

# Robot-assisted total mesorectal excision for rectal cancer: casematched comparison of short-term surgical and functional outcomes between the da Vinci Xi and Si

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### Abstract

*Background* Robotic rectal resection with da Vinci Si has some technical limitations, which could be overcome by the new da Vinci Xi. We compare short-term surgical and functional outcomes following robotic rectal resection with total mesorectal excision for cancer, with the da Vinci Xi (Xi-RobTME group) and the da Vinci Si (Si-RobTME group).

*Methods* The first consecutive 30 Xi-RobTME were compared with a Si-RobTME control group of 30 patients, selected using a one-to-one case-matched methodology from our prospectively collected Institutional database, comprising all cases performed between April 2010 and September 2016 by a single surgeon. Perioperative outcomes were compared. The impact of minimally invasive TME on autonomic function and quality of life was analyzed with specific questionnaires.

*Results* The docking and overall operative time were shorter in the Xi-RobTME group (p < 0.001 and p < 0.05respectively). The mean differences of overall operative time and docking time were -33.8 min (95% CI -5.1 to

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-64.5) and  $-6 \min (95\% \text{ CI} - 4.1 \text{ to } -7.9)$ , respectively. A fully-robotic approach with complete splenic flexure mobilization was used in 30/30 (100%) of the Xi-RobTME cases and in 7/30 (23%) of the Si-RobTME group (p < 0.001). The hybrid approach in males and patients with BMI > 25 kg/m<sup>2</sup> was necessary in ten patients (45 vs. 0%, p < 0.001) and in six patients (37 vs. 0%, p < 0.05), in the Si-RobTME and Xi-RobTME groups, respectively. There were no differences in conversion rate, mean hospital stay, pathological data, and in functional outcomes between the two groups before and at 1 year after surgery. Conclusion The technical advantages offered by the da Vinci Xi seem to be mainly associated with a shorter docking and operative time and with superior ability to perform a fully-robotic approach. Clinical and functional outcomes seem not to be improved, with the introduction of the new Xi platform.

Keywords Rectal cancer  $\cdot$  Robotic rectal anterior resection  $\cdot$  TME  $\cdot$  Robotic surgery  $\cdot$  Functional results

The Robotic System was introduced to overcome the limitations of laparoscopic technique for mini-invasive surgical procedures. Robot-assisted laparoscopic colectomy was first described by Weber et al. in 2002 [1], and since then, various authors have analyzed the theoretical advantages of robotic surgery. However, the da Vinci Si has some technical limitations resulting in prolonged docking and overall operative time as well as difficulties in multi-quadrant surgery such as rectal resection, due to the bulky robotic platform. In April 2014, Intuitive Surgical (Sunnyvale, USA) introduced its latest version, the da Vinci Xi, to overcome some of the disadvantages of the previous platform to ensure easier docking, a wider range of motion with its smaller, thinner arms, an ability to attach the endoscope to any arm, and better anatomic access to different anatomical regions. Initial published reports are encouraging, showing operative advantages in different specialties, e.g., nephroureterectomy with lymphadenectomy, prostatectomy in urology, and in colon-rectal surgery, the new robotic version is considered an improved platform for this specialty [2–7]. However, these studies all provide preliminary assessment based only on operative data in a limited number of patients without any mid-term data and functional outcome [3–5].

The aim of this study is to report on a larger cohort of patients for evaluation of robotic rectal resection with total mesorectal excision (TME) for rectal cancer performed with the da Vinci Xi (Xi-RobTME group) and the da Vinci Si (Si-RobTME group) by a single surgeon, the comparative assessment being based on short-term surgical results including postoperative autonomic function.

## Materials and methods

Although retrospective, this study used prospectively collected data from 80 patients who underwent robotic rectal resection with TME since January 2010. Robotic procedures with the da Vinci Xi were performed from January 2015 to September 2016, whereas robotic procedures with the da Vinci Si were performed from April 2010 to December 2014. All the procedures were performed by a single surgeon previously experienced with rectal cancer surgery (>100 cases), with laparoscopy (>100 cases), and who started his robotic experience with da Vinci Si in November 2009. Data on patient outcomes, surgical procedures, and postoperative course were collected prospectively in a dedicated database. The preoperative work-up included colonoscopy with biopsy, abdominal and transrectal ultrasonography, chest radiography, abdomen and pelvic CT scan, and/or magnetic resonance imaging. Patients with clinical stage I cancer (T1-2, N0, M0) were referred for prompt surgical treatment. Patients with clinical stage II-III cancer with T3 and/or N-positive received neoadjuvant chemoradiation (continuous 5-FU infusion/ RT) followed by surgical resection within 8 weeks. T4 lesions were operated through an open approach and excluded from the study. Patients with clinical stage IV cancer (metastatic disease) were excluded from the study. The first consecutive 30 Xi-RobTME were compared with a control group of 30 patients with similar rectal tumors, selected using a one-to-one case-matched methodology using the Student's t test, where each patient undergoing Xi-RobTME was matched with a patient undergoing Si-RobTME, using the following criteria: age, sex, body mass index, American Society of Anesthesiologists (ASA) score, neoadjuvant chemoradiotherapy, stage of the disease (I vs. II–III), distance of distal margin of tumor from the anal verge, and type of operation [anterior rectal resection (ARR), intersphincteric resection (ISR) or abdomino-perineal resection (APR)].

Obesity (BMI  $>30 \text{ kg/m}^2$ ) or previous abdominal or pelvic surgical procedures were not considered contraindication for a minimally invasive approach. An anterior resection of the rectum (ARR) was used for lesions whose caudal margin was located at least 2 cm above the dentate line. Intersphincteric resection (ISR) with colo-anal anastomosis was considered for lesions located between 2 and 0.5 cm above the dentate line, while lesions located less than 0.5 cm above the dentate line underwent an APR. A diverting ileostomy was performed in all ARR and ISR patients.

