Original article

Multicentre study of robotic intersphincteric resection for low rectal cancer

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Background: **There is a lack of information regarding the oncological safety of robotic intersphincteric resection (ISR) with coloanal anastomosis. The objective of this study was to compare the long-term feasibility of robotic compared with laparoscopic ISR.**

Methods: **Between January 2008 and May 2011, consecutive patients who underwent robotic or laparoscopic ISR with coloanal anastomosis from seven institutions were included. Propensity score analyses were performed to compare outcomes for groups in a 1 : 1 case-matched cohort. The primary endpoint was 3-year disease-free survival.**

Results: **A total of 334 patients underwent ISR with coloanal anastomosis, of whom 212 matched patients (106 in each group) formed the cohort for analysis. The overall rate of conversion to open surgery was 0·9 per cent in the robotic ISR group and 1·9 per cent in the laparoscopic ISR group. Nine patients (8·5 per cent) in the laparoscopic group and three (2·8 per cent) in the robotic ISR group still had a stoma at last follow-up ($P = 0{\cdot}075$). Total mean hospital costs were significantly higher for robotic ISR (€12 757 *versus* €9223 for laparoscopic ISR; $P = 0{\cdot}037$). Overall 3-year local recurrence rates were similar in the two groups (6·7 per cent for robotic and 5·7 per cent for laparoscopic resection; $P = 0{\cdot}935$). The combined 3-year disease-free survival rates were 89·6 (95 per cent c.i. 84·1 to 95·9) and 90·5 (85·4 to 96·6) per cent respectively ($P = 0{\cdot}298$).**

Conclusion: **Robotic ISR with coloanal anastomosis for rectal cancer has reasonable oncological outcomes, but is currently too expensive with no short-term advantages.**

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Introduction

Abdominoperineal resection was originally the standard surgical approach for patients with rectal adenocarcinoma located within 4 cm of the anal verge. Intersphincteric resection (ISR) with coloanal anastomosis (CAA) was developed to avoid a permanent colostomy for such patients[1–3]. This procedure involves resection of part of, or the entire, internal sphincter and restoration of bowel continuity while obtaining sufficient distal margins. Laparoscopic ISR is associated with less surgical trauma, improved immediate postoperative outcomes and shorter recovery times compared with conventional open surgery, but similar long-term oncological outcomes[4–6]. Laparoscopy offers an optimal pelvic dissection with the visceral pelvic fascia remaining intact, and an enhanced view deeper within the pelvis than in the open technique. However, the use of non-articulated forceps, camera tremor and surgeon fatigue make laparoscopic ISR technically demanding, and it is restricted to a few specialized centres.

Robotic surgical systems have been adopted in an effort to overcome such intrinsic disadvantages of laparoscopic surgery. The robotic platform can facilitate safe and efficient sphincter-saving options by offering improved dexterity and visualization[7–9]. However, controversy remains because these conclusions are based on single-centre data, unreliable control groups, relatively small numbers of procedures or only short-term follow-up[8,10,11]. Accordingly, the present multicentre case-matched study was carried out to assess better the widespread applicability of robotic ISR in the treatment of low rectal cancers. The aim of the study was to verify the long-term safety of robotic ISR for low rectal cancer compared with laparoscopic ISR by analysing long-term follow-up data for a large number of patients. Other endpoints were surgical outcomes, rate of anal function preservation, surgical morbidity and the success of postoperative recuperation.

Methods

A multicentre consortium of seven institutions participating in the Korean Laparoscopic Colorectal Surgery Study Group was established. Consecutive patients who underwent ISR with CAA between January 2008 and May 2011 comprised the data set for this analysis. Eligibility criteria included biopsy-proven adenocarcinomas, with the inferior margins located within 4 cm of the anal verge. Each surgeon who participated in this study provided specified perioperative, functional and oncological data using a common menu-driven database file that incorporated precise coding instructions. Each contributing institution was responsible for gaining institutional review board approval. All nine participating surgeons were experienced and skilled in rectal cancer surgery (total mesorectal excision or tumour-specific mesorectal excision) and each had experience of more than 200 rectal cancer procedures. Before employing a robotic surgical approach, eight of the nine surgeons had a history of performing 60 or more conventional laparoscopic operations per year for the treatment of rectal cancer.

