

## 2016 Colorectal Cancer: Global view

# Dealing with robot-assisted surgery for rectal cancer: Current status and perspectives

Roberto Biffi, Fabrizio Luca, Paolo Pietro Bianchi, Sabina Cenciarelli, Wanda Petz, Igor Monsellato, Manuela Valvo, Maria Laura Cossu, Tiago Leal Ghezzi, Kassem Shmaissany

Roberto Biffi, Fabrizio Luca, Paolo Pietro Bianchi, Sabina Cenciarelli, Wanda Petz, Igor Monsellato, Manuela Valvo, Maria Laura Cossu, Tiago Leal Ghezzi, Kassem Shmaissany, Department of Gastrointestinal Surgery, European Institute of Oncology, 20141 Milan, Italy

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**Correspondence to:** Roberto Biffi, MD, FSPS, Medical Director, Department of Gastrointestinal Surgery, European Institute of Oncology, Via G.Ripamonti 435, 20141 Milan, Italy. [roberto.biffi@ieo.it](mailto:roberto.biffi@ieo.it)  
Telephone: +39-2-57489710  
Fax: +39-2-94379215

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## Abstract

The laparoscopic approach for treatment of rectal cancer has been proven feasible and oncologically safe, and is able to offer better short-term outcomes than traditional open procedures, mainly in terms of reduced length of hospital stay and time to return to working activity. In spite of this, the laparoscopic technique is usually practised only in high-volume experienced centres, mainly because it requires a prolonged and demanding learning curve. It has been estimated that over 50 operations are required for an experienced colorectal surgeon to achieve proficiency with this technique. Robotic surgery enables the surgeon to perform minimally invasive operations with better vision and more intuitive and precise control of the operating instruments, thus promising to overcome some of the technical difficulties associated with standard laparoscopy. It has high-definition three-dimensional vision, it translates the surgeon's hand movements into precise movements of the instruments inside the patient, the camera is held and moved by the first surgeon, and a fourth robotic arm is available as a fixed retractor. The aim of this review is to summarise the current data on clinical and oncologic outcomes of robot-assisted surgery in rectal cancer, focusing on short- and long-term results, and providing original data from the authors' centre.

**Key words:** Rectal cancer; Robotic total mesorectal excision; Robotic surgery; Robotic resection; Circumferential resection margin; Lymph node yield; Distal resection margin positivity

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**Core tip:** The aim of this review is to summarise the current data on clinical and oncologic outcomes of

robot-assisted surgery in rectal cancer, focusing on short- and long-term results, and providing original data from the authors' centre. A detailed review of this topic is provided, including the most recent findings of prospective studies. Future perspectives are also analyzed.

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## INTRODUCTION

The optimization of surgical technique with the introduction of total mesorectal excision (TME)<sup>[1,2]</sup> was a main innovation for the treatment of rectal cancer, together with the introduction of multimodal preoperative chemo-radiation therapy for locally advanced stage disease.

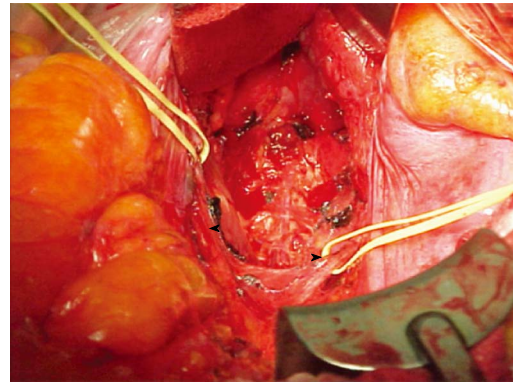
In some series, correctly-performed TME surgery has been demonstrated to decrease the rate of local recurrence to less than 10%, when compared to conventional dissection<sup>[3]</sup>, and TME surgery, preceded by neoadjuvant chemo-radiation, emerged as the standard treatment for locally advanced rectal cancer<sup>[4]</sup>, Figure 1.

Laparoscopic colectomy has proven to be a feasible and oncologically safe procedure with an increasing diffusion, but minimally-invasive TME is still less adopted, because of its technical difficulties. The percentage of conversions to open surgery remains quite high, confirming the technical difficulties of the procedure and also the necessity of an accurate selection of patients<sup>[5-8]</sup>.

The general opinion in the oncologic surgical community is that LTME (Laparoscopic Total Mesorectal Excision) is a difficult operation to master, and has been associated with learning curves as high as 50-150 cases to achieve consistent results<sup>[9]</sup>.

In the United States, laparoscopic rectal resection did not make up 20% of the overall rectal resections and its conversion rate to open surgery is still high (46.2%), without any significant improvement in recent years<sup>[10]</sup>. For this reason, still in 2012, the National Comprehensive Cancer Network guidelines for treatment in rectal cancer recommended the use of laparoscopy for rectal cancer treatment only within a study protocol and in highly specialized centers<sup>[4]</sup>. It is therefore commonly believed that TME as originally proposed by Heald is *per se* a technically demanding operation<sup>[4]</sup>, and that the addition of laparoscopic technique seems to increase these technical difficulties.

Robotic surgery has emerged as a new technique



**Figure 1** View of male pelvic cavity after total mesorectal excision and rectal resection, hypogastric nerves are identified and preserved (arrow heads).

that might overcome some difficulties of the standard laparoscopic approach in the pelvis, providing magnified three-dimensional optics, surgeon-controlled camera vision, working arms allowing very stable retraction and unparalleled ergonomics of instrument motion, with much less fatigue for the surgeon. These are all the rational reasons for its increasing use in rectal cancer, with the addition of a reduced learning curve, if compared with the traditional laparoscopy procedure<sup>[11-13]</sup>.

