Robotic Total Mesorectal Excision for Rectal Cancer: Short-Term Oncological Outcomes of Initial 178 Cases

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Abstract
Emerging techniques in minimally invasive rectal resection include robotic total mesorectal excision (R-TME). The Da Vinci Surgical System offers precise dissection in narrow and deep confined spaces and is gaining increasing acceptance during recent times. The aim of this study is to analyse our initial experience of R-TME with Da Vinci Xi platform in terms of perioperative and oncological outcomes in the context of data from recently published randomised ROLARR trial amongst minimally invasive novice surgeons. Patients who underwent R-TME or tumour specific mesorectal excision for rectal cancer between May 2016 and November 2019 were identified from a prospectively maintained single institution colorectal database. Demographic, clinical-pathological and short-term oncological outcomes were analysed. Of the 178 patients, 117 (65.7%) and 31 (17.4%) patients had lower and mid third rectal cancer. Most of the tumours were locally advanced, cT3–T4: 138 (77.5%). One hundred/178 (56.2%) underwent sphincter preserving TME. Eighty-seven (48.8%) were grade II adenocarcinoma. Nonmucinous adenocarcinoma was the predominant histology, 138 (78.4%). One hundred one cases (56.7%) were pT3. The mean number of lymph node yield was 13 ± 5. Distal resection margin and circumferential resection margin were positive in 2 (1.12%), 12 cases (6.74%) respectively. Eleven cases (6.7%) had to be converted to open TME. Mean blood loss and duration of surgery was 170 ± 60 ml and 286 ± 45 min respectively. Five percent cases had an anastomotic leak. Grade IIIa–IIIb Clavien Dindo (CD) morbidity score was reported to be in 12 (6.75%) and 10 (5.61%) cases. Median length of hospitalisation was 7 days (range 4–14 days).

Perioperative and pathologic outcomes following robotic rectal resection is associated with good short-term oncological outcomes and is safe, effective, and reproducible by a minimally invasive novice surgeon.

Keywords Rectal cancer · Robotic rectal resection · Robotic total mesorectal excision · Da Vinci surgical system

Introduction
Neoadjuvant chemoradiotherapy (NACRT) has a major role in the treatment of locally advanced rectal tumours [1]. Oncological outcomes have improved following widespread acceptance of the principles of TME [2]. Surgical techniques govern oncological outcomes in rectal cancer surgery. Tumour-specific mesorectal excision or total mesorectal excision (TME) and achieving a negative circumferential resection margin (CRM) are associated with lower recurrence rates and improved overall survival [3–9].

There have been numerous prospective randomized studies about the superior short-term outcomes of laparoscopic surgery for rectal cancer in comparison with open rectal resections [10–14]. Few studies have raised concerns on the quality of TME, composite pathological outcomes, and the oncological safety associated with the laparoscopic total mesorectal excision (L-TME approach) [15–17]. The question remains still open after the publication of the results of the latest trials [17–20].

Poor visibility coupled with difficult access in deep and narrow pelvis makes dissection and distal division a technical challenge, which may result in suboptimal pathological outcomes and hence are the fundamental concerns with L-TME. This has led some surgeons to adopt robotic-assisted approach which aims to improve the ease and quality of TME while still retaining the potential benefits of minimally invasive approach.
Robotic-assisted approach offers magnified three-dimensional vision, a surgeon-controlled camera and operating platform, instruments with various degrees of freedom and articulation, enhanced ergonomics and tremor filtration [21]; these advantages may translate to superior TME quality and improved autonomic functional outcomes [22–24].

ROLARR randomized trial, compared laparoscopic versus robotic surgery and reported robotic approach may have a lower overall conversion rate particularly benefiting obese men subgroup. The study did not find any statistical significant differences in the rest of the short-term outcomes including bladder and sexual dysfunction [25].

R-TME at our institution is being performed since 2016 and has become the preferred procedure of choice in patients who are suitable for a minimally invasive approach. The objective of this study was to prospectively evaluate the initial experience with R-TME and associated perioperative and oncologic outcomes in the context of data from recently published ROLARR trial.

Materials and Methods

Retrospective review of a prospectively maintained colorectal database identified 178 patients who had undergone robotic rectal resections using Da Vinci Xi Robotic system (Intuitive Surgical Inc., Sunnyvale, CA, USA) for biopsy confirmed primary rectal adenocarcinoma or melanoma at Kidwai Memorial Institute of Oncology, Bengaluru, India, between May 2016 to November 2019. Rectal cancer was defined as tumours that were ≤15 cm from the anal verge and were grouped into upper (11–15 cm), mid (6–10 cm), and lower (≤5 cm) based on distance from anal verge.