The preoperative data included in the current series were: patient demographics, the ASA scores, body mass index (BMI), neoadjuvant treatment, distance of tumor from the anal verge, and preoperative urinary and sexual function. The perioperative data were: operative time, docking time, the use of Hybrid or Full-robotic approach, splenic flexure mobilization (SFM), blood transfusions, conversion to open or hand-assisted laparoscopic surgery (HALS) [8]. The postoperative data included: postoperative length of hospital stay, postoperative complications (using the Clavien-Dindo Classification [9]), the incidence of anastomotic leak documented with a routine water-soluble contrast enema study 1 month after surgery and postoperative urinary and sexual function. Pathological data included: tumor stage, number of harvested lymph nodes and status, vascular invasion, and distal and circumferential resection margins.

The impact of surgery on autonomic function was assessed with questionnaires given to patients preoperatively, and at 1, 6, and 12 months postoperatively. All patients were available at all follow up time points. For sexual dysfunction the International Index of Erectile Function (IIEF) questionnaire for males and the Female Sexual Function Index (FSFI) for females were used [10]. Evaluation of urinary dysfunction, was assessed in accordance with the International Consultation on Incontinence Male/Female Lower Urinary Tract Symptoms (ICIQ-MLUTS, ICIQ-FLUTS) questionnaires [11]. Each module uses a common question format with 5-point Likert scales to assess the presence or absence of a symptom and its severity, followed by a scale to assess the associated degree of bother, measured by a visual analog scale. The higher numerical value indicated by the patient corresponds to a more severe degree of urinary dysfunction or decrease in quality of life (QoL).

The study was approved by Institutional review board. All patients received an extensive explanation of the procedure and provided informed consent.

## Surgery

## Surgical technique

For the Si-RobTME group, we used a single docking fullrobotic or hybrid technique, based on patient characteristics and intra-operative findings. Main criteria for the hybrid approach were: difficulties in exposure of inferior mesenteric vein or splenic flexure; uncomfortable position of small bowel, visceral obesity, and need of multiple changes of table position.

The patients were placed in a modified lithotomy position with a 30° Trendelenburg angle and a tilt to the right side. In the full-robotic technique, a 12 mm optical trocar for the camera was inserted 3 cm right and lateral to the umbilicus. An 8-mm trocar for the robotic arm was placed under direct vision at the point of intersection between the mid-clavicular line and the line between the umbilicus and the anterior superior iliac spines in the right side. The other two robotic trocars were inserted in the epigastric region, one on the right side and one on the left side of the falciform ligament. Another 12 mm trocar, for the assistant surgeon, was inserted into the right flank (Fig. 1A). In the hybrid technique, the first part of the operation (inferior mesenteric vessel ligation, left colon, and splenic flexure mobilization) was carried out laparoscopically. The trocar for the camera was in the same position as the full-robotic technique, the two operative trocars were epigastric (8 mm) and suprapubic (12 mm); an 8 mm robotic trocar was placed in the left flank (Fig. 1B). The choice to use a hybrid technique was made after the placement of the optical trocar and the suprapubic trocar for the exposure and the evaluation of the quality of the surgical field exposure obtained also with the changes of the operating table position. For the robotic step of the intervention (the TME), the cart was positioned to the patient's left side, along an imaginary line between the anterior superior iliac spine and the umbilical scar, at a  $60^{\circ}$  angle. During this surgical step, the surgeon inserted the 8 mm trocar into the 12 mm trocar (trocar in trocar) and a 12 mm trocar for the assistant's use was placed in the right flank.

For the Xi-RobTME group, patients were placed in a modified lithotomy position with a 30° Trendelenburg angle and a tilt to the right side. The first 8 mm robotic trocar was placed in the umbilical region, along the right pararectal line. The four trocars were then inserted under visualization in an oblique fashion following the 'classic' universal port placement guidelines provided by Intuitive Surgical for 'left lower' abdominal procedures that provides for positioning an 8 mm port in the right iliac fossa, a 12 mm assistant's trocar in the right flank, and two 8 mm robotic ports in the periumbilical region and the left hypochondriac space, respectively. However, as we already described in a previous article [4, 5, 12], we have chosen to translate all trocars by 2-5 cm to the right side, to permit a greater workspace and an easier approach to the splenic flexure with the fourth arm (Fig. 1C). 'Patient-left' was the selected approach, and the surgical cart was driven to position the green laser crosshairs on the initial endoscope port. After docking, the scope was pointed at the inferior mesenteric pedicle of the sigmoid colon, and function 'targeting' was performed. The boom was then rotated in a clockwise direction to ensure the optimal configuration for dividing the inferior mesenteric pedicles and mobilizing the left colon until the splenic flexure. To perform TME, we changed only the targeted anatomical site of the camera from the left side to the pelvis, changing the arm direction, and, consequently, the orientation of the boom-mounted system.

The colon was exteriorized through a Pfannenstiel suprapubic mini-laparotomy for its preparation for the anastomosis. The anastomosis was then performed with a double stapled end to end anastomosis technique under the mini-invasive robotic control.

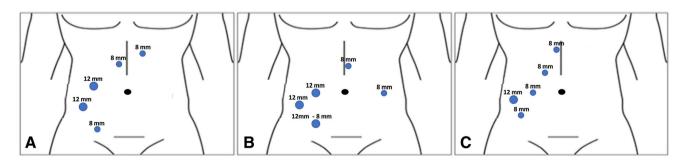


Fig. 1 Different disposition of trocars in robotic rectal resection with the da Vinci Si and Xi. A Full-robotic technique with da Vinci Si, B Hybrid technique with the da Vinci Si, C Full-robotic technique with da Vinci Xi

# Statistical analysis

Data analysis was performed at the General Surgery Unit, University of Pisa, Italy. Analysis was carried out on an intent-to-treat basis.  $\chi^2$  test (or Fisher's exact test) was used to define associations between categorical factors and surgical groups. Continuous variables are given as mean  $\pm$  standard deviation (SD) and compared using Student's *t* test; *p* < 0.05 was considered statistically significant. Variables with a non-normal distribution are expressed as median and compared using the Wilcoxon Test. Data were analyzed using SPSS (Statistical Production and Service Solution for Windows, SPSS Inc., Chicago, IL, USA).