Recently, our group and others demonstrated that robot-assisted tumor-specific mesorectal excision for rectal cancer was technically feasible and a safe surgical option in terms of the long-term oncologic outcomes<sup>[14,15]</sup>, while results of randomized trials are awaited to provide concrete evidence for this approach.

This review summarizes the current status of robotic TME (RTME), in addition to experience and notes from the authors' institution and future perspectives of this topic.

## ROBOTIC TME - REVIEW OF CURRENT STATUS: SHORT AND LONG-TERM OUTCOMES

The results so far available on RTME are quite limited, as they mainly originate from single-center experiences (usually from academic high-volume centers) and few from large prospective studies, all contributing to the assumption that RTME is a safe and effective procedure. A variety of approaches - both totally robotic and hybrid procedures performing part of the operation laparoscopically - have been used, but in all patients the TME was performed as entirely robotic procedure<sup>[15-22]</sup>.

Our group first proposed with others a full robotic technique to perform RTME, with preliminary good quality results<sup>[23]</sup>. In this study we described a method that standardizes robot and trocar position, and allows for a complete mobilization of the left colon and the

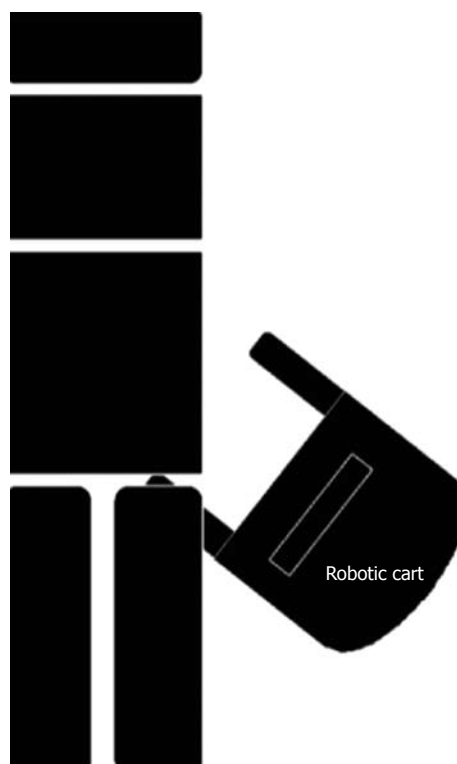


Figure 2 Position of the robotic cart.

rectum, without repositioning of the surgical cart, Figures 2 and 3.

A total of 55 consecutive patients affected by rectal and left colon cancer were operated on, with full robotic technique, using the Da Vinci robot. The following procedures were performed: 27 left colectomies, 17 anterior resections, 4 intersphincteric resections, 7 abdominoperineal resections. There were 21 female and 34 male patients with a mean age of  $63 \pm 9.9$  years. Mean operative time was  $290 \pm 69$  min, ranging from 164 to 487 min. None were converted to open surgery. The median number of lymph nodes harvested was  $18.5 \pm 8.3$  (range 5-45), and circumferential margin was negative in all cases. Distal margin was  $25.15 \pm 12.9$  mm (range 6-55) for patients with rectal cancer, and  $31.6 \pm 20$  mm for all the patients in this series. Anastomotic leak rate was 12.7% (7/55); in all cases conservative treatment was successful.

