Quality Assessment and Safety Committee

Rectal Cancer Overview

Introduction

Within the field of colon and rectal surgery, no topic is closer to our hearts than the optimal treatment of rectal cancer. In the treatment of rectal cancer, colorectal surgeons exercise the greatest amount of clinical judgment, and work with the broadest range of other medical specialties. It is therefore appropriate that this topic be the first area for review. With this review we cover several important, trending topics in the area of rectal cancer treatment, from the perspective of quality and patient safety.

Rectal Cancer Coordinating Committee

The Rectal Cancer Coordinating Committee (RCCC) of the ASCRS was established to coalesce knowledge and activity regarding ongoing North American rectal cancer initiatives.

A goal of the RCCC is to develop a surgical skills verification module for total mesorectal excision (TME). Within the Commission on Cancer (CoC), an emerging standard is completion of this skills module by surgeons within 3 years. Conor Delaney has been charged with leading the fundamentals of rectal cancer surgery committee to develop this platform. The project is well underway in partnership with Kryterion, the same organization that worked with SAGES in developing the Fundamentals of Endoscopic Surgery course.

Additional information regarding the RCCC can be found online at: https://www.fascrs.org/rectal-cancer-coordinating-committee.

Rectal Cancer Surgery Checklist

Recognizing that the treatment of rectal cancer represents a complex process similar to those in aviation, a recent ASCRS effort has resulted in the development of a checklist-based tool that would be useful for standardizing care. This effort assimilated inputs from medical literature as well as thought leaders within the ASCRS. The final product, the ASCRS Rectal Cancer Surgery checklist, is comprised of 25 items that span the continuum of pre-operative, intra-operative, and post-operative care.
The ASCRS Rectal Cancer Surgery checklist is available for download from the ASCRS website (https://www.fascrs.org/sites/default/files/downloads/publication/best_practices_checklist_for_rectal_cancer_final.pdf). Additionally, the checklist is slated for publication in Diseases of the Colon and Rectum. The checklist is designed to be a living document and will reflect changes in care over time. Suggestions for improvements or changes to the checklist are welcome. Member input will be reviewed bi-annually by the QASC and published to the website.

Recent Evidence: Laparoscopic vs. Open Rectal Cancer Surgery

Two recently published randomized controlled trials published in the Journal of the American Medical Association in October 2015 compared laparoscopic-assisted versus open resection of rectal cancer. The ACOSOG Z6051 trial (conducted in the United States and Canada) randomized stage II-III rectal cancers within 12 cm from the anal verge after completion of neoadjuvant therapy.[3] In contrast, the ALaCaRT trial (conducted in Australia and New Zealand) included stage I-III rectal cancers within 15cm of the anal verge, and the decision to complete neoadjuvant chemoradiation was based on patient and surgeon preference.[4]

Both trials had criteria for surgeon credentialing in order to ensure high quality surgery by experienced laparoscopic surgeons. The two trials analyzed a similar set of oncologic outcomes, including circumferential radial margin (>1mm), clear distal margin (>1mm), and complete total mesorectal excision. Also, a composite outcome encompassing whether or not an operation achieved all of these individual oncologic outcomes was analyzed.

Rates of post-operative complications were similar between laparoscopic and open approaches in both of these trials. A comparison of oncologic outcomes experienced by patients treated in these two trials is shown in the table below. For each of the individual oncologic outcomes, as well as the composite outcome, rates of surgical success were statistically similar between the two approaches. However, both trials failed to establish non-inferiority between laparoscopic-assisted and open resection of rectal cancer – as a result, both studies concluded that routine use of laparoscopic surgery cannot be routinely recommended.

	ACOSOG Z6051		**ALaCaRT**	
Negative Circumferential Radial Margin	87.9% lap 92.3% open	p 0.11	93% lap 97% open	p 0.06
Negative Distal Margin	98.3% open 98.2% lap	p 0.91	99% lap 99% open	p 0.67
Complete Total Mesorectal Excision	92.1% open 95.1% lap	p 0.20	87% lap 92% open	p 0.06
Successful Resection (based on composite pathologic outcomes)	81.7% lap 86.9% open	p 0.41	82% lap 89% open	p 0.38

What does non-inferiority mean? Why are the outcomes of laparoscopic vs. open approaches in these trials considered different when the results are statistically similar? A comprehensive description of what is meant by a non-inferiority trial can be found here.[4] Simply stated, the threshold for determining inferiority is lower (more relaxed) than the standard threshold for determining statistical significance ($p < 0.05$).

What do these trials mean for the future of laparoscopic rectal cancer surgery? Evaluation of longer-term outcomes such as local recurrence and survival are needed to determine if the laparoscopic and open techniques are oncologically equivalent for treatment of rectal cancer. The results and interpretations of these trials are highly controversial, and this controversy highlights the importance of standardizing and analyzing the quality of surgical care for patients with rectal cancer.

References

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2. Rickles AS, Dietz DW, Chang GJ, et al. High Rate of Positive Circumferential Resection Margins Following Rectal Cancer Surgery: A Call to Action. *Ann Surg* 2015; 262(6):891-8.
3. Fleshman J, Branda M, Sargent DJ, et al. Effect of Laparoscopic-Assisted Resection vs Open Resection of Stage II or III Rectal Cancer on Pathologic Outcomes: The ACOSOG Z6051 Randomized Clinical Trial. *JAMA* 2015; 314(13):1346-55.
4. Stevenson AR, Solomon MJ, Lumley JW, et al. Effect of Laparoscopic-Assisted Resection vs Open Resection on Pathological Outcomes in Rectal Cancer: The ALaCaRT Randomized Clinical Trial. *JAMA* 2015; 314(13):1356-63.