# Results

**Table 1** Patient characteristics and surgical procedure

The baseline data are summarized in Table 1. Each group comprised 22 cases of ARR, six cases of ISR and two cases of APR. The mean distance of distal margin of the tumor from the anal verge was  $6.4 \pm 4.3$  cm in the Xi-RobTME group and  $7.1 \pm 4.1$  cm in the Si-RobTME (p = 0.26).

Perioperative data are summarized in Table 2. Overall operative time was longer in the Si-RobTME group  $(318 \pm 57 \text{ min})$ in the Si-RobTME group versus  $285 \pm 49$  min in the Xi-RobTME group; p < 0.05). The mean difference of overall operative time was -33.8 min (95% CI 5.1-64.5 min). The mean docking time was significantly shorter in the Xi-RobTME groups  $(17.5 \pm 3.4 \text{ min})$ the Xi-RobTME in group vs  $23.5 \pm 2.7$  min in the Si-RobTME group; p < 0.001). The mean difference in the docking time was  $-6 \min (95\% \text{ CI} 4.1-7.9 \min)$ . There were no conversions to conventional laparoscopy, HALS while in one case in each group the procedure was converted to a traditional open approach, for visceral obesity in the Si-RobTME group, and for the difficulty of identifying planes due to constant oozing from dissection planes because of coagulopathy in a patient with liver cirrhosis in the Xi-RobTME group.

In the Xi-RobTME group, all procedures were performed using the full-robotic technique, with complete mobilization of the splenic flexure, while the same association (full-robotic technique and complete SFM) was possible in only 7/30 cases (23%) in the Si-RobTME group (p < 0.001). Whereas a hybrid approach with complete SFM was used in 12/30 patients in the Si-RobTME group (40%), a fully-robotic approach was used in 18/30 patients (60%), 11 of whom had partial SFM. Ten of the 12 patients (83%) of Si-RobTME hybrid subgroup were males with a mean BMI of 25.1 kg/m<sup>2</sup>.

In males, the hybrid approach was necessary in ten patients in the Si-RobTME group compared to none in the Xi-RobTME group (45 vs. 0%, p < 0.001); and in six patients with BMI >25 kg/m<sup>2</sup> in the Si-RobTME group compared to none in Xi-RobTME group (37 vs. 0%, p < 0.01).

There were no significant differences between the groups with respect to pathological findings (Table 3). The mean distal resection margin was  $2.3 \pm 1.1$  cm in the Si-RobTME group versus  $2.2 \pm 1.2$  cm in the Xi-RobTME group (p = 0.64). A mean of  $19 \pm 8$  lymph nodes per patient were removed in the Si-RobTME group versus  $16.6 \pm 8.0$  in the Xi-RobTME group (p = 0.31). No

Parameter	Si-RobTME group	Xi-RobTME group	p value
Mean age, years (range)	67.4 ± 10.8 (44-83)	67.2 ± 10.5 (38-86)	0.96
Males, n (%)	22 (73.3%)	22 (73.3%)	1
Females, n (%)	8 (22.7%)	8 (22.7%)	1
Mean body mass index, kg/m <sup>2</sup> (range)	$24.4 \pm 3.4 \; (17.6  30.5)$	$24.9 \pm 3.5 \; (18.9  35.5)$	0.52
ASA score, n (%)			
ASA I	0 (0%)	1 (3.3%)	0.31
ASA II	15 (50%)	16 (53.4%)	0.80
ASA III	15 (50%)	13 (43.3%)	0.60
ASA IV	0 (0%)	1 (3.3%)	0.31
Surgical procedure, n (%)			
Anterior resection	22 (73.3%)	22 (73.3%)	1
Intersphincteric resection	6 (20%)	6 (20%)	1
Abdomino-perineal resection	2 (6.7%)	2 (6.7%)	1
Neoadiuvant radio-chemoterapy, n (%)	15 (50%)	12 (40%)	0.44
Tumor stage			
Stage I	15 (50%)	18 (60%)	0.44
Stage II/III	15 (50%)	12 (40%)	0.44

#### Table 2 Perioperative data results

Parameter	Si-RobTME group	Xi-RobTME group	p value
Mean overall operative time, min (range)	318 ± 57 (215–480)	285 ± 49 (200–395)	0.05
Mean docking time, min (range)	$23.5 \pm 2.7$ (20–30)	$17.5 \pm 3.4 \ (15-25)$	0.001
Type of surgical technique, n (%)			
Full-robotic technique	18 (60%)	30 (100%)	0.001
Hybrid technique	12 (40%)	0 (0%)	0.001
Complete robotic splenic flexure mobilization, n (%)	7 (23.3%)	30 (100%)	0.001
Conversion to open approach, n (%)	1 (3.3%)	1 (3.3%)	1

## Table 3 Pathological data

Parameter	Si-RobTME group	Xi-RobTME group	p value
Lymph nodes, n (range)	19 ± 8 (5–31)	$16.6 \pm 8.0 (5-30)$	0.31
Mean distance from anal verge, cm (range)	$7.1 \pm 4.1 \ (0.5 - 18)$	$6.4 \pm 4.3 \; (1.5  15)$	0.26
Distal resection margin, cm (range)	$2.3 \pm 1.1 \ (0.2-4)$	$2.2 \pm 1.2 \; (0.2 - 4.2)$	0.64
Circumferential resection margin, n (%)	0 (0%)	0 (0%)	1

patients had involvement of circumferential resection margins ( $\leq 1$  mm) and the quality of the mesorectum, according to Quirke's criteria [13, 14], was 'complete' in all cases.