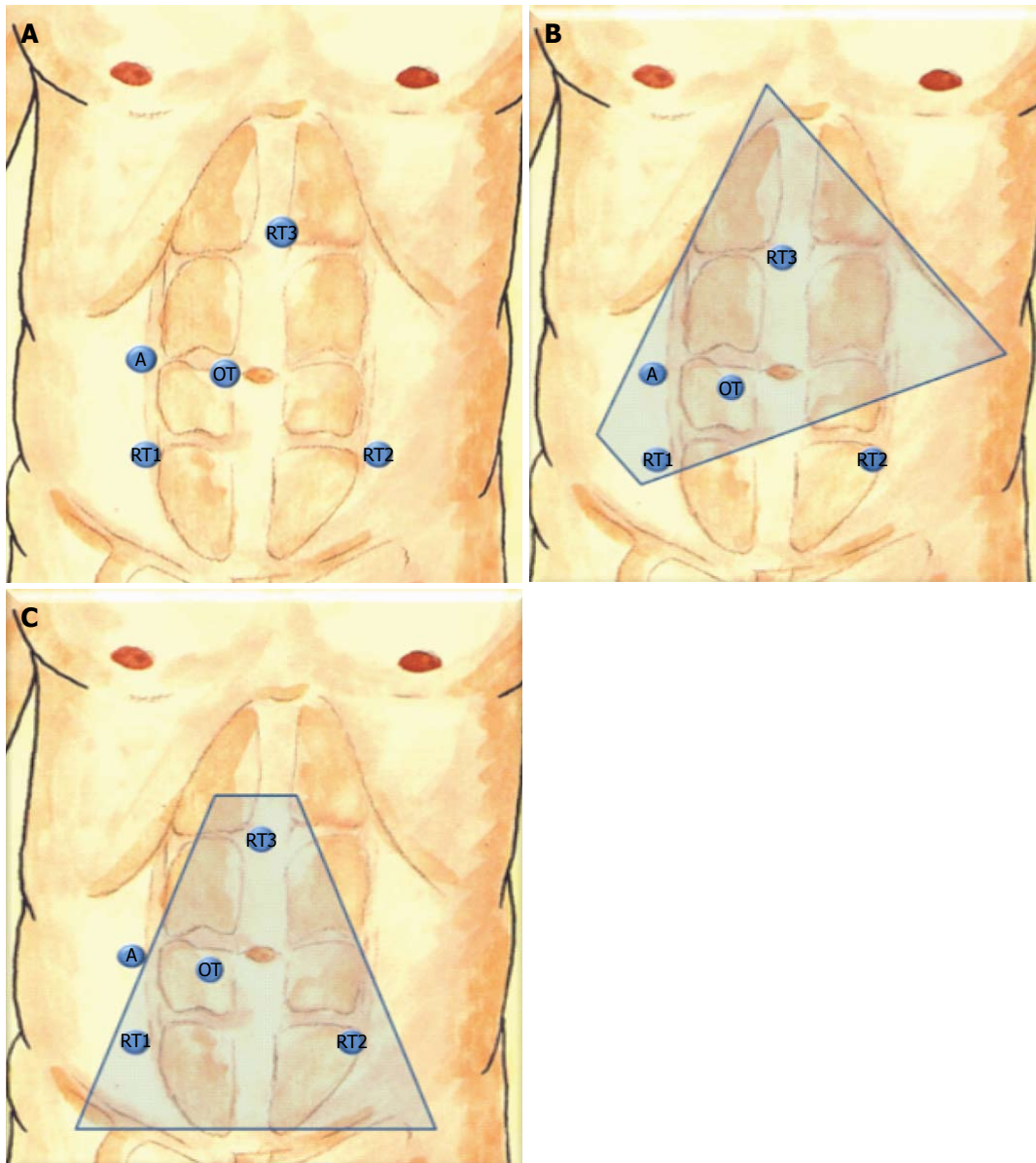
We could conclude that full robotic colorectal surgery is a safe and effective technique that exploits the advantages of the Da Vinci robot during the whole intervention, without the need to make use of hybrid operations, Figure 4. Outcome and pathology findings are comparable with those observed in open and laparoscopy procedures.

Few studies have compared robotic surgery to standard treatment of open resection, and in these studies robotic surgery resulted oncologically safe in terms of length of specimen, resection margins, and number of lymph nodes harvested<sup>[24,25]</sup>. As robotic

views of the operating field during RTME procedures require a relatively bloodless field, robotic resection might be expected to lead to less operative blood loss than open conventional rectal surgery. This has some interest for clinicians, as it has been reported that allogenic blood transfusion might be associated with an increased risk of tumor recurrence after colorectal cancer surgery<sup>[26]</sup>. Studies of blood loss after open rectal cancer surgery have had variable results, with rates of perioperative transfusions ranging from 20% to 75%<sup>[27]</sup>. To date, some studies have reported estimated blood loss (EBL) after RTME<sup>[28,29]</sup>, but no study has investigated this topic as a case-matched model, comparing open and robotic approaches. A study from our group compared blood loss as measured by EBL, mean drop in hemoglobin levels with surgery, and blood product use in patients undergoing open and robotic TME in different periods of time at the same institution, maintaining the same guidelines for transfusion in the postoperative period<sup>[30]</sup>. Briefly, forty-nine patients in the RTME and 105 in the OTME group were matched for age, gender, BMI (body mass index), ASA (American Society of Anesthesiology) class, tumor-node-metastasis (TNM) classification and UICC (Union for International Cancer Control) stage, distance of the lower edge of the tumor from the anal verge, presence of co morbidities, and preoperative hemoglobin (Hb). EBL was significantly higher in the open group ( $P < 0.001$ ); twelve units of packed red blood cells were globally transfused in the open group, compared to one unit only in the robotic one ( $P = 0.051$ ). A significantly higher postoperative Hb drop ( $3.0$  g/dL vs  $2.4$  g/dL,  $P = 0.015$ ) was registered in the OTME patients. The length of hospital stay was much lower for the RTME group ( $8.4$  d vs  $12.4$  d,  $P = 0.001$ ). The number of harvested lymph nodes ( $17.4$  vs  $13.5$ ,  $P = 0.006$ ) and extent of distal margin ( $2.9$  cm vs  $1.9$  cm,  $P = 0.001$ ) were significantly higher in the RTME group. Open surgery was confirmed as the sole variable significantly associated ( $P = 0.001$ ) with blood loss (OR = 4.41, 95%CI: 2.06-9.43). It was a confirmed prognosticator of blood loss ( $P = 0.006$ ) when a preoperative clinical predictive model was built, using multivariate analysis (OR = 3.95, 95%CI: 1.47-10.6). In conclusion, RTME produced less operative blood loss and less drop in postoperative hemoglobin when compared to OTME. Other clinically relevant outcomes were similar or superior to OTME, Table 1.

