

## Short-term clinical outcomes of robot-assisted intersphincteric resection and low rectal resection with double-stapling technique for cancer: a case-matched study

Luca Morelli<sup>1,2</sup> · Simone Guadagni<sup>1</sup> · Gregorio Di Franco<sup>1</sup> · Matteo Palmeri<sup>1</sup> · Giovanni Caprili<sup>1</sup> · Cristiano D'isidoro<sup>1</sup> · Roberta Pisano<sup>1</sup> · Emanuele Marciano<sup>1</sup> · Andrea Moglia<sup>2</sup> · Giulio Di Candio<sup>1</sup> · Franco Mosca<sup>2</sup>

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Dear Editor:

Survival for patients with rectal cancer has been improving with the development of surgical techniques and combined neo-adjuvant therapies. Traditionally, low rectal cancer located less than 5 cm from the anal verge required abdominoperineal resection (APR) with permanent colostomy. The advent of mechanical low-stapling, double-stapling techniques have made low anterior resection (AR) the procedure of choice for the majority of patients with low rectal cancer increasing the frequency of sphincter salvage. However, in some patients, a narrow pelvis and very low tumor site pose limitations to the use of stapled colorectal anastomosis. For such patients, intersphincteric resection (ISR) with coloanal anastomosis as employed by Schiessel in 1994 may be an acceptable alternative. ISR may also be done laparoscopically; however, it was historically associated with a higher functional complication rate than the Knight Griffen technique. The Da Vinci Si HD Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) can render an operation more like an open surgery with all the benefits of laparoscopy, expanding the range of feasibility of minimally invasive surgery. However, the use of robotic-assisted surgery for ISR has been reported in few centers and some surgeons question the value of robotic

assistance to treat patients with low rectal cancer and allows to manage this type of procedures with good functional results. Herein, we present our experience with robotic-assisted ISR with total mesorectal excision (R-ISR-TME) and provide a case control comparison with robotic TME, using the double-stapling technique (R-DS-TME) for low rectal cancer with specific attention to functional and short-term oncologic outcomes.

Between April 2010 and December 2014, 52 patients with histologically proven rectal cancer underwent robot-assisted rectal resection with TME at our General Surgery Unit, including 15 R-ISR-TME (eight males and seven females, mean age 70.1 years, mean body mass index 24.9 kg/m<sup>2</sup>). A control group of 15 patients (eight males and seven females, mean age 69.6 years, mean body mass index 23.1 kg/m<sup>2</sup>) with low rectal tumors (<5 cm from the dentate line) undergoing R-DS-TME was selected by one-to-one case-matched methodology, where each patient undergoing R-ISR-TME was matched with a patient undergoing R-DS-TME according to the following criteria: age, gender, body mass index, American society of Anesthesiologists score, and neo-adjuvant chemo-radiotherapy. Patients with cT3 or node-positive disease (five in each group) received preoperative chemoradiotherapy (capecitabine 825 mg bid plus 50.4 Gy in 28 fractions). The operation was performed 6–8 weeks after the end of the radiation. Exclusion criteria for robotic surgery were preoperative diagnosis of locally advanced malignancy, history of major lower abdominal surgery, and contraindications to anesthesia. Analyzed variables included overall operative time (from creation of pneumoperitoneum to application of dressing), blood loss, length of hospital stay, postoperative complications, number of harvested lymph nodes, margin status, and functional results. Patients received a physical exam and blood tests 1 and 2 weeks and 1 month after discharge. Just before ileostomy

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✉ Matteo Palmeri  
palmeri.matteo@gmail.com

<sup>1</sup> General Surgery Unit, Department of Oncology, Transplantation and New Technologies, University of Pisa, Via Paradisa 2, 56124 Pisa, Italy