Postoperative course is summarized in Table 4. The median postoperative length of hospital stay was 8 days (range 5–32) for the Si-RobTME group versus 6.5 days (range 5–31) for the Xi-RobTME group (p = 0.077). Medical complications were observed in ten patients in the Si-RobTME group (two cases of grade I, six cases of grade II, and two cases of grade III on the Clavien-Dindo Classification) versus 8 in the Xi-RobTME group (five cases of grade I and three cases of grade II according to the Clavien-Dindo Classification) (p = 0.57). Two patients in the Si-RobTME group vs one patient in the Xi-RobTME group

(p = 0.55) experienced transient small bowel obstruction, which resolved with insertion of a 24-F Foley catheter in the ileostomy. There was no clinically relevant fistula in both groups. The incidence of radiologic anastomotic leak at the 1 month control enema, was 3/30 cases (10%) in the Xi-RobTME group versus 2/30 (6.7%) cases in the Si-RobTME group (p = 0.64). In the subgroup of patients without a complete SFM in the Si-RobTME group, 1/11 case (9.1%) of anastomotic insufficiency were reported, versus 3/30 (13.3%) of the Xi-RobTME group, in which all cases were performed a complete SFM (p = 0.93), and versus 1/19 case (5.3%) in the subgroup of Si-RobTME group with complete SFM (p = 0.69). One patient in the Xi-RobTME group underwent laparoscopic exploration with closure of the ileostomy on 17th postoperative day for

Table 4	Postoperative	course
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Parameter	Si-RobTME group	Xi-RobTME group	<i>p</i> value 0.077	
Median postoperative length of hospital, days (range)	8 (5–32)	6.5 (5–31)		
Overall complications, n (%)	8 (26.7%)	6 (20%)	0.54	
Complication, n (%)				
Transient small bowel obstructions	2 (6.7%)	1 (3.3%)	0.55	
Abdominal collection	2 (6.7%)	0	0.15	
Peristomal phlegmon	0	1 (3.3%)	0.31	
Medical complications	4 (13.3%)	3 (10%)	0.69	
Anastomotic radiological leak	3 (10%)	2 (6.7%)	0.64	
Reintervention, n (%)	0	1 (3.3%)	0.31	
Mortality	0	0	1	

acute abdomen due to perforation of the afferent loop of the ileostomy (p = 0.31). No in-hospital mortality was noted in the two groups.

The results of the urinary function evaluation are summarized in Table 5 for patients of the Si-RobTME group and in Table 6 for patients of the Xi-RobTME group. Males presented with a significant worsening of voiding symptoms 1 month after surgery in both groups  $(2.10 \pm 0.83 \text{ vs.} 3.38 \pm 0.92 \text{ in the Xi-RobTME group}$ and  $1.95 \pm 1.63$  vs.  $3.43 \pm 2.06$  in the Si-RobTME group; p < 0.01). Incontinence worsened 1 month after surgery in both group  $(1.71 \pm 0.78 \text{ vs. } 3.29 \pm 1.10 \text{ in the Xi}$ RobTME group and 1.33  $\pm$  0.48 vs. 2.57  $\pm$  0.98 in the Si-RobTME group; p < 0.01). Nevertheless, a gradual improvement in incontinence and voiding symptoms were observed and at 6 months and at one year after surgery the grade of incontinence and voiding symptoms were not statistically different when compared with the preoperative status: 2.19  $\pm$  1.33 1-year after surgery versus 1.71  $\pm$  0.78 preoperative for incontinence symptoms (p = 0.16) and  $2.48 \pm 1.25$  1-year after surgery versus  $2.10 \pm 0.83$  preoperative for voiding symptoms (p = 0.25) in the Xi-RobTME group;  $1.57 \pm 0.93$  1-year after surgery versus  $1.33 \pm 0.48$  preoperative for incontinence symptoms (p = 0.30) and  $2.38 \pm 1.47$  1-year after surgery versus  $1.95 \pm 1.63$  preoperative for voiding symptoms (p = 0.38) in the Si-RobTME group.

The analyses of urinary function in female patients showed no difference between the preoperative and post-operative scores concerning voiding symptoms, in both groups. Conversely, there was a significant increase of incontinence in females 1 month after surgery in both groups ( $3.25 \pm 0.46$  preoperatively versus  $4.25 \pm 0.46$  at 1 month in the Xi-RobTME group with p < 0.01 and

Table 5Male and female urinary function data—Si-RobTME GroupM (22 Pts)RangeRefore surgery<sup>a</sup>30 days after surgery<sup>a</sup>

 $2.63 \pm 0.92$  preoperatively versus  $3.75 \pm 0.71$  at 1 month in the Si-RobTME group with p < 0.05). Also, filling symptoms worsened in both groups at 1 month after surgery:  $3.25 \pm 0.46$  preoperatively versus  $4.63 \pm 0.74$  at 1 month in the Xi-RobTME group (p < 0.01) and  $3\pm1.07$  preoperatively versus 4.25  $\pm$  0.89 at 1 month in the Si-RobTME group (p < 0.05). A gradual improvement in incontinence and filling symptoms were observed in both groups with no difference at 1 year when compared with the preoperative status:  $3.38 \pm 0.52$  1-year after surgery versus  $3.25 \pm 0.46$  preoperative for incontinence symptoms (p = 0.62) and 3.38  $\pm$  0.74 1-year after surgery versus  $3.25 \pm 0.46$  preoperative for filling symptoms (p = 0.69) and in the Xi-RobTME group;  $2.75 \pm 0.89$ 1-year after surgery versus  $2.63 \pm 0.92$  preoperative for incontinence symptoms (p = 0.79) and  $3.13 \pm 1.25$  1-year after surgery versus  $3.00 \pm 1.07$  preoperative for filling symptoms (p = 0.83) and in the Si-RobTME group.

With regards to impact of urinary symptoms on QoL (Tables 7, 8), patients experienced a worsening of QoL in the first month after surgery in both groups. However, with improvement of urinary symptoms 1 year after surgery, there was an improvement in QoL and no difference was observed at 1 year after surgery versus the preoperative period in both groups.