The evidence for the equivalence of LTME and the open approach (OTME) for rectal cancer surgery was provided by the findings of a couple of multicenter randomized controlled trial, the MRC CLASICC (Medical Research Council Conventional vs Laparoscopic-Assisted Surgery In Colorectal Cancer ) trial<sup>[30-32]</sup> and the COREAN trial (Comparison of Open vs laparoscopic surgery for mid and low REctal cancers After Neo-adjuvant chemoradiotherapy)<sup>[33]</sup>, both comparing

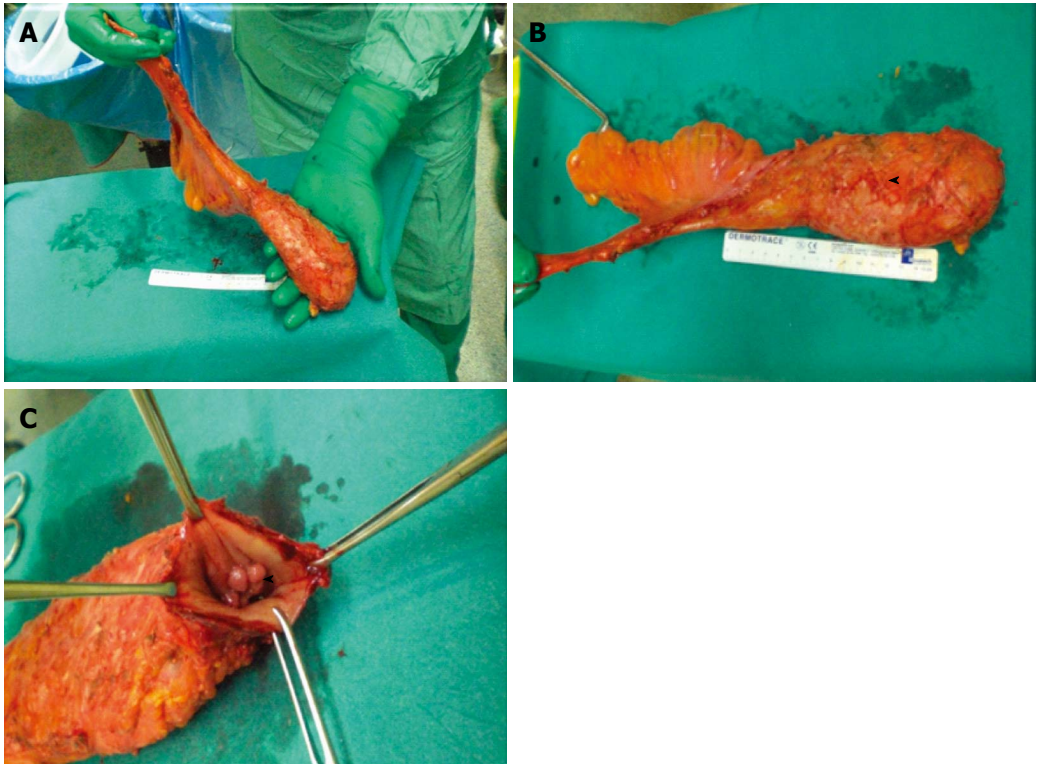




**Figure 3** Placement of the trocars, ROBOTIC LAR (A); IMA, IMV and splenic flexure, ROBOTIC LAR (B) and total mesorectal excision (C). OT: Optical trocar; R: Robotic arms; A: Assistant.

laparoscopy to open surgery in rectal cancer. Subgroup ex-post analysis of CLASICC Trial revealed oncologic outcomes of LTME to be equal to those of open TME, with a substantial limitation for LTME represented by a high conversion rate to open surgery of 34%, and an increased radial margin positivity rate of 12% in the laparoscopic arm, compared to 4% in the open arm, though this did not translate into an increase in recurrence rate or worse overall survival<sup>[34]</sup>. In the COREAN Trial the conversion rates and CRM positivity were very low, as compared to the CLASICC study. Although participating surgeons had greater experience in laparoscopic surgery than did surgeons participating in the CLASICC trial, the differences in percentage of CRM positivity were similar in the two groups: 4.1% in the open group and 2.9% in the laparoscopic group, Table 2<sup>[35]</sup>.

It is important to underline that the surgeons in the COREAN study were highly experienced, with a median case load of 75 cases before the trial and that the trial was performed by only three highly trained surgeons as against a mean case load of only 20 colorectal operations in the MRC study and multiple participating centers. The most recently published COLOR II study<sup>[36]</sup>, also comparing laparoscopic to open surgery in rectal resections, did not reveal any significant difference between the two procedures in terms of morbidity, mortality, and complication rates, and confirmed the benefits of the minimally invasive approach as less blood loss, more rapid recovery of bowel function, and shorter hospital stay. Although the participating surgeons were all experts in laparoscopic surgery, the conversion rate to open surgery was still high (16%), confirming the technical challenges of



**Figure 4** Surgical specimen of robot-assisted total mesorectal excision. A: This figure shows a very smooth mesorectal fat pad which tapers distally consistent with complete excision of the mesorectum. Grade 3 according to Quirke; B: Grade 3 complete excision according to Quirke showing the wisps of fascia that surrounds the mesorectum indicating that a fascial plane actually exists and points to a complete excision by surgeon, mesorectal vessels contained within the mesorectum can be seen; arrow head; C: Opened specimen showing the tumor; arrow head.