Surgical procedures and follow-up

The surgical indications were not standardized between the various institutions during the study interval, and the surgical approach was determined by a preoperative joint decision between the patient and physician. At the time of surgery, there was no intention to compare the two procedures. However, most participating surgeons did not carry out an ISR in patients with incurable metastasis, invasion of the external sphincter or levator ani muscles, or those who were not fully continent before surgery. Patients with clinical T3–4 or node-positive disease received long-course preoperative chemoradiotherapy (50 Gy in 25 fractions for 5 weeks). All procedures were performed using similar techniques, but differing slightly in the means of trocar placement (hybrid approach by 4 surgeons, totally robotic approach by the other 5). Techniques and trocar arrangements for robotic and laparoscopic ISR have been described in detail elsewhere[9,11,12].

Perioperative outcomes included skin-to-skin duration of surgery, estimated blood loss, length of hospital stay, morbidity and conversion to an open procedure. Postoperative complications were stratified according to the Dindo–Demartines–Clavien classification of surgical complications[13]. The total numbers of postoperative complications were counted for all events related to morbidity. Defaecatory function (daily defaecation frequency, pad use, antidiarrhoeal drug use and presence of a stoma) and genitourinary function (retrograde ejaculation) were evaluated at 24 months after the primary surgery.

Total cost was evaluated, defined as total expenses incurred from admission to discharge. Total hospital charges included benefit service charges and non-benefit service charges. In Korea, 95 per cent of benefit service charges are reimbursed by the National Health Insurance (NHI) Corporations (everyone has to enrol in the insurance system by law). All non-benefit service charges and 5 per cent of benefit service charges are paid by patients. Currently, costs of some operating room resources (trocar system, basic endoscopic instruments, advanced energy devices) employed for laparoscopic surgery are refunded by the NHI, whereas robotic surgery is not covered by the NHI in Korea.

Statistical analysis

The primary endpoint of the study was 3-year disease-free survival (DFS). Survival was calculated from the time of surgical resection of the primary tumour to the last visit, or to the death of the patient. The probabilities of local recurrence, overall survival and DFS were estimated using the Kaplan–Meier method, and Cox proportional hazards models were used for unadjusted survival analyses. The log rank test and Breslow test were used to compare survival between groups; the minimum length of follow-up was 3 years.

To minimize the influence of potential confounders on the selection bias, the propensity score matching method was applied by using binary logistic regression. One-to-one matching between the groups was accomplished using the nearest-neighbour matching method.

Continuous variables with a normal distribution are presented as mean(s.d.) and those with a non-normal distribution as median (i.q.r.). Student's t test was used for analysis of continuous variables and the χ^2 test for comparison of proportions. $P < 0{\cdot}050$ was considered statistically significant. All statistical analyses were performed using SPSS® for Windows® version 18.0 (IBM, Armonk, New York, USA).