The results of the sexual function evaluation are summarized in Table 9 for Si-RobTME patients and in Table 10 for Xi-RobTME patients. Analysis of the IIEF questionnaire showed that sexual function and overall sexual satisfaction decreased significantly after surgery in both groups. In male patients, the scores for erectile function were  $20.82 \pm 2.32$  (preop) versus  $15.55 \pm 1.85$ (p < 0.01) at 1 month and  $17.32 \pm 2.18$  at 6 months (p < 0.01) for Xi-RobTME and  $18.95 \pm 4.50$  (preop)

M (22 Pts.)	Range	Before surgery <sup>a</sup>	30 days after surgery <sup>a</sup>	$p^{\mathrm{b}}$	6 month after surgery <sup>a</sup>	$p^{\mathrm{b}}$	1 year after surgery <sup>a</sup>	$p^{\mathrm{b}}$
Male								
VS	(0–20)	$1.95 \pm 1.63$	$3.43\pm2.06$	0.01	$2.62 \pm 1.50$	0.18	$2.38 \pm 1.47$	0.38
IS	(0–20)	$1.33\pm0.48$	$2.57\pm0.98$	< 0.01	$1.81\pm0.98$	0.06	$1.57\pm0.93$	0.30
F (8 Pts.)	Range	Before surgery <sup>a</sup>	30 days after surgery <sup>a</sup>	$p^{\mathrm{b}}$	6 month after surgery <sup>a</sup>	$p^{\mathrm{b}}$	1 year after surgery <sup>a</sup>	$p^{\mathrm{b}}$
Female								
FS	(0–16)	$3.00 \pm 1.07$	$4.25\pm0.89$	< 0.05	$3.38 \pm 1.06$	0.49	$3.13 \pm 1.25$	0.83
VS	(0–12)	$2.75\pm1.04$	$3.50\pm0.93$	0.15	$3.13\pm0.83$	0.44	$2.88\pm0.83$	0.79
IS	(0–20)	$2.63\pm0.92$	$3.75\pm0.71$	< 0.05	$2.88\pm0.83$	0.58	$2.75\pm0.89$	0.79

VS voiding symptoms, IS incontinence symptoms, FS filling symptoms

<sup>a</sup> Mean  $\pm$  SD expressed

<sup>b</sup> Comparison with the preoperative score

M (22 Pts.)	Range	Before surgery <sup>a</sup>	30 days after surgery <sup>a</sup>	$p^{\mathrm{b}}$	6 month after surgery <sup>a</sup>	$p^{\mathrm{b}}$	1Year after surgery <sup>a</sup>	$p^{b}$
Male								
VS	(0–20)	$2.10\pm0.83$	$3.38\pm0.92$	< 0.01	$2.71 \pm 1.23$	0.06	$2.48 \pm 1.25$	0.25
IS	(0–20)	$1.71\pm0.78$	$3.29 \pm 1.10$	< 0.01	$2.38 \pm 1.32$	0.06	$2.19 \pm 1.33$	0.16
F (8 Pts.)	Range	Before surgery <sup>a</sup>	30 days after surgery <sup>a</sup>	$p^{\mathrm{b}}$	6 month after surgery <sup>a</sup>	$p^{\mathrm{b}}$	1 year after surgery <sup>a</sup>	$p^{\mathrm{b}}$
Female								
FS	(0–16)	$3.25\pm0.46$	$4.63\pm0.74$	< 0.01	$4.00\pm0.93$	0.06	$3.38\pm0.74$	0.69
VS	(0–12)	$3.13\pm0.64$	$4.00\pm1.07$	0.07	$3.88 \pm 1.13$	0.12	$3.00\pm0.53$	0.68
IS	(0-20)	$3.25 \pm 0.46$	$4.25 \pm 0.46$	< 0.01	$3.63 \pm 0.52$	0.15	$3.38 \pm 0.52$	0.62

Table 6 Male and female urinary function data—Xi-RobTME Group

VS voiding symptoms, IS incontinence symptoms, FS filling symptoms

 $^a\,$  Mean  $\pm$  SD expressed

<sup>b</sup> Comparison with the preoperative score

Table 7 Impact on QoL of urinary function in male and female patients-Si-RobTME Group

M (22 Pts.)	Range	Before surgery	30 days after surgery	$p^{\mathrm{a}}$	6 month after surgery	$p^{\mathrm{a}}$	1 year after surgery	$p^{\mathrm{a}}$
Male								
VS	(0–50)	$2.75\pm3.92$	$7.12\pm 6.42$	< 0.05	$6.21 \pm 5.18$	< 0.05	$5.33 \pm 4.51$	0.07
IS	(0–60)	$1.25\pm2.09$	$2.29\pm2.45$	0.15	$2.15\pm2.29$	0.17	$1.71 \pm 2.11$	0.48
F (8 Pts.)	Range	Before surgery	30 days after surgery	$p^{\mathrm{a}}$	6 month after surgery	$p^{\mathrm{a}}$	1 year after surgery	$p^{\mathrm{a}}$
Female								
FS	(0-40)	$3.25\pm2.18$	$3.59\pm2.65$	< 0.05	$3.48 \pm 2.78$	0.85	$3.33\pm2.26$	0.9
VS	(0–30)	$1.39 \pm 1.75$	$2.12\pm2.42$	0.47	$1.78 \pm 2.21$	0.70	$1.45 \pm 1.81$	0.89
IS	(0–50)	$3.55\pm2.29$	$7.18\pm 6.59$	< 0.05	$5.75\pm5.65$	0.31	$4.21 \pm 4.57$	0.68

VS voiding symptoms, IS incontinence symptoms, FS filling symptoms

<sup>a</sup> Comparison with the preoperative score

 Table 8 Impact on QoL of urinary Function in male and female patients—Xi-RobTME Group

(22 Pts.)	Range	Before surgery	30 days after surgery	$p^{\mathrm{a}}$	6 month after surgery	$p^{\mathrm{a}}$	1 year after surgery	$p^{\mathrm{a}}$
Male								
VS	(0–50)	$4.89\pm5.56$	$9.42\pm9.12$	< 0.05	$8.38\pm8.39$	0.12	$5.61 \pm 7.22$	0.72
IS	(0–60)	$1.25\pm1.68$	$5.75\pm9.05$	< 0.01	$4.89\pm7.85$	< 0.01	$3.25\pm 6.98$	0.09
(8 Pts.)	Range	Before surgery	30 days after surgery	$p^{\mathrm{a}}$	6 month after surgery	$p^{\mathrm{a}}$	1 year after surgery	$p^{\mathrm{a}}$
Female								
FS	(0-40)	$2.75 \pm 4.12$	$3.89 \pm 4.41$	< 0.01	$3.89 \pm 4.41$	< 0.01	$3.05 \pm 3.45$	0.45
VS	(0–30)	$0.99\pm1.65$	$2.12\pm3.21$	0.39	$1.85\pm3.12$	0.50	$1.41 \pm 2.61$	0.67
IS	(0–50)	$2.51 \pm 3.49$	$4.78\pm 6.54$	< 0.01	$4.12\pm5.82$	0.07	$3.65\pm5.45$	0.12