Table 1 Clinically relevant outcomes			
Outcome	Open-LAR	Robotic-LAR	P value <sup>1</sup>
Intraoperative transfusions	0	0	-
Death	0	0	-
Postoperative transfusions patients n (%)	6 (5.7)	1 (2.0)	0.432
Surgical complications (30 <sup>th</sup> postop day)			
Units	12	1	0.051
Infectious	15 (14.3)	8 (16.3)	0.189
Non-infectious	11 (10.5)	10 (20.4)	
Both	5 (4.5)	0	
Overall	31 (29.5)	18 (36.7)	0.371
Reinterventions (30 <sup>th</sup> postop day)	0	2 (4.1)	0.100
Length of hospital stay (d) mean ± SD (Median)	12.4 ± 3.2 (12.0)	8.4 ± 9.3 (7.0)	< 0.001
Post-operative Hb (g/dL) mean ± SD (Median)	10.6 ± 1.6 (10.8)	11.0 ± 1.4 (10.8)	0.124
Hb drop (g/dL) mean ± SD (Median)	3.0 ± 1.4 (2.9)	2.4 ± 1.6 (2.0)	0.015

<sup>1</sup>Two-sample two-sided Wilcoxon test, unpaired *t*-test; <sup>2</sup>or two-sided Fisher's exact test as appropriate. Modify from Biffi *et al*<sup>[30]</sup>.

laparoscopic TME.

Recently, some meta-analyses comparing robotic and laparoscopy TME have been already published, despite the lack of evidence<sup>[37-41]</sup>. In all of these studies, the only significant data was that robotic surgery resulted in a lower percentage of conversion

Table 2 Comparison between MRC CLASICC and COREAN trial		
Variable	MRC CLASICC	COREAN Trial
Number of participating Centers	27	3
Number of procedures per surgeon before Trial	20	75
Conversion rate, n (%)	82 (34)	2 (1.2)
CRM involvement	16%	2.9%

CRM: Circumferential resection margin.

to open surgery, compared to the laparoscopic groups. Regarding short-term clinical and oncologic outcomes, no significant differences were found between laparoscopy and robotic surgery, Tables 3-5<sup>[42]</sup> showed that RTME in the treatment of mid or low rectal cancer was associated with decreased analgesia use, less postoperative pain, and a shorter hospital stay. Recently, Park *et al*<sup>[43]</sup> furthermore reported that the rate of conversion was significantly lower for RTME than LTME (0.0% vs 7.1%, *P* = 0.003). Similarly, the short-term outcomes from two meta-analyses revealed that RTME was associated with a significantly lower conversion rate and equivalent oncologic adequacy compared with LTME<sup>[44]</sup>.

The only published randomized data from a pilot study comparing laparoscopic and robotic TME with 18 patients in each arm, found no difference in operative time, conversion rates or pathologic

**Table 3** Perioperative outcomes of robotic total mesorectal excision for rectal cancer *n* (%)

Ref.	<i>n</i>	BMI (kg/m <sup>2</sup> )	OR time (min)	Conversion rate	Anastomotic leak rate
Hellan <i>et al</i> <sup>[16]</sup>	39	26 (16-44)	285 (180-540)	1 (2.6)	4 (12.1)
Baik <i>et al</i> <sup>[17]</sup>	56	23.4 (18-33)	178 (120-315)	0	1 (1.8)
Choi <i>et al</i> <sup>[18]</sup>	50	23.2 (19.4-29.2) <sup>1</sup>	304.8 (190-485) <sup>3</sup>	0	4 (8.3)
Baek <i>et al</i> <sup>[19]</sup>	64	26.8 (16.5-44)	270 (150-540)	9.4	4 (7.7)
Pigazzi <i>et al</i> <sup>[15]</sup> (multicentric study)	143	26.5 (16.5-44) <sup>2</sup>	297 (90-660) <sup>3</sup>	7 (4.9)	16 (10.5)
Baik <i>et al</i> <sup>[20]</sup>	370	23.3 ± 2.9 (13.8-32.7) <sup>2</sup>	363.3 ± 94.8 (138.0-702.0) <sup>2</sup>	3 (0.8)	28 (7.7)
IEO series <sup>[14]</sup>	102	28.2 (17.6-43)	330 (155-540)	2 (1.9)	5 (6.6)

Only sphincter-saving operations included for calculating leak rates, values expressed as median (range) except where specified, <sup>1</sup>mean (range); <sup>2</sup>mean ± SD (range); <sup>3</sup>mean (range).

**Table 4** Clinical results of laparoscopic and robotic surgery for rectal cancer

Ref.	Conversions (%)		<i>P</i> value	Hospital stay (d)		<i>P</i> value	Complications (%)		<i>P</i> value
	ROB	LAP		ROB	LAP		ROB	LAP	
Park <i>et al</i> <sup>[58]</sup>	0	0	1.000	9.9	9.4	0.500	29.3	23.2	0.400
Kang <i>et al</i> <sup>[33]</sup>	2	3	1.000	11.7	14.4	0.006	20	27	0.400
Kwak <i>et al</i> <sup>[59]</sup>	0	3.4	0.400	NA	NA		32	27	NS
Baek <i>et al</i> <sup>[50]</sup>	7.3	22	0.116	6.5	6.6	0.800	22	27	1.000
Bianchi <i>et al</i> <sup>[60]</sup>	0	4	NA	6.5	6	0.400	16	24	0.500
Baik <i>et al</i> <sup>[17]</sup>	0	10.5	0.013	5.7	7.6	0.001	10.7	19.3	0.025
Patriti <i>et al</i> <sup>[63]</sup>	0	19	< 0.05	11.9	9.6	> 0.05	30.6	18.9	> 0.05

ROB: Robotic resection; LAP: Laparoscopic resection; NA: Not available; NS: Not significant.