Preoperative Staging and Neoadjuvant Treatment

All patients underwent preoperative staging of pelvis with magnetic resonance imaging (MRI) and computed tomography (CT) scans of the abdomen and thorax. NACRT was offered to patients with clinical stage T3–T4 N0 or any T N+ with or without mesorectal fascia (MRF) involvement. The NACRT regimen included oral capecitabine-based chemotherapy and external beam radiation (a total dose of 50.4 Gy in 25 fractions). After completion of NACRT, all patients underwent restaging pelvic MRI. If MRF/CRM remained positive, additional 4 cycles of capecitabine- and oxaliplatin-based chemotherapy were administered. Surgery was performed between 7 and 8 weeks postNACRT.

Early T3 (T3a–T3b) [26], CRM/MRF negative cases received short-course radiotherapy (SCRT: 25Gy in 5 fractions) and underwent surgery between 3 and 7 days postSCRT. All patients received adjuvant chemotherapy for a period of 6 months.

Eligibility Criteria

Patients who underwent abdomen/pelvic dissection after docking were included in the analysis. Robotic surgery was not offered for patients requiring extended resection, complex abdominal wall reconstruction, or synchronous liver resection with laparotomy. Cases with presence of significant intraabdominal adhesions limiting access to the distal colon or pelvis or peritoneal deposits on staging/diagnostic laparoscopy were excluded.

Outcome Assessment

The primary measures of this analysis were perioperative and pathological outcomes. < 1 mm between deepest tumour extension to the CRM was defined as positive CRM while < 1 mm between the lowest aspect of tumour and distal cut edge of specimen was considered as a positive distal resection margin (DRM) [27].

Defining Conversion

Conversion to open surgery was defined as the use of an abdominal incision to continue the procedure under direct visualization before completion of the TME, due to any cause.

Surgical Complications

Any adverse events within and after 30 days after surgery were defined as postoperatively early and delayed complications respectively. Anastomosis leakage was defined as feculent discharge in surgically placed drains, radiological evidence of contrast extravasation or perianastomotic collection requiring drainage, or anastomotic dehiscence as determined on digital rectal examination or flexible sigmoidoscopy.

Technique of Totally Robotic TME for Rectal Cancer

In the present study, all patients underwent single docking, single stage and complete R-TME using the Da Vinci Surgical System Xi [28].

Data Collection and Statistical Analysis

All demographic, operative, pathological and postoperative recovery data were obtained from the prospectively maintained colorectal database. Surgical complications were stratified by Clavien Dindo classification system [29]. All statistical analyses were carried out with the Statistical Package for the Social Sciences version 21 (SPSS Chicago, IL, USA). Continuous variables were used to derive the mean ± SD (SD, standard deviation).
Ethics

The data of the present study were collected in the course of common clinical practice, and, accordingly, the signed informed consent was obtained from each patient for any surgical and clinical procedure. The study protocol conforms to the ethical guidelines of the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, as revised in Tokyo 2004. No approval of the institutional review committee was needed.

Results

A total of 335 robotic resections were performed during the study period of which 178 cases underwent robotic rectal resection Table 1, Fig. 1. R-TME was performed initially by a single surgeon with 2 additional surgeons progressively transitioning from open to robotic during the study period with annual increase in the total number of cases performed robotically.

Table 1 Institutional database of robotic resections

| Procedures                          | Numbers (n) = 335 |
|-------------------------------------|-----------------|
| 1. Lower GI                         | 210             |
| a. R-TME                            | 178             |
| b. R-CME                            | 32              |
| 2. Upper GI                         | 82              |
| a. TTE                              | 70              |
| b. Subtotal gastrectomy             | 10              |
| c. Total gastrectomy                | 02              |
| 3. Genitourinary                    | 36              |
| a. Radical nephrectomy              | 19              |
| b. RCIC                              | 10              |
| c. RARP                             | 06              |
| d. Adrenalectomy                    | 01              |
| 4. Hepatobiliary                    | 06              |
| a. PPPD                             | 01              |
| b. DPS                              | 01              |
| c. Radical cholecystectomy          | 01              |
| d. Simple cholecystectomy           | 03              |
| 5. Mediastinum and thorax           | 01              |
| a. Thymoma excision                 |                 |

R-TME Robotic total mesorectal excision, R-CME robotic complete mesocolic excision, RCIC radical cystectomy with ileal conduit, RARP robotic-assisted radical prostatectomy, PPPD pylorus preserving pancreatico-duodenectomy, DPS distal pancreatico-splenectomy

Patient Characteristics

The demographic characteristics are summarized in Table 2. Median age was 51 years (range: 23–87 years). 51.7% (n = 92) and 48.3% (n = 86) were men and women respectively. Mean body mass index was 22.8 ± 4. Lower third and middle third rectal tumours amounted for 65.7% (n = 117) and 17.4% (n = 31) cases respectively. Locally advanced T3–T4 tumours were predominant, accounted for 77.5% (n = 138) of the cases. 65.5% received neoadjuvant therapy.