VS voiding symptoms, IS incontinence symptoms, FS filling symptoms

<sup>a</sup> Comparison with the preoperative score

MIIEF (22 Pts.)	)	Range	Before surgery <sup>a</sup>	30 days after surgery <sup>a</sup>	$p^{\mathrm{b}}$	6 month after surgery <sup>a</sup>	$p^{\mathrm{b}}$	1 year after surgery <sup>a</sup>	$p^{b}$
Male									
Erectile functi	ion	(0–30)	$18.95 \pm 4$	4.50 $14.22 \pm 4.69$	<0.	01 14.90 $\pm$ 4.72	< 0.01	$16.64 \pm 5.10$	0.12
Orgasmic fun	ction	(0–10)	$8.05 \pm 2$	2.57 $5.27 \pm 2.25$	<0.	01 $5.82 \pm 2.17$	< 0.01	$6.68 \pm 2.61$	0.09
Sexual desire		(2–10)	$6.95 \pm 1$	$1.76  5.00 \pm 1.85$	<0.	01 $5.65 \pm 1.72$	< 0.05	$6.00 \pm 1.74$	0.11
Intercourse satisfaction		(0–15)	$8.90 \pm 2$	2.61 $6.55 \pm 2.87$	<0.	01 $6.95 \pm 2.74$	< 0.05	$7.80\pm2.78$	0.21
Overall satisfa	action	(2–10)	$7.25 \pm 0$	$5.10 \pm 1.06$	<0.	01 $5.70 \pm 0.92$	< 0.01	$6.85\pm0.71$	0.08
FFSFI (8 Pts.)	Range	Before	e surgery <sup>a</sup>	30 days after surgery	$p^{b}$	6 month after surger	$y^a p^b$	1 year after surgery <sup>a</sup>	$p^{\mathrm{b}}$
Female									
Desire	(1.2–6)	3.68 ±	± 0.68	$1.65 \pm 0.62$	< 0.01	$1.95 \pm 0.77$	< 0.01	$3.15 \pm 0.70$	0.15
Arousal	(0–6)	3.00 ±	E 0.91	$1.61 \pm 0.39$	< 0.01	$1.99 \pm 0.77$	< 0.05	$2.55 \pm 0.83$	0.32
Lubrication	(0–6)	2.89 ±	± 1.22	$1.69 \pm 0.45$	< 0.05	$2.03\pm0.69$	0.10	$2.48 \pm 1.13$	0.49
Orgasm	(0–6)	2.75 ±	± 1.31	$1.55\pm0.33$	< 0.05	$2.10\pm0.79$	0.25	$2.65 \pm 1.23$	0.88
Satisfaction	(0.8–6)	4.25 ±	± 0.21	$2.55\pm0.37$	< 0.01	$3.00\pm0.30$	< 0.01	$4.00 \pm 0.30$	0.07
Pain	(0–6)	2.85 ±	± 1.43	$1.70 \pm 0.47$	< 0.05	$2.15\pm0.85$	0.25	$2.60 \pm 1.23$	0.71

Table 9 Sexual function data—Si-RobTME Group

<sup>a</sup> Mean  $\pm$  SD expressed

<sup>b</sup> Comparison with the preoperative score

Table 10	Sexual	function	data—	-Xi-RobTME	Group
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MIIEF (22 pts.)	)	Range	Before surgery <sup>a</sup>	30 days after surgery <sup>a</sup>	$p^{b}$	6 month after surgery <sup>a</sup>	$p^{b}$	1 year after surgery <sup>a</sup>	p <sup>b</sup>
Male									
Erectile functi	ion	(0–30)	$20.82 \pm 2$	2.32 $15.55 \pm 1.84$	< 0.0	$1 17.32 \pm 2.28$	< 0.01	$19.50 \pm 2.18$	0.06
Orgasmic fund	ction	(0–10)	$7.19 \pm 0$	$5.05 \pm 1.21$	< 0.0	$1 5.50 \pm 1.01$	< 0.01	$6.68 \pm 1.04$	0.09
Sexual desire		(2–10)	$7.60 \pm 0$	$0.51  5.60 \pm 0.58$	< 0.0	$1  6.35 \pm 0.80$	< 0.01	$7.25 \pm 0.61$	0.07
Intercourse satisfaction		(0–15)	$11.4 \pm 1$	.22 8.95 ± 1.32	<0.0	1 9.25 $\pm$ 1.33	< 0.01	$10.65 \pm 1.11$	0.06
Overall satisfa	action	(2–10)	$7.05 \pm 0$	$0.58   5.60 \pm 0.66$	< 0.0	$1  6.00 \pm 0.81$	< 0.01	$6.80\pm0.50$	0.17
FFSFI (8 pts.)	Range	Before	e surgery <sup>a</sup>	30 days after surgery <sup>a</sup>	p <sup>b</sup>	6 month after surgery <sup>a</sup>	$p^{b}$	1 year after surgery <sup>a</sup>	$p^{\mathrm{b}}$
Female									
Desire	(1.2–6)	3.60 ±	- 0.79	$1.80 \pm 0.72$	< 0.01	$1.80 \pm 0.72$	< 0.01	$3.08\pm0.75$	0.19
Arousal	(0–6)	2.78 ∃	= 1.03	$1.46 \pm 0.43$	< 0.01	$1.69 \pm 0.68$	< 0.05	$2.14\pm0.72$	0.17
Lubrication	(0–6)	2.70 ±	= 1.16	$1.69\pm0.55$	< 0.05	$1.84 \pm 0.72$	0.10	$2.10\pm1.00$	0.29
Orgasm	(0–6)	2.55 ±	= 1.47	$1.35\pm0.37$	< 0.05	$1.50 \pm 0.73$	0.09	$1.85\pm0.98$	0.28
Satisfaction	(0.8–6)	4.05 ∃	- 0.75	$2.45\pm0.58$	<0.01	$2.60 \pm 0.57$	< 0.01	$3.45\pm0.70$	0.12
Pain	(0–6)	2.70 ±	= 1.35	$1.55\pm0.58$	< 0.05	$1.80 \pm 0.90$	0.14	$2.05 \pm 1.12$	0.31