**Table 5** Oncologic results of laparoscopic and robotic surgery for rectal cancer

Ref.	Harvested lymph nodes ( <i>n</i> )		<i>P</i> value	Distal resection margin (cm)		<i>P</i> value	Positive CRM (%)		<i>P</i> value
	ROB	LAP		ROB	LAP		ROB	LAP	
Park <i>et al</i> <sup>[58]</sup>	17.3	14.2	0.06	2.1	2.3	NS	4.9	3.7	0.5
Kang <i>et al</i> <sup>[33]</sup>	14.7	16.6	NS	2.7	2.6	0.09	3	2	NS
Kwak <i>et al</i> <sup>[59]</sup>	20	21	0.7	2.2	2.8	0.8	1.7	0	> 0.9
Baek <i>et al</i> <sup>[50]</sup>	13	16	0.07	3.6	3.8	0.6	2.4	4.9	1
Bianchi <i>et al</i> <sup>[60]</sup>	18	17	0.7	2.0	2.0	1	0	4	0.9
Baik <i>et al</i> <sup>[17]</sup>	18.4	18.7	0.8	4.0	3.6	0.4	7	8	0.7
Patriti <i>et al</i> <sup>[63]</sup>	10.3	11.2	> 0.05	2.1	4.35	> 0.05	0	0	NS

CRM: Circumferential resection margin; ROB: Robotic resection; LAP: Laparoscopic resection; NS: Not significant.

quality of the specimen<sup>[44]</sup>. A statistically significant shorter hospital stay was however found favouring the robotic arm (Standard laparoscopic arm, 8.7 ± 1.3 d; robotic assisted arm 6.9 ± 1.3 d; *P* < 0.001). There are at present a number of publications involving systematic reviews and case matched series, which show equivalent clinical and oncologic outcomes. The meta-analysis by Trastulli which focused on short-term outcomes revealed a markedly lower conversion rate in the Robotic arm (2% vs 7.5%, *P* = 0.0007) with operative time, lymph node harvest, CRM positivity rate and anastomotic leak rates being similar. Another large meta-analysis by Xiong *et al*<sup>[45]</sup> showed statistically significant lower CRM positivity and conversion rates favouring the robotic approach with operative times and local recurrence rates remaining similar. Long-term outcomes (3 year) expressed as disease-free survivals are between 73.7% and 79.2%,

whereas overall survivals range between 92% and 97% (Table 6).

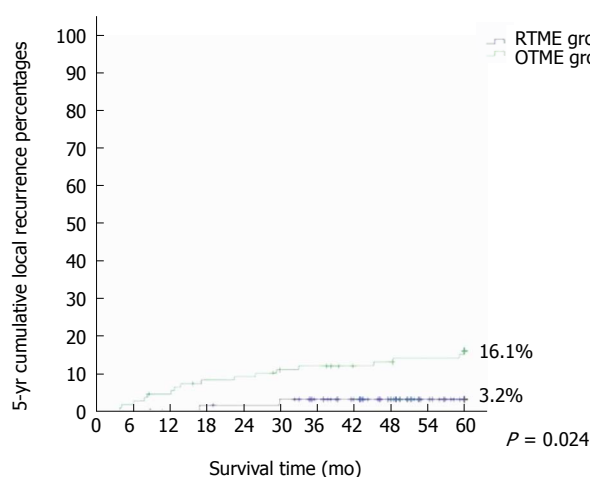
Randomized clinical trials such as the COLRAR trial (NCT01423214) and ROLARR trial (NCT01196000) are currently ongoing to clarify this issue, and more objective data may be obtained from these clinical trials in the future.

Our own data on long-term results are synthesized in a recent case-control paper, that provided long-term oncologic results; perioperative outcomes were comparable to open surgery, with a significantly decreased blood loss, while long term oncologic outcomes were equivalent especially with reference to mesorectal grade, CRM positivity, lymph node yield and disease free and overall survival. We however found a significant reduction in local recurrence rate and a higher, though not statistically significant long-term cancer specific survival in the RTME group Figure

**Table 6** Short-term and long-term oncologic outcomes of robotic TME for rectal cancer

Ref.	LN yield	CRM+ <i>n</i> (%)	DRM+ <i>n</i> (%)	FU (mo)	LR (%)	DR (%)	DFS (3 yr), (%)	OS (3 yr), (%)
Hellan <i>et al</i> <sup>[16]</sup>	13 (7-28) <sup>1</sup>	0	0	13 <sup>2</sup>	0	10.3	-	-
Baik <i>et al</i> <sup>[17]</sup>	17.5 (4-43) <sup>1</sup>	4 (7.1)	0	14.3 <sup>2</sup>	0	3.6	-	-
Choi <i>et al</i> <sup>[18]</sup>	20.6 (6-48) <sup>3</sup>	1 (2)	0	-	-	-	-	-
Baek <i>et al</i> <sup>[19]</sup>	14.5 (3-28) <sup>1</sup>	0	0	20.2 <sup>4</sup>	3.1	9.4	73.7	96.2
Pigazzi <i>et al</i> <sup>[15]</sup> (Multicenter study)	14.1 (1-39) <sup>3</sup>	1 (0.7)	1 (0.9)	17.4 <sup>4</sup>	1.5	9.0	77.6	97
Baik <i>et al</i> <sup>[20]</sup>	15.6 ± 9.0 (1-49) <sup>4</sup>	21 (5.7)	-	26.5 <sup>4</sup>	3.6	17.6	79.2	93.1
Ieo series, Ghezzi <i>et al</i> <sup>[14]</sup>	14.5 (2-45) <sup>3</sup>	5 (4.9)	2 (1.9)	30.0 <sup>2</sup>	4.0	10.7	79.2	92

<sup>1</sup>mean ± SD (range); <sup>2</sup>median follow-up; <sup>3</sup>mean lymphnode yield; <sup>4</sup>mean followup. LN: Lymph node; CRM+: Circumferential resection margin positivity; DRM+: Distal resection margin positivity; FU: Follow up; LR: Local recurrence; DR: Distant recurrence; DFS: Disease free survival; OS: Overall survival.