Operative Outcomes

Table 3 illustrates operative parameters. One hundred sixty-seven/178 underwent complete robotic rectal resections. Sphincter preservation procedures amounted for 56% (n = 100) of cases, and the remaining 44% (n = 78) were Abdomino-perineal resections (APR). Mean total operating time, docking and surgeon console time were 286 ± 45 min, 13 ± 5 min and 220 ± 20 min respectively. Mean blood loss was 170 ± 60 ml.

Docking Time

Mean docking time is 13 ± 5 min. Our analysis showed that with a standardised six port technique the docking time plateaus after 18 consecutive cases (Fig. 2).

Time Stratified Analysis

During the first year, the ratio of APR to sphincter preserving procedures was 4:1, with increasingly gaining experience the ratio was 2:2 during the first half of the second year and 1:4 thereafter (Fig. 3).
An annual analysis of cases showed that the mean operative time during the first year was 180 ± 30 min, 230 ± 40 min during the second year, and 300 ± 30 min during the third year.

**Conversion Rates**

Eleven out of 178 had a conversion to open approach. Conversion was more often in men and in whom sphincter preservation strategy was desired. Seven out of 11 converted cases (63.63%) were amongst men and 36.37% women (p = 0.04) in whom a sphincter preservation was planned. Reasons for conversion are listed in Table 4.

In 18.2% cases (17 of 93 sphincter preservation procedures (ISR excluded)) midline utility incision was utilised for rectal division (after completion of TME).

**Histopathologic Outcomes (Table 5)**

Signet cell adenocarcinoma constituted a small volume of 08 (4.5%) cases. 56.7% (n = 101) cases were reported to be pT3. Complete pathological response was noted in only 2.8% (n = 5) cases. Mean distal resection margin length was 2.6 ± 1.8 cm. Two cases (1.12%) (one low anterior resection and one intersphincteric resection) had microscopic distal resection margin involvement on final histopathological examination for which a second surgery, APR, was performed on 12th and 15th postoperative day respectively. 6.74% (n = 12) cases had a positive CRM, and most of these cases had undergone an APR (Fig. 4). Mean number of lymph nodal retrieval was 13 ± 5.

**Postoperative Complications**

Outcomes of postoperative recovery are presented in Tables 6 and 7. Mean time to first flatus passage was 2 ± 1 days; time to resume to oral intake of liquids was 1.5 ± 0.5 day. Mean length of hospital stay was 6 ± 2 days for APR procedures and 8 ± 1 days following sphincter preserving procedures. Urinary catheter removal was performed after 6 days following sphincter preservation procedure and after 8 following APR. Eight/100 (8%) patients had anastomotic leakage. Twelve/178 (6.74%) and 10/178 (5.61%) cases had Clavien-Dindo grade IIIa and IIIb complications respectively. There was one postoperative death, due to an unexpected cardiac event that occurred on postoperative day 6 following APR.

**Discussion**

This study is perhaps the largest series from the Indian subcontinent, and to the best of our knowledge, this is the only Indian series identified in the literature from a regional cancer centre which has analysed short-term oncological outcomes following robotic rectal resection by a robotic novice surgeon. ALaCaRT and ACOSOG Z6051 randomised trials failed to demonstrate noninferiority of laparoscopic surgery with open surgery for rectal cancer in terms of pathological success, raising concerns about its effect on clinical outcomes.
Planned analysis of secondary outcomes after a minimum follow-up of 2 years has not found significant differences in disease-free survival nor locoregional recurrence, although estimates of treatment effect favoured open resection indicating that an alternative platform such as robotics may improve oncological outcomes of minimally invasive surgery. Robotic rectal resection was developed to overcome the limitations of conventional laparoscopy and to achieve a superior quality of oncologic resection [30].