<sup>a</sup> Mean  $\pm$  SD expressed

<sup>b</sup> Comparison with the preoperative score

versus  $14.22 \pm 4.69$  (p < 0.01) at 1 month and  $14.90 \pm 4.72$  (p < 0.01) at 6 months for Si-RobTME. The same occurred for orgasm:  $7.19 \pm 0.85$  (preoperatively)

versus 5.05  $\pm$  1.21 at 1 month (p < 0.01) and 5.50  $\pm$  1.01 (p < 0.01) at 6 month for Xi-RobTME and 8.05  $\pm$  2.57 (preoperatively) versus 5.27  $\pm$  2.25 (p < 0.01) at 1 month

and 5.82  $\pm$  2.18 (p < 0.01) at 6 months in the Si-RobTME group. These scores increased over time, and 1 year after surgery their values were comparable to baseline:  $19.50 \pm 2.18$  1-year after surgery versus  $20.82 \pm 2.32$ preoperative for erectile function (p = 0.06)and  $6.68 \pm 1.04$  1-year after surgery versus  $7.19 \pm 0.85$  preoperative for orgasm (p = 0.09) in the Xi-RobTME group;  $16.64 \pm 5.10$  1-year after surgery versus  $18.95 \pm 4.49$ preoperative for erectile function (p = 0.12)and  $6.68 \pm 2.61$  1-year after surgery versus  $8.05 \pm 2.57$  preoperative for orgasm (p = 0.09) and in the Si-RobTME group. The deterioration in erectile function and orgasm was associated with lowered overall satisfaction, intercourse satisfaction, and sexual desire 1 and 6 months after surgery in both groups. However, these values improved spontaneously over time without any treatment with improvement of erectile function and orgasm, and 1 year after surgery there were no differences versus baseline.

In females, lubrication and pain were significantly worse at 1 month after intervention in the both groups:  $2.70 \pm 1.16$  preoperatively versus  $1.69 \pm 0.55$  at 1 month  $2.7 \pm 1.35$ preoperatively (p < 0.05)and versus  $1.55 \pm 0.58$  at 1 month (p < 0.05) respectively for Xi-RobTME group and  $2.89 \pm 1.22$  preoperatively versus  $1.69 \pm 0.45$  at 1 month (p < 0.05) and  $2.85 \pm 1.43$  preoperatively versus  $1.7 \pm 0.47$  at 1 month (p < 0.05) respectively for Si-RobTME. However, these scores increased over time and 1 year after surgery lubrication and pain scores were comparable to preoperative values in both groups. The same occurred for orgasm:  $2.55 \pm 1.47$ (preoperatively) versus  $1.35 \pm 0.37$  at 1 month (p < 0.05) in Xi-RobTME group and  $2.75 \pm 1.30$  (preoperatively) versus  $1.55 \pm 0.33$  at 1 month (p < 0.05) in Si-RobTME group. Also in females, the deterioration in lubrication and orgasm and a painful sexual rapport were associated with lowered satisfaction, arousal, and sexual desire at 1 and 6 month after surgery in both groups. However, these values improved over time with improvement of other scores and 1 year after surgery there were no differences versus baseline in both groups.

# Discussion

The use of da Vinci robotic surgery systems has spread rapidly in the field of colon and rectal cancer surgery because of its advantages compared to laparoscopic TME, including a lower conversion rate, a shorter learning curve, and good functional outcome [15–23]. Despite these benefits over the direct manual laparoscopic approach, the da Vinci Si presents some technical aspects that limit its use. In the field of colon-rectal surgery, robotic approach has been criticized by many authors for its complicated setup,

limited ability to reach all the required abdominal quadrants without rearrangement of robotic arms, re-docking and/or repositioning of the surgical cart resulting in longer OR times, and less cost effective procedures versus alternative methods [6]. The da Vinci Xi exhibits several innovations and technologies over the previous robotic versions. These may help to translate into surgical and perioperative benefits in this setting as described by the initial recently published reports. Thus, Hagen et al. reported six colorectal procedures performed with a single docking approach without any difficult access from splenic flexure to pelvic floor [6]. Along the same line, Protyniak et al. [7] in a comparison between forty-four patients in the da Vinci Si group and 26 patients in the Xi group undergoing sigmoidectomy or low anterior resection showed that splenic flexure was mobilized in more cases performed with da Vinci Xi cases compared to da Vinci Si. Mobilization could not be performed using the single-dock da Vinci Si System in 15.4% of patients undergoing sigmoidectomy, requiring laparoscopic assistance. This author also reported that single-dock multi-quadrant robotic surgery was more frequently performed using the da Vinci Xi platform [7]. Ozben et al. [3] in a comparative study between 25 patients in the da Vinci Si group and 28 patients in the Xi group could perform all the operations with a totally robotic and single docking of the robotic system in the Xi group. In the Si group 40% of patients they had to use a hybrid (laparoscopic-robotic) procedure and in the remaining 60% of patients undergoing totally robotic operations, the robot had to be redocked during the procedure.