**Figure 5** Comparison of 5-year local recurrence. Modified from Ref<sup>[14]</sup>.5<sup>[14]</sup>.

## GENITOURINARY FUNCTION AFTER ROBOTIC TME

This is an important aspect of Robotic TME, as better visualization of the autonomic plexii in the pelvis could translate into better preservation of genitourinary function as assessed by erectile dysfunction and voiding function. Although the introduction of TME has resulted in improved genitourinary functional preservation, most colorectal surgeons are still faced with challenging conditions such as injuries to the hypogastric nerves and/or the sacral splanchnic nerve during pelvic dissection<sup>[46]</sup>. As a matter of fact, the MRC CLASICC trial showed a trend towards increased sexual dysfunction in the laparoscopic arm in comparison to the open group<sup>[31]</sup>. Theoretically, the use of a robotic system can decrease the risk of collateral injury to the pelvic autonomic nerves. However, there are currently only limited studies evaluating the impact of robotic technology on urogenital complications after TME. Thus, whether these theoretical advantages of R-TME translate into significant favorable urogenital function still remains to be determined. Comparison of robotic and laparoscopic groups in the study by Kim

*et al*<sup>[47]</sup> showed decreased sexual desire and voiding function in both groups one month after surgery with more rapid and complete recovery of both parameters in the robotic group; this is possibly due to a more delicate operation with the robotic apparatus.

Another study on 60 patients (males only) reported a quicker and complete recovery of erectile function in the robotic group and partially in the laparoscopy-treated group<sup>[48]</sup>.

Our group found better preservation of voiding and sexual function in both genders with robotic TME in comparison with open and laparoscopic TME as provided by the literature, with complete recovery of both functions one year after surgery<sup>[49]</sup>. A total of 74 patients undergoing fully robotic resection for rectal cancer were prospectively included in this study. Urinary and sexual dysfunctions affecting quality of life were assessed with specific self-administered questionnaires in all patients undergoing robotic RTME. The analyses of the questionnaires completed by the 74 patients who underwent RTME showed that sexual function and general sexual satisfaction decreased significantly one month after intervention for erectile function and for general satisfaction in men, and for arousal and general satisfaction, respectively, in women. Subsequently, both parameters increased progressively, and one year after surgery, the values were comparable to those measured before surgery. Concerning urinary function, the grade of incontinence measured one year after the intervention was unchanged for both sexes. We could conclude that RTME allows for preservation of urinary and sexual functions. This is probably due to the superior movements of the wristed instruments that facilitate fine dissection, coupled with a stable and magnified view that helps in recognizing the inferior hypogastric plexus. Clearly, all these findings need confirmation by larger randomized studies (Table 7).

## COST ISSUES

One of the main concerns about robotic technology is the high costs of purchase and maintenance of the equipment. Robotic surgery is more expensive than laparoscopic or open surgery for a number of reasons,



**Table 7 Urinary and sexual dysfunctions results in robotic rectal resection**

Ref.	Study	Results
Kim <i>et al</i> <sup>[13]</sup> , 2012	39 LAP vs 30 ROB (urinary)	Earlier recovery of normal voiding and sexual function
D'Annibale <i>et al</i> <sup>[48]</sup> , 2013	20 LAP vs 18 ROB (sexual male only) 30 LAP vs 30 ROB (male only)	Erectile function was restored completely in the ROB group and partially in the LAP group
Luca <i>et al</i> <sup>[49]</sup> , 2013	74 ROB (38 males and 36 females)	Sexual function and general sexual satisfaction were restored completely. Urinary function unchanged after surgery

LAP: Laparoscopic rectal surgery; ROB: Robotic rectal surgery.

including the fixed costs of purchase and maintenance which have to be amortized, the increased operative time and the cost of consumable items, as instruments have limited lifespan and need to be changed. In addition, the da Vinci surgical system (Intuitive surgical Inc, Sunnyvale CA, United States) is the only surgical robot currently available for use. The lack of competition may be a factor keeping costs static and high today.

Baek *et al*<sup>[50]</sup> showed increased costs in robotic rectal resection compared to those in the standard laparoscopic procedure, with a significantly lower hospital profit in the robotic group. Similarly, one study of our group demonstrated that robotic surgery was much more expensive in comparison to open as well as laparoscopic procedures, overall morbidity rates being similar among groups and perioperative mortality nil<sup>[51]</sup>.

Operative time is a critical issue when studying outcomes of robotic rectal surgery because it decreases the number of procedures that can be performed and drives up the operating room costs. Operative times are related to some extent to the learning curves and with increasing surgeon and institution volumes the gulf between robotic and laparoscopic colorectal procedure times is steadily decreasing. D'Annibale *et al*<sup>[48]</sup>, published their experience showing no difference in total operating times between laparoscopic and robotic groups, though patient preparation and operating room times were prolonged in the robotic group<sup>[52]</sup>. They found that the time added in robotic docking was balanced by faster, more accurate dissection due to use of the robot. Standardization of the procedure, consistency of surgical-nursing teams, and incremental increase in surgeon experience and volumes all have the potential to decrease operative time.