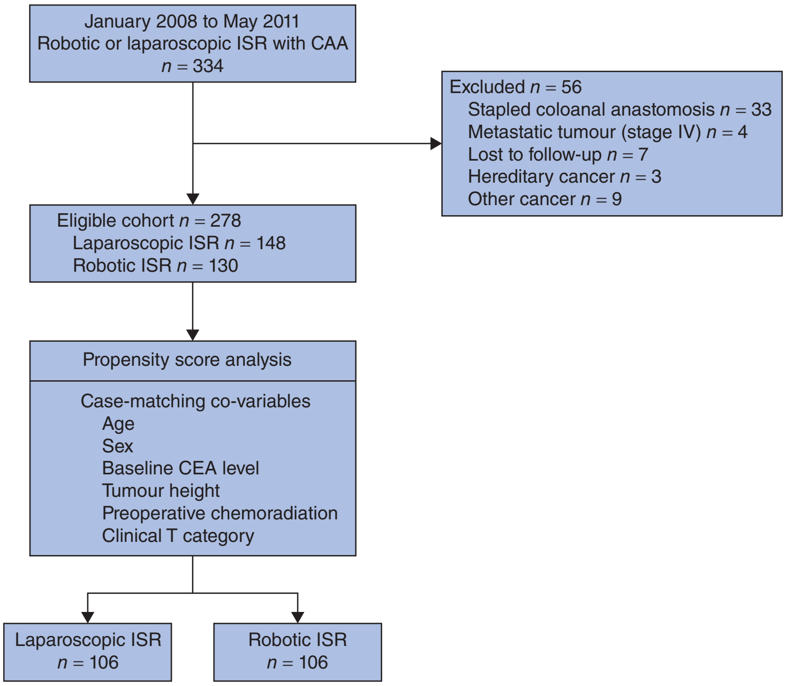

Fig. 1 Study flow diagram. ISR, intersphincteric resection; CAA, coloanal anastomosis; CEA, carcinoembryonic antigen

Results

During the study interval, 334 patients underwent ISR with CAA for low rectal cancer (163 robotic surgery, 171 laparoscopic surgery). Fifty-six patients were excluded from the cohort for the following reasons: stage IV disease (4), a history of other malignancies (9), lost to follow-up within 12 months (7), stapled CAA (33), and familial adenomatous polyposis or hereditary non-polyposis colorectal carcinomas (3). A case-matched analysis was then carried out to eliminate confounding variables resulting from the different indications for a particular surgical method between the two groups. This aimed to balance multidimensional observed co-variables and was done by propensity score analysis. A total of 106 patients in each group were selected from the original data set after matching by sex, age, clinical T category, preoperative chemoradiation, tumour height and baseline carcinoembryonic antigen level (*Fig. 1*). The robotic and laparoscopic ISR groups were balanced in terms of baseline characteristics and clinical T category (*Table 1*).

Perioperative results and morbidity for the matched patients are shown in *Table 2* (corresponding data for the original unmatched cohort can be found in *Table S1*, supporting information). A total of three procedures in the propensity-matched cohort were converted to open surgery because of a difficult dissection in a narrow pelvis (2) and intraoperative bleeding (1). The duration of surgery was longer in the robotic group than in the laparoscopic group ($P = 0{\cdot}001$). Intraoperative blood transfusion was required in one patient in each group, and the estimated blood loss similar after both procedures ($P = 0{\cdot}054$).

No patient died during the first 30 days after surgery in either group. There was a significant difference in

Table 1 Patient characteristics

	Laparoscopic ISR (*n* = 106)	Robotic ISR (*n* = 106)	*P*†
Age at surgery (years)*	61·7(9·6)	59·6(10·8)	0·148‡
Sex ratio (M : F)	71 : 35	75 : 31	0·553
Body mass index (kg/m^2)*	23·8(3·3)	24·3(2·8)	0·322‡
ASA fitness grade			0·162
I	42 (39·6)	48 (45·3)	
II	50 (47·2)	52 (49·1)	
III	14 (13·2)	6 (5·7)	
Tumour height (cm)*	3·3(1·1)	3·2(1·0)	0·444‡
Baseline serum CEA (ng/ml)*	4·0(4·7)	4·3(7·7)	0·708‡
Neoadjuvant CRT	60 (56·6)	68 (64·2)	0·261
Clinical tumour category			0·890
T1/T2	58 (54·7)	59 (55·7)	
T3	45 (42·5)	43 (40·6)	
T4	3 (2·8)	4 (3·8)	

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). ISR, intersphincteric resection; ASA, American Society of Anesthesiologists; CEA, carcinoembryonic antigen; CRT, neoadjuvant chemoradiation. †χ^2 test, except ‡Student's *t* test.