<sup>2</sup> EndoCAS (Center for Computer Assisted Surgery), University of Pisa, Pisa, Italy

closure 2 months after surgery, patients were checked for absence of anastomotic dehiscence and stenosis by contrast enema. After stoma closure, patients were seen in the outpatient clinic monthly. The International Index of Erectile Function (IIEF) questionnaire was used to assess male sexual function, and the Female Sexual Function Index (FSFI) questionnaire was used to assess female sexual function. For evaluating urinary tract symptoms and the impact on quality of life, the International Consultation on Incontinence-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) and the International Consultation on Incontinence-Male Lower Urinary Tract Symptoms (ICIQ-MLUTS) questionnaires were used. Fecal incontinence was assessed using the Wexner Continence Grading scale. The defecation quality of life was evaluated based on a modified fecal incontinence quality of life (mFIQL) score in which a single 14-item composite scale was derived from lifestyle, coping, and behavior items. Patients completed the questionnaires regarding their sexual and urinary function before surgery and at 1 month, 6 months, and 1 year after intervention. For fecal continence, the values were checked 2 months after stoma closure and then 1 year after surgery. All patients received an extensive explanation of the procedure and provided informed consent. The study was approved by the Institutional Review Board. Data analysis was performed at the General Surgery Unit, University of Pisa, Pisa, Italy. Analysis was carried out on an intent-to-treat basis. Fisher's exact test was used to define associations between categorical factors and surgical groups. Continuous variables are given as a mean ( $\pm$ standard deviation) and compared using Student's *t* test.  $p < 0.05$  was considered statistically significant. Data were analyzed with SPSS (Statistical Production and Service Solution for Windows, SPSS Inc., Chicago, IL, USA).

The analyses of the data showed similar results for R-ISR-TME and R-DS-TME regarding the operative, pathological and oncologic results. No re-operation or in-hospital mortality was observed. The quality of the mesorectum, according to Quirk's criteria, was "complete" in all cases. Sexual and urinary parameters decreased early after surgery but all of them increased progressively and 1 year after the intervention, all values were comparable to those measured before surgery. Severe sexual or urinary dysfunction after surgery was not observed in any patients. In addition, comparing the two groups, the difference between scores was not statistically significant in all phases. Wexner score was statistically worse in both groups 2 months after stoma closure when compared with the pre-operative status (R-ISR-TME group  $0.8 \pm 0.6$  vs  $8.6 \pm 1.6$ ,  $p < 0.001$ ; R-DS-TME group  $0.9 \pm 0.8$  vs  $7.1 \pm 1.3$ ,  $p < 0.001$ ). The grade of incontinence tended to reduce progressively but remained statistically different 1 year after surgery in both groups ( $0.8 \pm 0.6$  vs  $3 \pm 1.0$ ,  $p = 0.01$  for R-ISR-TME group;  $0.9 \pm 0.8$  vs  $2.2 \pm 1.1$ ,  $p = 0.02$  for R-DS-TME group). As regards the comparison between the two study

groups, the average daily frequency of defecation 2 months after stoma closure was  $3.5 \pm 0.9$  for R-ISR-TME group and  $2.6 \pm 0.5$  for R-DS-TME group ( $p = 0.02$ ) whereas Wexner score was  $8.6 \pm 1.5$  for R-ISR-TME group and  $7.1 \pm 1.3$  for R-DS-TME group ( $p = 0.01$ ). Both parameters, however, were not statistically different 1 year after surgery:  $1.9 \pm 0.9$  in R-ISR-TME group versus  $1.8 \pm 0.3$  in R-DS-TME group for bowel movements ( $p = 0.3$ ) and  $3.0 \pm 1.1$  versus  $2.2 \pm 1.0$  for Wexner score ( $p = 0.2$ ). Thirteen percent of patients (two cases with mean age 82 years) in R-ISR-TME group initially were unable to differentiate between defecation and passing of flatus, their sphincter function improved progressively, and 1 year after surgery, only occasional incontinence of flatus was present. In both patients, neo-adjuvant therapy was administered. No patient suffered from urgency or developed anastomotic stenosis. No difference was measured for R-ISR-TME group at 1 year compared to R-DS-TME group regarding the impact of incontinence symptoms on patients' quality of life. Incontinence quality of life score was  $30.3 \pm 19.1$  in the R-ISR-TME group versus  $27.5 \pm 14.5$  in the R-DS-TME group,  $p = 0.2$ . In a mean follow-up period of  $18.2 \pm 9.4$  months, no local recurrences or peritoneal carcinomatosis were recorded. Two patients (13 %) in the R-DS-TME group developed liver metastasis during the follow-up period. The 2-year overall survival rate was 100 % in both groups ( $p = 0.1$ ). No statistical difference in 2-year disease-free survival was observed in the two groups (100 % R-ISR-TME versus 80 % R-DS-TME;  $p = 0.2$ ).

