

Randomized Clinical Trials in Colon and Rectal Cancer

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KEYWORDS

- Colon cancer • Rectal cancer • Colorectal cancer • Surgery • Radiation
- Chemotherapy • Adjuvant • Neoadjuvant

KEY POINTS

- Surgery remains the mainstay of curative treatment for both colon and rectal cancers.
- Colon cancer outcomes have improved with the use of laparoscopic techniques, enhanced recovery pathways, and adjuvant chemotherapy.
- Multimodality management of rectal cancer continues to evolve with total mesorectal excision being the cornerstone.
- Oncologic results from recent studies do not support the use of laparoscopic resection in patients with rectal cancer.
- Preoperative radiation for stage II or III rectal cancer has less toxicity than postoperative treatment. Long course chemoradiation offers greater tumor downstaging and improved local control.

COLON CANCER

Surgical Approach and Techniques

The feasibility of laparoscopic surgery was highlighted by more than 24 randomized, controlled trials (RCTs) including 5 level I RCTs in the previous review with mostly consistent results.¹ Only the UK CLASICC trial (Conventional Versus Laparoscopic-assisted Surgery in Patients with Colorectal Cancer), which included patients with rectal cancer, noted an insignificantly increased rate of positive circumferential margins in the laparoscopic cohort without an increase in long-term tumor recurrence.² Since the last review, 14 additional RCTs and metaanalyses on laparoscopic surgery for colon cancer have confirmed the short-term benefits and oncologic noninferiority to the open approach. This includes a metaanalysis (including 23 RCTs and 20

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systematic reviews for RCTs)³ and the Australasian Laparoscopic Colon Cancer Study Trial.⁴ In total, laparoscopic surgery compared with open surgery had been shown to be technically feasible with multiple short-term benefits (less blood loss, less narcotics use, earlier return of bowel function, and decreased duration of hospital stay), similar or noninferior oncologic outcomes (lymph node retrieval, margins, overall survival [OS], disease-free survival [DFS]), and lower rates of incisional hernia and adhesive small bowel obstruction. As such, laparoscopic colectomy for colon cancer should currently be considered an acceptable alternative to an open resection in the hands of experienced surgeons. Only 1 RCT has investigated a robotic approach compared with laparoscopic colectomy for right-sided tumors with the robotic approach providing few benefits (similar pain, hospital stay, complication rates, and pathologic outcomes) to justify the greater cost and longer duration.⁵ Thus, the robotic approach does not currently have RCT data to justify use over laparoscopic surgery.

Historical RCTs¹ have demonstrated no oncologic benefit with the no-touch technique, high ligation of the inferior mesenteric artery and an increased radiologically detected leak rate with hand-sewn compared with stapled anastomosis.¹ Since the last review, an RCT compared iso-versus antiperistaltic stapled side-to-side anastomosis (SSSA) and showed no significant difference in outcomes, but was suspended after detecting increased morbidity in the isoperistaltic SSSA group (which had the only two anastomotic leaks).⁶ An RCT demonstrated no difference in terms of infection rates between subcuticular and interrupted suture closure of clean-contaminated wounds after colon cancer resection.⁷ Specimen extraction through the anus versus mini-laparotomy showed no significant difference in terms of operative time, blood loss or length of hospital stay with the exception of less postoperative pain and no infections in the former group.⁸

Endoscopic Stent for Colonic Obstruction

For the purposes of this review, we will focus on the role of colonic stents (SEMS) in avoiding surgery at the time of emergent bowel obstruction. The majority of literature on this subject is nonrandomized with very few RCTs and conflicting results. A systematic review of uncontrolled trials and case reports on SEMS revealed a clinical success rate of 72% when used as bridge to surgery and uncommon major complications.⁹ These results were not supported by the first RCT on this topic (Stent-In 2 trial) which revealed stent-related perforations in 13%–23% of patients and a higher risk of cancer recurrence if a perforation occurred.¹⁰ This raised long-term oncologic apprehension, but a metaanalysis of four RCT's and seven subsequent RCTs suggested similar cumulative mortality rates after stenting as a bridge to surgery versus surgery alone.¹¹ Interestingly, while overall stoma rates differed significantly in favor of SEMS, the permanent stoma rates were similar.

Based on the available RCT data, the use of SEMS is associated with a higher rate of a successful primary anastomosis, lower rate of short-term colostomy requirement and avoids the need for a second procedure for colostomy reversal. The length of stay for SEMS placement and elective surgery (within 1–2 weeks) is also shorter than that for emergency surgery. This makes SEMS an attractive option despite the higher than anticipated perforation rate, noting that OS is not negatively impacted.

Primary Tumor Resection in Setting of Metastatic Disease

Current guidelines limit primary tumor resection (PTR) in the presence of metastatic disease (mCRC) to symptomatic patients, which is supported by literature. However, the role of PTR in asymptomatic patients to avoid future symptoms or improve survival is controversial. No RCTs have currently addressed this topic but two trials are

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