Considering value in rectal cancer surgery

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As new surgical technologies are introduced into the market, their cost and overall efficacy must be critically evaluated. One area of ongoing debate is the role of robotic surgery in rectal cancer resection. As it is clear that robotic surgery is becoming increasingly utilized for proctectomy in the US, a better understanding of the potential benefits and limitations is needed. Particularly three areas need to be addressed: (I) short-term oncologic outcomes: quality of TME resection, margin status, lymph node harvest; (II) cost; and (III) long-term oncologic outcomes. In the May 2016 issue of Annals of Surgery (Epub ahead of print), Silva-Velazco et al. have introduced an interesting and unique article titled "Considering value in rectal cancer surgery: an analysis of costs and outcomes based on the open, laparoscopic, and robotic approach for proctectomy" comparing value in open versus laparoscopic versus robotic rectal cancer surgery.

To compare the different approaches to rectal cancer surgery, the authors used a single center prospective database spanning from January 2010 to December 2014. An intent to treat analysis was used: if a minimally invasive surgery was converted to open, the patient remained in the original minimally invasive cohort. A total of 488 patients were included. Demographics between the three groups were similar with the exception of female sex (significantly higher in laparoscopic group) and body mass index (significantly lower in the laparoscopic group). Major comorbidities amongst the groups were similar. Tumor characteristics (pathological and clinical TNM staging, tumor grade, use of neoadjuvant chemoradiotherapy) were similar except for a significantly higher rate of positive lymph nodes on final pathology in the open surgery group. The endpoints evaluated were direct costs of hospitalization for the primary resection, 30-day readmissions, and ileostomy closure. Secondary endpoints were short-term oncologic results, postoperative outcomes, and 30-day perioperative morbidity. To compare cost data, total technical direct cost was collected for all hospitalizations. This cost data includes all costs accrued by the patient from admission to discharge: imaging, anesthesia, medications, OR time, consumable supplies, nursing, diagnostic procedures, laboratory tests, pathology assessment, and all other ancillary services needed during the admission. It does not included surgeon or other physician salaries. Of note, a portion of the total cost of the robot itself was applied evenly to all three patient groups, and no additional fees for robotic surgery were captured.

The first issue addressed when comparing the three groups is short-term oncologic outcomes. To characterize this variable, the authors used four criteria: (I) number of lymph nodes examined; (II) involvement of the distal margin; (III) involvement of the circumferential resection margin (CRM); (IV) mesorectal grading. If the distance between the tumor and the circumferential margin was less than or equal to 1 mm, the margin was considered involved. The authors defined a successful resection as one with a negative CRM, a negative distal margin, and completeness of the total mesorectal excision. When comparing the three groups, there were no significant differences between any of the short-term oncologic outcome parameters. A successful resection was achieved in 83.9% to 89.5% of all cases. This data is compared to a recent national study examining the effects of surgical approach on short-term oncologic outcomes in rectal cancer. Utilizing the 2010 National Cancer Database, Midura et al. analyzed outcomes

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of 8,712 patients undergoing open, laparoscopic, and robotic resections (1). The short-term oncologic outcomes measured were resection margin status and lymph node harvest. Overall, 7% of cases had positive margins, and one-third of cases had an inadequate number of lymph nodes harvested (<12). After propensity score matching analysis, a minimally invasive approach was associated with an improved R0 resection rate, though despite matching, these patients were not randomized, and the distinct possibility of selection bias, where more difficult tumors received open surgery exists. The paper by Silva-Velazco et al. suggests overall higher success in regards to short term surgical outcomes than national data; however, a relatively small sample size and a single-center study can skew these results. Recent randomized clinical trials investigating laparoscopic approach versus open approach in rectal surgery have been published. ACOSOG Z-6051 failed to show non-inferiority of laparoscopic surgery when compared to open surgery regarding a composite oncologic outcome specified as a distal margin without tumor (greater than >1 mm), a circumferential radial margin greater than 1 mm, and the total mesorectal excision quality (complete: smooth surface of mesorectal fascia with all fat contained in the enveloping fascia to a level 5 cm below the tumor for upper rectal cancer or the entire mesorectal envelope for low rectal cancer; nearly complete: the mesorectal envelop was intact except for defects no more than 5 mm deep) (2). Additionally, in the COREAN trial, there was no statistically significant difference in short-term oncologic outcomes between laparoscopic and open surgical approaches following neoadjuvant therapy (3). While there are no large randomized controlled trials published evaluating laparoscopic versus robotic rectal surgery, the ROLARR trial currently underway aims to compare the two. Preliminary data shows no statistically significant difference in conversion to open surgery or completeness of the CRM, though long-term oncologic data have yet to be seen.

The second issue addressed in the paper by Silva-Velazco *et al.* is cost. The authors showed that the overall cost was 31% higher for patients undergoing robotic proctectomy when compared to open surgery. The cost of laparoscopic surgery was only 4% higher when compared to open surgery. This was despite shorter hospital stays and lower rates of complications. Recent literature supports this finding as well. Other studies demonstrate a 32% higher cost associated with robotic surgery when compared to

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laparoscopic surgery (4) and a 59% increase with robotic surgery compared to open surgery (5).

One issue not addressed in this study is long-term oncologic outcomes for rectal surgery. The COREAN study found that there was no significant difference in long term oncologic outcomes (3-year disease free survival) between laparoscopic and open rectal surgery following neoadjuvant therapy (3). Unfortunately, there is no data looking at long term oncologic outcomes following robotic rectal surgery.

Though robotic surgery is being utilized increasingly for rectal cancer, current data shows longer operative times, higher cost and unclear short-term oncologic benefit. The ultimate utility of this technology will be better understood when long-term oncologic outcomes are available.

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