As a new surgical procedure, worldwide R-TME is adopted increasingly by surgeons. Patient selection is of utmost importance during the initial period of learning. In our series, all three surgeons were making a transition from open to robotic approach and were novice with laparoscopic approach; hence during the initial year, the surgeons selected cases suitable for robotic APR which were less complex until more experience was gained; this explains our APR rates of 43.82% (78/178) cases. During the first year, the ratio of APR to sphincter preserving procedures was 4:1; with increasingly gaining experience, the ratio was 2:2 during the first half of the second year and 1:4 thereafter.

Existing literature demonstrate longer operative time for robotics compared with open and laparoscopic rectal resections [31–34]. ROLARR trial reported a mean duration of

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**Fig. 2** Duration of docking

**Fig. 3** Annual case selection distribution
surgery of 298.5 ± 88.71. Mean operative time in our series is 286 ± 45 min. Further, an annual analysis of cases showed that the mean operative time during the first year 180 ± 30 min and 230 ± 40 min and 300 ± 30 min during the second and third year. This progressively increasing annual operative time is due to routine splenic flexure mobilisation and more number of sphincter preservation procedures which are been performed from second year onwards.

The landmark laparoscopic rectal cancer trials, MRC CLASICCC, COLOR-II, ACOSOG-Z6051, ALaCaRT reported a conversion rates of 34%, 16%, 11% and 9% respectively. The conversion rates reported in ROLARR trial is 12.2% in the laparoscopic group and 8.1% in the robotic-assisted group. The present series reports a conversion rate of 6.7% (11/178). Table 4 illustrates the reasons for conversion, and conversion rates were more often in men and when the intended procedure was sphincter preservation procedure as compared with APR. In 5/11, failure to progress into the pelvis was noted and more often in the initial few cases. Indeed, the rate of conversion in the current series is lower than reported in ROLARR but consistent with other reports from experienced centres [35]. Optimal preoperative imaging, evaluation and case selection are the attributable factors for the low conversion rates.

Robotic approach seems to facilitate mesorectal dissection, particularly in mid and low rectal tumours, hence one of the major benefit thought to be conferred by this novel approach was lower positive CRM rates. Our evaluation of CRM positivity and DRM involvement assessed the quality of mesorectal excision. Our study reports 12/178 (6.74%) CRM positive rates and 2/178 (1.12%) DRM involvement.

CRM positive was more common amongst patients who had underwent APR (Fig. 3). Ten/12 and 2/12 patients with positive CRM had underwent APR and low AR respectively. Seven/10 APR patients with positive CRM had persistent MRF involvement despite NACRT and additional FOLFOX × 4. Three/10 APR had positive CRM secondary to tumour perforation. One patient with DRM involvement following intersphincteric resection (ISR) underwent completion APR; the other ISR patient did not consent for APR and is on follow-up. Our CRM positive rates are slightly higher than ROLARR trial, reported to be 5.1%; this is probably attributed to undertaking APR procedures for mucinous or signet ring adenocarcinoma with persistently MRF positive despite NACRT and additional chemotherapy. The response to neoadjuvant treatment in this histology group is nonfavourable [36, 37].

### Table 4 Factors favouring conversion to open approach

| Unfavourable parameters                                                                 | Numbers (n = 11) |
|-----------------------------------------------------------------------------------------|-----------------|
| 1. Uncontrolled bleeding from Inferior mesenteric artery                                 | 01              |
| 2. Hem-o-lock clip slippage from inferior mesenteric artery stump                        | 01              |
| 3. Common iliac artery bleeding while dissecting the left ureter                         | 01              |
| 4. Peri-hilar bleeding while splenic flexure mobilisation                                | 01              |
| 5. Descending colon perforation while mobilising splenic flexure                         | 01              |
| 6. Pre-sacral venous plexus injury and bleed                                             | 01              |
| 7. Rectal perforation while dividing meso-rectum                                        | 01              |
| 8. Rectal disruption while insertion of stapler                                         | 02              |
| 9. Iatrogenic tumour perforation                                                       | 01              |
| 10. Incidentally detected multiple bulky lateral pelvic lymph nodes                     | 01              |