In the present study, we observed no significant difficulties and no significant need to change the positions of the instruments, robot, or patient with this setup following the 'modified' Left Lower Abdominal Procedures Universal Port Placement Guidelines from Intuitive that we had described in our reports [4, 5, 12]. In our opinion, the modified trocar disposition could facilitate the approach to the transverse colon and splenic flexure because provide more space to the maneuver, without causing difficulties during the pelvic phase, because of the flexibility offered by the Xi. The same changes in trocar disposition, to gain more space or work in left quadrant are not possible with da Vinci Si because of the lower flexibility of arms which restricts the ability to dissect during the pelvic phase because of conflicts. We think that this enhanced maneuverability possible with the new robotic platform is the crucial factor in facilitating the splenic flexure mobilization, aside from enhancing exposure of operative field, with consequential reduction of conversion rate, and contributing to the reduced operative time. We were able to perform fully-robotic TME in all the study patients of Xi-RobTME group, even those that we consider 'difficult cases' because of a low-lying tumor, a narrow male pelvis, and a high body mass index. Interestingly, ten of the 12 cases (83%) of Si-RobTME hybrid subgroup were males and the mean BMI was 25.1 kg/m<sup>2</sup>. In the present study, increased BMI was one of the principal risk factors associated with the need for conversion from a full robotic to a hybrid approach. The thickness of the greater omentum and retroperitoneal fat increase the difficulty in the exposure of the splenic flexure and inferior mesenteric pedicle which, together with problems related to limited range of motion of da Vinci Si instruments, leads some surgeons to prefer the manual laparoscopic technique for the first part of the operation reserving, the robotic dexterity for the proctectomy. By virtue of the flexibility of the Da Vinci Xi and its capability to cope with multi-quadrant surgery, we prefer the fully-robotic approach during the surgical planning and could complete the surgical operation with complete splenic flexure mobilization in all cases, and without the need of an additional trocar or conversion to a hybrid approach, both in male and obese patients.

From an operative time, standpoint, other studies [3-5], have shown a shorter operative and console time with the use of the new da Vinci Xi. Considering their primary outcome, Ozben et al. demonstrated that the Xi robot, by itself, is an independent factor associated with reduced console time although the Xi robot appears to be associated to shorten total operative time, this finding did not reach a statistical significance in a multivariate analysis [3]. In our study, we confirmed a significantly shorter docking time and a trend towards a shorter overall operative time in the Xi-RobTME versus the Si-RobTME group. These data are very important as operative time is one of the main criticisms of robot as it impacts negatively on the costs of this approach and its widespread adoption. In combination with reduced fixed costs with the experience in robotic surgery suggested by several reports, the availability of new flexible and easy to use platform, should contribute to flattening the difference with laparoscopy.

The increasing emphasis and scientific interest on functional outcomes in recent years is regarding direct manual laparoscopic and da Vinci Si robotic assisted rectal surgery, is due to the iatrogenic nerve dysfunction, which remain one of the most important adverse complications, which significantly impacts on the QoL of patients, and must be considered in the choice by the surgeon on the best surgical approach [24]. However, to date, no functional analysis have been published regarding the role of the new da Vinci Xi in this setting. The present study, unlike the previous reports, includes data on postoperative functional parameters; it evaluates whether the improvements offered by da Vinci Xi had a positive impact on sexual and urinary functions, and on the Quality of Life. In this aspect, the present study has found no difference between Si-RobTME and Xi-RobTME, as sexual function and general sexual satisfaction 1 year after surgery were observed to be comparable to those before surgery. Likewise, urinary symptoms were unchanged 1 year post intervention compared with the preoperative status in both groups. In fact, we observed a transient impairment of urinary continence, filling and voiding symptoms, and a worsening of sexual function after RobTME in both group, but symptoms improved over time and at 1 year after surgery, there were no differences versus baseline, probably due to resolution of postoperative inflammation of pelvic tissues and repair of minimal nerve damage caused by intra-operative manipulations [25]. This result is not surprising, because in our experience, the main technological improvements offered by the da Vinci Xi are due to its increased flexibility and range of motion of the cart and arms, which enable increases instrument spacing in the different quadrants, and uninterrupted the workflow. Conversely, there are no significant major differences that we have observed in the instruments, in vision, and thus the precision and accuracy during local dissections. The absence of any significant difference between the two robotic versions in quality of local dissection during TME explains the absence of any difference in functional results between the two groups and QoL observed in the present study.

Finally, it is useful to analyze the introduction of the new platform for rectal resection for cancer on the pathological outcomes. The advanced technology of the robotic system may allow more precise cancer resection and achieve complete mesorectal excision. This is thought to be crucial for long term oncologic outcomes [2, 26]. Moreover, the number of harvested and examined lymph nodes is pivotal for accurate postoperative tumor staging. We found comparable results between the two robotic platforms about pathological results, specifically no statistical differences in the number of harvested lymph nodes, or circumferential and distal resection margins between Si-RobTME and Xi-RobTME, in agreement with published data [4, 27].

A possible limitation of the present study, aside from its retrospective nature and the small sample size, may be related to a 'proficiency-gain effect' that may create a bias in favor of one or other group. However, we think that because 'the proficiency-gain effect' is related only to the use of the new robotic technology and not to the surgical operation itself (rectal resection), because the surgeon was just experienced in laparoscopy and in rectal cancer surgery, the same 'new proficiency-gain curve' should be considered also for the Xi and so should balance this possible bias. In fact, changing from Si to Xi the surgeon must deal with new trocar dispositions, robotic cart position, new functions (pointing, targeting, camera hopping, etc.), new docking system, and robotic arms regulation. For these reasons, for the first Xi cases, as well as for the first Si cases, the surgeon underwent a similar proficiency-gain phase which is difficult. On this basis, as the proficiency-gain learning curve affected both groups, it is unlikely that it influenced the results.

# Conclusions

The present comparative study has demonstrated that the new da Vinci Xi platform is an improvement on its Si predecessor in robotically-assisted laparoscopic rectal resections. It overcomes exposure/flexibility limitations of the Si platform, thereby facilitating total robotically-assisted rectal resections with a single docking uninterrupted procedure, avoiding the need for port hopping or alterations of the manipulator arms. These technical advantages result in a shorter docking and operative time and permit the execution of a fully-robotic approach, even in difficult operations, e.g., male and obese patients. These advantages of the Xi may reduce costs. However, the present study has not demonstrated any change between the Si and the Xi da Vinci platforms in the conversion rate, pathologic, and functional outcome.

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#### Compliance with ethical standards

**Disclosures** Luca Morelli, Gregorio Di Franco, Simone Guadagni, Leonardo Rossi, Matteo Palmeri, Niccolò Furbetta, Desirèe Gianardi, Mattero Bianchini, Giovanni Caprili, Cristiano D'Isidoro, Franco Mosca, Andra Moglia, and Alfred Cuschieri have no conflicts of interest or financial ties to disclose.

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