Table 2 Perioperative metrics

	Laparoscopic ISR (*n* = 106)	Robotic ISR (*n* = 106)	*P*§
Duration of surgery (min)*	232·6(79·2)	271·6(83·9)	0·001¶
Estimated blood loss (ml)*	187·3(212·2)	129·5(162·3)	0·054¶
Conversion to open surgery	2 (1·9)	1 (0·9)	0·561
Protective stoma	73 (68·9)	76 (71·7)	0·652
Time to toleration of diet (days)*	5·2(4·0)	4·6(2·9)	0·251¶
Hospital stay (days)*	11·7(8·8)	9·9(3·9)	0·050¶
Stoma-free at last follow-up	97 (91·5)	103 (97·2)	0·075
Postoperative mortality	0 (0)	0 (0)	1·000
Postoperative morbidity†	32 (30·2)	20 (18·9)	0·042
Anastomotic leakage	6 (5·7)	4 (3·8)	0·517
Rectovaginal/urethral fistula	3 (2·8)	1 (0)	0·155
Anastomosis stricture	4 (3·8)	2 (1·9)	0·341
Intra-abdominal abscess	2 (1·9)	1 (0·9)	0·081
Stoma-related complication	2 (1·9)	0 (0)	0·561
Ileus	5 (4·7)	4 (3·8)	0·733
Wound infection	2 (1·9)	3 (2·8)	0·316
Anaemia requiring transfusion	1 (0·9)	2 (1·9)	0·498
Medical complication	4 (3·8)	4 (3·8)	1·000
Urinary retention	10 (9·4)	5 (4·7)	0·060
Grade of morbidity‡			0·585
I–II	20 (63)	13 (65)	
III–V	12 (37)	7 (35)	

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). †Number of patients with at least one complication during the first 30 days after surgery. ‡Graded according to Dindo–Martines–Clavien system. ISR, intersphincteric resection. §χ^2 test, except ¶Student's *t* test.

Table 3 Pathological characteristics

	Laparoscopic ISR (*n* = 106)	Robotic ISR (*n* = 106)	*P*†
Tumour size (cm)*	2·8(1·9)	2·8(1·7)	0·954‡
Proximal margin (cm)*	21·0(10·7)	20·3(7·4)	0·575‡
Distal margin (cm)*	1·2(0·7)	1·2(0·8)	0·739‡
Radial resection margin (mm)*	7·2(7·3)	6·9(5·7)	0·845‡
CRM			0·976
Negative (> 1 mm)	58 (91)	65 (92)	
Positive (≤ 1 mm)	6 (9)	6 (8)	
No. of retrieved LNs*	15·2(10·8)	13·2(7·3)	0·126‡
No. of positive LNs*	0·7(1·8)	0·8(2·0)	0·712‡
Histology			0·177
Well differentiated	14 (13·2)	8 (7·5)	
Moderately/poorly differentiated	92 (86·8)	98 (92·5)	
pTNM stage			0·882
I–II	74 (69·8)	73 (68·9)	
III	32 (30·2)	33 (31·1)	

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). ISR, intersphincteric resection; CRM, circumferential resection margin; LN, lymph node. †χ^2 test, except ‡Student's *t* test.

30-day postoperative morbidity between groups (32 of 106 after laparoscopic and 20 of 106 after robotic surgery; $P = 0.042$). Acute voiding difficulties requiring a urinary catheter were more frequent after laparoscopic ISR, but all patients recovered within 1 month. The overall anastomosis-related morbidity of laparoscopic ISR, including leakage, fistulas, strictures and pelvic abscesses, was almost twice that in the robotic ISR group (15 of 106 *versus* 8 of 106 respectively; $P = 0.122$). Nine patients in the laparoscopic group and three in the robotic group still had a protective stoma at last follow-up ($P = 0.075$). Anastomotic strictures, intractable pelvic abscesses and chronic fistulas (rectovaginal or rectourethral) were the most common causes (7 instances) of palliative or permanent stomas. Among these, three and two patients requested a permanent stoma because of local recurrence and poor bowel function respectively.

Total mean hospital cost was €9223(2173) for laparoscopic surgery, and €12 757(2193) for robotic surgery ($P = 0.037$). Total charges were classified into payment by the NHI Corporation and payment by the patient. Patients in the robotic ISR group paid significantly more than those in the laparoscopic ISR group (€7725 *versus* €4530; $P < 0.001$).

Tumour size, number of harvested lymph nodes and tumour differentiation were similar in the two groups (*Table 3*). Circumferential resection margins (CRMs) were assessed in 71 (67·0 per cent) of 106 patients in the robotic group and 64 (60·4 per cent) of 106 in the laparoscopic group. CRM positivity was similar between groups (8 and 9 per cent respectively; $P = 0.976$).