Cost needs to be weighed against parameters such as shorter length of stay and oncologic outcomes. Without robust randomized data however, cost continues to remain an issue especially in systems where robotic surgery is paid on par with laparoscopic surgery. The additional cost is borne either by the hospital or the patient and does not make for a good economic model. Another emerging problem in the costs' evaluation is the appropriate use of the technology by low volume centers/surgeons; in fact a

higher number of complications are reported by Keller *et al*<sup>[52]</sup> in the low volume users when compared to middle- and high-volume centers and surgeons.

One modifiable factor, which can decrease this cost, is an increase in the annual caseload of robotic procedures, which reduces the amortized costs of the robot and the annual maintenance per procedure<sup>[53]</sup>. Having a consistent team of surgeons, perioperative nurses and scrub personnel also reduces setup times markedly, as shown by Hanly *et al*<sup>[54]</sup>, who demonstrated reduced setup times by 29.2% and 56.1% on the second and third robotic setups respectively.

## CONCLUSION

In conclusion, robotic total mesorectal excision has several benefits in the treatment of rectal cancer, especially in technically demanding cases such as narrow male pelvis and very low located huge tumours. Therefore, a robot-assisted technique should be part of the armamentarium of the experienced surgeon dealing with this disease. The intraoperative ergonomics are superbly facilitated by excellent vision and manoeuvrability, and this translates into a more reproducible operation, which could be an advantage for teaching and tutoring. While cost remains an issue, as with laparoscopy costs are expected to decrease with time, especially in a multispecialty setup where multiple departments are using the robot<sup>[55]</sup>. Operative time is still higher than that in the laparoscopic approach, but it rapidly decreases with experience and is likely to be less of an issue once advanced platforms that permit multiquadrant surgery without the need for re-docking are more widely available.

A couple of very recent studies - comparing robot assisted and laparoscopy TME - added more data to the conclusion that robotic surgery for rectal cancer failed so far to offer any oncologic or clinical benefits as compared with laparoscopy, despite an increased cost. The first study analyzed 217 patients enrolled prospectively, who underwent minimally invasive surgery for rectal cancer with stage I - III disease (robot, *n* = 133; laparoscopy, *n* = 84). Perioperative clinicopathologic outcomes demonstrated no significant differences, except for the conversion rate and length of hospital stay. No significant differences were found



in the 5-year overall, disease-free survival and local recurrence rates between robotic and laparoscopic surgical procedures<sup>[43]</sup>.

The second is a case-matched study aimed at comparing the postoperative complications and short- and long-term outcomes of RTME and LTME for rectal cancer. Authors identified 278 rectal cancer patients who underwent RTME; a propensity score matching was used to match this group with 278 patients who underwent LTME. The conversion rate, length of hospital stay, and recovery of pain and bowel motility were similar between both groups. The rates of circumferential resection margin involvement and early complications were similar between both groups (L-TME vs R-TME: 4.7% vs 5.0%,  $P = 1.000$ ; and 23.7% vs 25.9%,  $P = 0.624$ , respectively), as were the 5-year overall survival, disease-free survival, and local recurrence rates (93.1% vs 92.2%,  $P = 0.422$ ; 79.6% vs 81.8%,  $P = 0.538$ ; 3.9% vs 5.9%,  $P = 0.313$ , respectively)<sup>[56]</sup>. This study showed that RTME was significantly associated with a much lower incidence of late voiding dysfunction than LTME (0.7% vs 4.3%,  $P = 0.012$ ).

Both these studies are not randomized, and most conclusions should be taken with caution. In addition, sexual adverse effects were not here investigated.

The ROLARR Trial (Robotic assisted vs laparoscopic assisted resection for rectal cancer) is an international multicenter prospective, controlled, unblinded, parallel group superiority trial of robotic-assisted vs standard laparoscopic surgery for the curative treatment of rectal cancer, which randomized > 200 patients in each arm<sup>[57]</sup>.

Initial results of ROLARR trial were presented at the ASCRS conference in Boston on 1<sup>st</sup> June 2015 and again at the EAES conference in Bucharest on 6<sup>th</sup> June. These results included analysis of data up to 30 d post operatively, including the primary endpoint of conversion to open surgery, CRM positivity and safety data up to 30 d post operatively. These data did not show any statistically significant differences between the arms (laparoscopy and robot-assisted surgery) with respect to a number of variables. Here the most relevant conclusions are listed: Observed conversion rate lower following robotic surgery, but no statistically significant evidence of superiority compared to laparoscopic surgery. In a subgroup analysis, a possible benefit in males, low anterior resection and obese patients was found, but this requires further research to be confirmed. Among the secondary endpoints, similar rates in CRM positivity were observed, as well as rates of 30-d complications and mortality (Personal communication from Dr D. Jayne).

Although the results available on robotic surgery are still few, robotic assistance seems to reduce the percentage of conversions to open surgery among expert surgeons and is promising as a method to attenuate the learning curve of a well-conducted

TME<sup>[58-63]</sup>. At the moment, the robotic system has higher costs than laparoscopy and its use should be planned within a clearly defined educational program, preferably in a hospital conducting high volumes of minimally invasive colorectal procedures, in order to avoid an increase in complication rates and related costs.

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