the patient. The overall conversion rate to open surgery was 9% in our series compared with about 15% reported in large national database reviews of laparoscopic colonic resections [4, 5]. A recent meta-analysis concluded that RAL surgery for rectal cancer was associated with a lower conversion rate than laparoscopy [6].

The set-up time was constant for all procedures, with no trend towards a reduction over time. The set-up time will probably remain constant, but in contrast to what is often stated, the skin-to-skin surgical time is probably faster in RAL surgery than in laparoscopy [7]. Consequently, the difference in total operative time is probably much smaller than previously expected [7, 8].

The relatively long procedure time for colectomies in this study is, in part, due the robotic system. Approaching the splenic flexure, the robotic arms are positioned in relatively extreme positions, which makes dissection and manoeuvring difficult. The robot must then be "un-docked" and "re-docked" on the opposite site, which is time-consuming, to reach and dissect the whole colon.

RAL rectopexia was performed with good perioperative results with no recurrences registered within 30 days post-operatively. We regard the procedure as safe, which has also been documented in a randomized trial [9], although functional outcome data were not provided. RAL rectopexia is a technically simple procedure which includes dissection of the rectum in the "holy plane" before rectal resection is introduced.

FIGURE 2

Number of robot-assisted laparoscopic colorectal procedures per month and cumulated over the two-year study period, April 2010-April 2012.

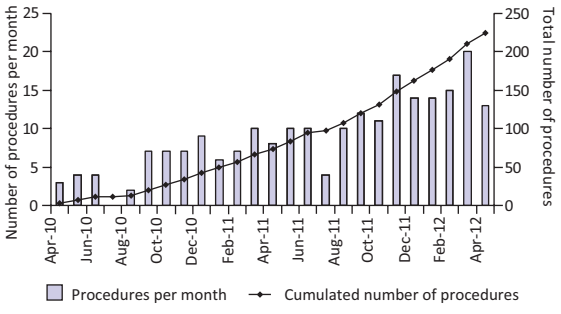
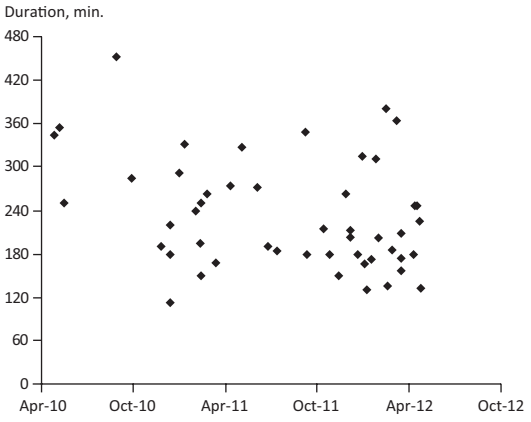


FIGURE 3

Learning curve for robot-assisted laparoscopic (RAL) anterior rectal resection: duration of each RAL low anterior rectal resection during the study period, April 2010-April 2012. A significant decrease in surgical time was observed over time (p = 0.02).



The 30-day mortality was 0.5% after colorectal resection compared with the 1.43-2% reported in large database studies [10, 11]. The intra- and post-operative complication rates (5.4% and 16% overall) were comparable to national (Danish Colorectal Cancer Group (DCCG)) [12] and international results [13]. In a review by Antoniou et al [14], the overall post-operative complication rate after RAL anterior rectal resection was found to be 8.9%. This finding represents the result of 440 procedures from 19 different studies, of which only eight included more than 20 patients, and complications were not always pre-defined or reported in these studies.

In a recently published retrospective cohort study from our institution comparing RAL and conventional laparoscopic colonic resections [7], we found no difference in complications or mortality, conversion rate, overall procedure time, length of hospital stay or number of harvested lymph nodes. There is still no evidence that RAL improves oncological outcome or sexual and bladder function after rectal surgery [15], but preliminary studies have shown a tendency towards less positive circumferential resection margins in RAL rectal resection [16]. No studies have found RAL procedures to be less expensive than conventional laparoscopy [17, 18], but a recent systematic review based on 11 studies on health technology assessment (HTA) of robotic surgery was inconclusive [19]. If the purchase and maintenance costs of the robot system are included, robotic surgery is certainly more expensive than conventional laparoscopy, but the costs of robotic systems will presumably decrease in the future.

During implementation, we found it important that each surgeon was familiar with all procedural and technical steps both at the patient site and in the robot console. The potential waiting status for the surgeon at the patient site was managed by switching from patient site to the console halfway through the procedure. This strategy keeps attention on the shared responsibility for the procedure, and we believe that the positive effect of sharing the learning phase and investigating technical efforts together is crucial.

Learning curve studies on the da Vinci system have concluded that the learning phase for rectal and rectosigmoid resections was completed after 15-25 procedures [20]. This corresponds to our finding of a significant learning curve on 50 anterior rectal resections. Additionally, by splitting console and patient time, each surgeon more frequently had time at the console, without a decrease in number of procedures.

CONCLUSION

In conclusion, RAL colorectal surgery is safe and can be implemented as standard procedure for several colorectal procedures with low complication rates. The primary costs of a RAL procedure are higher than those of similar laparoscopic procedures today. There have been no randomized clinical trials showing any clinical benefits of RAL compared with laparoscopy.

The results from on-going and future studies are awaited, and until then, robot-assisted procedures should mainly be performed as part of clinical trials.

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