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Editorial

State of the Art in Rectal Cancer Surgery: Historical Overview and New Perspectives After the COLOR II Trial*



Avances en cirugía del cáncer de recto: recorrido histórico y nuevas perspectivas después del estudio COLOR II

Rectal cancer treatment has significantly changed during the past two centuries. Development of new surgical techniques and introduction of (neo) adjuvant therapies have contributed to the improved prognosis of rectal cancer and reduced morbidity rates. The first technically successful excision of rectal cancer was performed by LisFranc in 1826. It was a primitive procedure without anesthesia or hemostasis and the patient did not survive.1 In those days operative mortality rates of 20% and local recurrence rates of 80% were reported.² In 1908 Miles published the concept of cylindrical lymphatic spread of cancer cells. He recommended more extensive mesenteric lymphadenectomy combined with resection of the anus and rectum in order to prevent recurrence.3 With the introduction of this radical 'abdominoperineal resection' (APR), Miles established the basis for modern rectal cancer surgery. Because the APR resulted in creation of a permanent colostomy, considered a great disadvantage for the patients, halfway through the twentieth century the focus shifted toward sphincter-sparing procedures and the 'anterior resection' (AR) became the standard treatment for mid and high rectal cancer. Subsequently, in the 1970s the restoration of bowel continuity after AR was introduced.4 In order to decrease anastomotic leakage rates and pelvic sepsis, adjustments were made such as creation of a colonic J-pouch anastomosis or diverting ileostomy. However, both the APR and AR included blunt dissection of the rectum along the presacral fascia with a cone-wise development of the most distal part of the rectum. This blunt technique resulted in high rates of involved circumferential resection margins (CRMs), which predisposes to local recurrence, and local recurrence rates up to 40% were reported. 5 In 1982 Heald et al. introduced

the technique of total mesorectal excision (TME), in which sharp excision of the complete mesorectum en bloc with the tumor to the level of the levator muscles was performed following the anatomical planes. This more extensive excision resulted in significant decrease of involved CRMs and decreased local recurrence rates to 3.7% at 5-years postoperatively.6 In the 1980s it was hypothesized that less surgical trauma would not only improve postoperative recovery, moreover it would result in less tumor recurrence and therefore improved survival. Following laparoscopic resection of the gallbladder and appendix, laparoscopic colorectal surgery was first described by Jacobs et al.8 For colon cancer, evidence was obtained that laparoscopic surgery was safe, causing less postoperative pain, shorter hospital stay, and resulting in comparable survival rates compared with open colectomy. 9,10 However, rectal cancer surgery is considered technically more challenging than colon surgery, mainly because of the limited workspace in the lower pelvis and fibrosis of the tissue as a result of neoadjuvant radiotherapy.

Recent studies showed improved short-term outcomes as well as comparable oncological outcomes after laparoscopic TME for rectal cancer compared with open TME. 11,12 However, these studies included small numbers of patients. The largest randomized trial comparing laparoscopic and traditional open resection for rectal cancer is the COLOR II trial. It was undertaken in 30 hospitals in 8 countries and 1044 patients were included. Short-term outcomes showed less blood loss, less pain and shorter hospital stay after laparoscopic resection with comparable quality of the resected specimen as in open surgery. 13 Recently, the COLOR II study group published their long-term outcomes and reported that laparoscopic surgery

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for rectal cancer resulted in similar rates of local recurrence and disease-free and overall survival compared with open surgery. 14 However, patients were included over a period of 6 years (2004–2010) and analysis of the long-term endpoints (including the primary endpoint) could at the earliest be performed 3 years after the inclusion of the last patient. The interval between commencement of randomized clinical trials accruing high numbers of patients and reporting long-term outcomes lasts in most instances approximately a decade. Within that time frame, management protocols in health care frequently change and are implemented in the care of those patients involved in the clinical trial rendering interpretation of some outcomes more complex. Furthermore, a major challenge in surgical cancer clinical trials is lack of consistency in surgical quality. Even though centers had to submit five unedited recordings of laparoscopic TME before entering the COLOR II trial, learning curve evaluation and quality assessment during the trial was not performed.

Although laparoscopic rectal cancer surgery has gained popularity over the past decade, there is potential for improvement with respect to reduction in incomplete resections, morbidity, and sphincter-saving procedures. In distal rectal tumors, mobilization of the rectum below the tumor can be difficult, due to the coning of the pelvis, and leading to unradical resection. Involvement of the CRM is reported in 3%-16% of the patients after rectal carcinoma resection. 11-13 In order to achieve clear CRMs, the surgeon might choose to perform an APR, which is performed in approximately 25%-30% of rectal resections. 11,13 Both un-radical resection and APR cause higher morbidity, which is reported up to 40%. 13 Because of the limited workspace in the pelvis, rectal resection with TME is probably more suitable for laparoscopic than for open resection. But especially in obese male patients and patients with bulky tumors resection of lower rectal cancers remains difficult.

The transanal TME (TaTME) has been introduced in 2009 by Lacy et al. In TaTME, the tumor is approached through the anus, giving better visualization and facilitating the mobilization of the distal rectum including its mesorectum. ¹⁵ Therefore, even in low rectal cancer a coloanal anastomosis can be created and the resection can be more radical.

Currently, several cohort series have been published showing rates of involved CRMs of 0%-5.4% and comparable short-term outcomes as traditional laparoscopic rectal cancer resection. 16-19 The transanal laparoscopic 'bottomup' TME appears a promising technique requiring evaluation in a randomized clinical trial. To the best of our knowledge, no randomized trials have been started. The COLOR II study group is preparing a proposal for a large international randomized trial comparing transanal TME and laparoscopic TME for mid and low rectal cancer. The trial will be named COLOR III trial and has an expected start in 2015. International collaboration is mandatory to reduce completion times of large randomized trials and is essential for the COLOR III trial. Furthermore, this study aims at addressing the limitation of evaluation of the surgical quality by applying a robust surgical quality assurance protocol prior to the start and throughout the clinical trial to ensure consistency and validity.

What if the TaTME proves to be better than laparoscopic surgery for rectal cancer? Will there be no place for the 'traditional' laparoscopic resection in the treatment of rectal cancer? As mentioned before, TaTME provides the most benefit in distal rectal tumors. For proximal rectal tumors, the laparoscopic resection is still the gold standard. However, laparoscopic rectal resection remains technically challenging and should only be performed in centers with experienced laparoscopic colorectal surgeons after sufficient training.

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