### Table 5 Histopathologic outcomes

| Variables                                    | Numbers (%) |
|----------------------------------------------|-------------|
| 1. Histopathology                            | n = 178     |
| a. Adenocarcinoma                            | 138 (78.4%) |
| b. Mucinous adenocarcinoma                   | 30 (17.0%)  |
| c. Signet ring adenocarcinoma                | 08 (4.5%)   |
| d. Melanoma                                  | 02 (1.12%)  |
| 2. Grade                                     | n = 176     |
| a. I                                         | 51 (28.7%)  |
| b. II                                        | 87 (48.8%)  |
| c. III                                       | 38 (22.4%)  |
| 3. Pathological T stage                      |             |
| a. pT1                                       | 9 (5.1%)    |
| b. pT2                                       | 63 (35.4%)  |
| c. pT3                                       | 101 (56.7%) |
| d. CPR                                       | 5 (2.8%)    |
| 4. Pathological nodal stage                  |             |
| a. N0                                        | 96 (53.9%)  |
| b. N1                                        | 43 (24.1%)  |
| c. N2                                        | 39 (21.9%)  |
| 5. Distal resection margin status            |             |
| a. Negative                                  | 176 (98.8%) |
| b. Positive                                  | 02 (1.12%)  |
| 6. Mean distal resection margin length       | 2.6 ± 1.8 cms|
| 7. Circumferential resection margin status   |             |
| a. Negative                                  | 166 (93.25%)|
| b. Positive                                  | 12 (6.74%)  |
| 8. Mean number of lymph nodal yield          | 13 ± 5      |

CPR Complete pathological response
The mean time to fist passage of flatus resume to oral liquid intake 2 ± 1 and 1.5 ± 0.5 days, respectively. Median length of hospitalisation was 7 days (range 4–14 days). Further gains in perioperative care and reduced length of stay may be possible by standardization of enhanced recovery after surgery programs. The overall complications (CD grade ≥ 2) reported in the present review is 29.76%. In the present study, major complications requiring radiologic intervention or surgical treatment were included in CD grade IIIa–IIIb. Of the 100 patients with an anastomosis, 8 (8%) cases had a leak. All the 8 cases required interventions as listed in Table 7. ROLARR trial reports overall 30-day complication and anastomotic leak rates of 33.1% and 12.2% respectively.

Although the results of this study are comparable with those of the ROLARR trial, there exist significant differences in the case selection and types of procedures between these two studies.

Our study results are in a good agreement with that reported by ROLARR group in terms of perioperative and pathological outcomes; however, this study has various limitations such as its retrospective nature, lack of data on bladder and sexual function, which may have reflected the quality of rectal dissection.

**Conclusion**

In conclusion, perioperative and pathological outcomes following robotic rectal resection reflect that it is safe, effective and reproducible by a minimally invasive novice surgeon. Careful patient selection, choosing less complex procedures and standardised protocol during the initial cases is of fundamental importance for a surgeon making a transition from open to laparotomy.

**Table 6** Postoperative outcomes and complications

| Parameters | Numbers (%) |
|------------|-------------|
| 1. Mean time to fist passage of flatus (days) | 2 ± 1 |
| 2. Mean time to resume to oral intake of liquids (days) | 1.5 ± 0.5 |
| 3. Mean length of hospital stay (days) | |
| a. APR | 6 ± 2 |
| b. Sphincter preservation R-TME | 8 ± 1 |
| 4. Anastomotic leak rate | 8 (8%) |
| 5. Clavein-Dindo complications | |
| a. Grade I | 125 (70.22%) |
| b. Grade II | 29 (16.29%) |
| c. Grade IIIa | 12 (6.74%) |
| d. Grade IIIb | 10 (5.61%) |
| e. Grade IV | 01 (0.56%) |
| f. Grade V | 01 (0.56%) |

**APR** Abdomino-perineal resection, **R-TME** robotic total mesorectal excision

**Table 7** Interventions for anastomotic leak

| Procedures | Interventions |
|------------|---------------|
| Two cases of low AR without DS | Exploration followed by peritoneal lavage and loop ileostomy |
| Low AR with DS | Laparoscopic peritoneal lavage in view of minimal pelvic confined contamination |
| Two cases with partial coloanal anastomotic dehiscence following ISR | Drainage of the pelvic collection with trans anal repair of the partial anastomotic dehiscence site |
| Low rectovaginal fistula following low AR | Completion APR |
| Two cases of low AR with DS in hemodynamically stable patients | Radiologically guided pigtail drainage of collection |

**AR** Anterior resection, **ISR** intersphincteric resection, **DS** diversion stoma, **APR** abdomino-perineal resection
robotic approach. Future studies are required to determine long-term oncologic and functional outcomes.

**Compliance with Ethical Standards**

**Conflict of Interest**  The authors declare that they have no conflict of interest.

**Ethics Approval**  The study protocol conforms to the ethical guidelines of the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, as revised in Tokyo 2004. No approval of the institutional review committee was needed.

**Consent for Publications**  All authors have consented for publication.

**Consent to Participate**  All patients had consented for the proposed surgery. This is a retrospective analysis of prospectively maintained database which does not necessitate consenting for analysis.

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