No significant differences in bowel function were observed between the two groups after a minimum of 24 months' follow-up. In the robotic ISR group, 21 patients (19·8 per cent) had more than ten active bowel movements per day. Fourteen patients (13·2 per cent) needed to wear pads and 38 (35·8 per cent) required antidiarrhoeal medication to control defaecation. In the laparoscopic ISR group, 19 patients (17·9 per cent) had more than ten active bowel movements per day. Sixteen patients (15·1 per cent) needed to wear pads and 34 (32·1 per cent) required antidiarrhoeal medication. Long-term assessments of sexual function were done for 68 men who were sexually active before surgery. The incidence of retrograde ejaculation showed a trend in favour of the robotic ISR group, but did not reach statistical significance (4 of 33 *versus* 7 of 35 in laparoscopic group; $P = 0.124$).

Median follow-up was 50·2 (38·4–66·3) months for the robotic group and 56·0 (42·6–68·8) months for the laparoscopic group. There was no significant difference in overall 3-year survival for all stages combined between the groups (*Table 4*). No recurrence was observed at the trocar or minilaparotomy site. Twenty-two patients in the robotic group experienced tumour relapse (5 liver metastases,

Table 4 Local recurrence, and disease-free and overall survival

	Laparoscopic ISR	Robotic ISR	*P**
Local recurrence (%)			0·935
3 years	5·7 (1·3, 10·1)	6·7 (1·9, 11·5)	
5 years	8·2 (2·7, 13·8)	8·7 (2·6, 14·9)	
Disease-free survival (%)			0·298
3 years	90·5 (85·4, 96·6)	89·6 (84·1, 95·9)	
5 years	82·8 (74·8, 90·9)	80·6 (71·7, 89·5)	
Overall survival (%)			0·899
3 years	94·8 (91·9, 99·8)	93·8 (89·0, 98·6)	
5 years	88·4 (81·1, 95·7)	88·5 (81·1, 95·9)	

Values are mean (95 per cent c.i.). ISR, intersphincteric resection. *Log rank test.

6 lung metastases, 4 pelvic side-wall tumours, 3 in the perianastomosis area, 4 others) compared with 19 in the laparoscopic group (4 liver metastases, 5 lung metastases, 6 pelvic side-wall tumours, 2 in the perianastomosis area, 2 others). After exclusion of patients with cT1–2 tumours, a subgroup analysis was performed to compare the oncological outcomes of patients with locally advanced tumours (cT3–4). Similar results were obtained for local recurrence and DFS stratified by T category. The 3-year local recurrence rate for patients with cT3–4 tumours was 9 (95 per cent c.i. 1 to 17) per cent in the robotic group and 8 (1 to 16) per cent in the laparoscopic group ($P = 0·930$). Three-year DFS rates for patients with cT3–4 tumours were 76 (63 to 88) and 79 (67 to 91) per cent respectively ($P = 0·887$).

Discussion

This multicentre retrospective case-matched study showed that curative robotic ISR achieved same long-term oncological outcomes in patients with very low rectal cancers as laparoscopic ISR.

Only a few studies assessing the clinical value of ISR with CAA have reported long-term survival data. Reports[14–17] on conventional open ISR have documented local recurrence and DFS rates ranging from 0 to 10·6 per cent and from 66·7 to 76·4 per cent respectively. Two studies[6,18] have compared laparoscopic and open ISR regarding oncological outcomes. Laurent and colleagues[18], with a median follow-up of over 53 months, found no difference in 5-year local recurrence and DFS rates between the two approaches. Another retrospective comparative study[6] reported similar 3-year local recurrence rates after laparoscopic and open surgery for rectal cancers (2·6 and 7·7 per cent respectively; $P = 0·184$). In the present study, 3-year DFS and local recurrence rates were similar in the two groups.