Despite recent advances in the oncologic treatment of rectal cancer, sexual and urinary dysfunction remain among the major complications of rectal surgery, with implications that impact the quality of life of patients so much that different authors claim they should be considered when deciding the best operative approach. Intersphincteric dissection, which is the last chance of performing sphincter-saving surgery in some cases, remains challenging, especially considering the competing objectives of achieving adequate oncologic clearance and preserving anal sphincter tone. This kind of surgery which is considered at risk of increasing the rate of functional dysfunction (sexual, urinary, and fecal incontinence) make robotic assistance potentially useful. There are few data in the literature about the functional outcomes of robotic surgery in anterior rectal resection and to our knowledge, the present study is the first that compare functional outcomes of R-ISR-TME with R-DS-TME for very low rectal cancer. The ISR technique is considered a surgical procedure to increase both distal clearance and sphincter preservation for patients with low-lying rectal cancer. We compared these two groups because in some instance, the indications for the double-stapling technique in low rectal cancer could be forced, putting the oncological radicality at risk. This is related to the general certainty that ISR increases the risk of autonomic and continence dysfunction. Our preliminary results show that

R-ISR-TME did not differ significantly from R-DS-TME as evidenced by our similar functional results. In fact, we recorded no significant differences in terms of sexual and urinary functions and fecal incontinence in the two groups. Furthermore, there was no significant difference observed in the mFIQL score evaluating the impact of bowel function on quality of life, between the R-ISR-TME and R-DS-TME groups. Another drawback of ISR for very low rectal cancer is local surgical clearance when compared with AR. From an oncologic viewpoint, local control is the most important surgical goal for lower rectal cancer. In our series, pathological results were comparable between the two groups without significant differences in terms of harvested lymph nodes or infiltration of circumferential and distal margins, showing no difference in terms of local surgical radicality. We have also observed good short term oncologic results in the R-ISR-TME and R-DS-TME groups with absence of local recurrence and similar 2-year disease-free survival. Contemporary series have demonstrated similar functional and oncologic results when open ISR is compared with open DS or APR. However, the common concern of surgeons is that minimally invasive ISR exposes patients to a higher risk of autonomic dysfunction compared to the double-stapling technique or a risk of local recurrence especially in very low rectal cancer. Our results suggest, instead, that ISR with robot assistance may obtain similar results as the DS technique.

In conclusion, different surgical techniques can be used for the treatment of low rectal cancer and data from our robot-

assisted experience compare favorably ISR with case-matched stapled anastomosis. We think that when R-DS-TME is at risk of stapling too near or above the tumor because of very low-lying cancer, R-ISR-TME could be performed safely without any significant additional complications or decline in sexual, urinary and continence outcomes even though it is a more complex surgical procedure. The main drawbacks of this study are the small sample involved and the absence of longer follow-up that precludes definitive conclusions. Our initial finding gives useful information regarding the possibility to use an intersphincteric robotic dissection in low rectal tumors without significantly worsening the good results of the low-stapled technique. This consideration enhances the potential role of robot-assisted laparoscopic surgery in low rectal cancer but further studies are needed.

#### Author contributions

Study concept and design were done by Morelli, Guadagni, Di Franco, Palmeri, D'isidoro, Pisano, Caprili, Moglia, Marciano, Di Candio, and Mosca. Acquisition of data was done by Morelli, Guadagni, Pisano, D'isidoro, Caprili, Di Franco, Moglia, Marciano and Palmeri. Analysis and interpretation of data were done by Morelli, Di Candio, and Mosca. Drafting of the manuscript was done by Morelli, Guadagni, and Di Franco. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved was done by Morelli, Di Candio, and Mosca. Final approval of the version to be published was done by Di Candio and Mosca.