Many surgeons are still sceptical about the safety of ISR for the treatment of locally advanced rectal cancers such as T3–4 lesions. Indeed, Akasu and co-workers[19] reported that local control was more difficult for T3 tumours than for T1–2 tumours. Without preoperative chemoradiotherapy, the 3-year cumulative local recurrence rate after ISR was 0 per cent for patients with T1–2 tumours compared with 15 per cent for those with T3 tumours[19]. Ninety-five (44·8 per cent) of the 212 patients in the present series who underwent ISR had stage cT3–4 tumours, including 97·8 per cent of patients who had preoperative chemoradiation treatment. Considering the duration of follow-up and tumour location, the overall local recurrence rate of 8·5 per cent in the subgroup analysis of patients with cT3–4 tumours compares favourably with the 2·6–16·1 per cent in population-based data for anterior resections or abdominoperineal resections with total mesorectal excision[20–23].

Laparoscopic dissection of the anal canal via a transabdominal approach has been technically challenging even for experienced surgeons, particularly in the setting of a narrow male pelvis, visceral obesity and previous irradiation[4,18,24]. Conversely, there is some evidence that robotic surgery could potentially overcome the technical limitations of conventional surgery during dissection of the levator ani muscles and sphincter. Nearly circular dissection of the intersphincteric space can be completed by using a stable camera and operating platform, together with good surgical dexterity[10–12]. The difficulties associated with the perineal approach were remarkably reduced by using this abdominal approach, and the tumour could be exteriorized easily. Impressively, robotic ISR has been conducted exclusively via the abdominal approach in selected patients[7,25].

Although the matched-pair analysis controlled for unbalanced factors among the two study cohorts, this study was subject to the limitations and selection biases inherent in any retrospective analysis. As with any new device or technology, the learning curve for both procedures was not equivalent. Although most patients underwent laparoscopic procedures conducted by expert surgeons, some results extracted from the robotic surgery data sets related to surgeons' initial experiences. The lack of data on functional outcomes based on objective tools is another limitation of this study. Studies[7,12] using validated questionnaires found that robotic ISR may be associated with a trend toward less faecal incontinence and early recovery of sexual functional compared with conventional ISR.

Robotic ISR with coloanal anastomosis provides acceptable outcomes but no clinical benefit to justify the excessive operational costs. As cost-effectiveness improves alongside technological advances, robotic surgery may enhance surgeon–patient interfacing in the operating theatre environment but outcomes are unlikely to be altered.

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Supporting information

Additional supporting information may be found in the online version of this article:

Table S1 Perioperative metrics of the unmatched cohort (Word document)

Editor's comments

There are two certainties in life. First, technology will continue to change the operative environment toward surgeon-directed, mechanically-assisted procedures. It has happened in anaesthesia, endovascular, ophthalmic, and urology spheres already. Robotic surgery is a misnomer of course; an incongruous juxtaposition of terms that belie the limits of the machine. Spawned from 1990's military research into the ill-conceived concept of conflict/trauma surgery controlled by surgeons at a remote location, the original hardware was bulky, slow to set-up, and had fewer applications than hoped (especially in the emergency setting). The gift of this research was the genesis of a new platform upon which to build the far more promising concept of enhanced surgeon–patient interfacing for standardized and better operative skills. As seen here, better results are difficult to demonstrate (over proficient laparoscopic surgery) using these initial, expensive iterations but these are early days.

The second certainty is that the cost of robotic-assisted surgery will come down as the usability, applicability, and accessibility improves. The market demands a more competitively priced, faster-developing, surgeon-enhanced yet safer patient experience. Motorized vehicles, once fossil-fuelled toys for the super-rich, are due to become inexpensive eco-conscious, machine-navigated pods in pre-set, multilayer lanes with advanced safety monitoring both inside and out. That took 100 years. Newer robotic equipment is likely to include technological treats like slowed-motion, artefact-eliminated, computer-assisted instrument articulation with compensated haptic feedback via helmet/visor/glove interfacing. Multidimensional, pluripolar holographic imaging, uploaded with patient-specific anatomical safety parameters, will not only permit extraordinary visual aspect (just as advanced sensors led to self-parking vehicles) but may limit surgeon error and iatrogenic injury. Powerful antidotes to the Luddite opposition to device-delivered surgery are the irrefutable facts that the future is mutable, the present already the past, and progress inevitable.

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