

Laparoscopic extraperitoneal rectal cancer surgery: the clinical practice guidelines of the European Association for Endoscopic Surgery (EAES)

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Abstract

Background The laparoscopic approach is increasingly applied in colorectal surgery. Although laparoscopic surgery in colon cancer has been proved to be safe and feasible with equivalent long-term oncological outcome compared to open surgery, safety and long-term oncological outcome of laparoscopic surgery for rectal cancer remain controversial. Laparoscopic rectal cancer surgery might be efficacious, but indications and limitations are not clearly defined. Therefore, the European Association for Endoscopic Surgery (EAES) has developed this clinical practice guideline.

Methods An international expert panel was invited to appraise the current literature and to develop evidence-based

recommendations. The expert panel constituted for a consensus development conference in May 2010. Thereafter, the recommendations were presented at the annual congress of the EAES in Geneva in June 2010 in a plenary session. A second consensus process (Delphi process) of the recommendations with the explanatory text was necessary due to the changes after the consensus conference.

Results Laparoscopic surgery for extraperitoneal (mid- and low-) rectal cancer is feasible and widely accepted. The laparoscopic approach must offer the same quality of surgical specimen as in open surgery. Short-term outcomes such as bowel function, surgical-site infections, pain and hospital stay are slightly improved with the laparoscopic approach. Laparoscopic resection of rectal cancer is not

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inferior to the open in terms of disease-free survival, overall survival or local recurrence. Laparoscopic pelvic dissection may impair genitourinary and sexual function after rectal resection, like in open surgery.

Conclusions Laparoscopic surgery for mid- and low-rectal cancer can be recommended under optimal conditions. Still, most level 1 evidence is for colon cancer surgery rather than rectal cancer. Upcoming results from large randomised trials are awaited to strengthen the evidence for improved short-term results and equal long-term results in comparison with the open approach.

Keywords Guidelines · Laparoscopy · Minimally invasive surgery · Rectal cancer

The incidence of fatal cases of colorectal cancer in Europe exceeds 200,000 per year. According to European registries, rectal cancer has prevalence of more than 50 per 100,000 (women and men) and accounts for almost 40% of all colorectal cancer cases [1, 2]. Despite ongoing efforts in screening and improvements in multimodal therapy, colorectal cancer is still one of the leading causes of cancer mortality. Especially local recurrence is a major problem in locally advanced rectal cancer. Surgery remains the mainstay of therapy, with a standardized and quality-controlled technique, i.e. total mesorectal excision (TME). Pioneers have shown feasibility of laparoscopic resection of rectal cancer, leading to a surge of this approach in recent years. Although the laparoscopic approach in colon cancer has been proved to be safe and feasible with equivalent long-term oncological outcome compared to open surgery [3–5], safety of laparoscopic surgery for rectal cancer remains debatable. Laparoscopic resection of rectal cancer might be efficacious, but this, as well as morbidity and oncological outcome, need to be demonstrated. The European Association for Endoscopic Surgery (EAES) therefore perceived the need to hold a consensus development conference (CDC) on laparoscopic extraperitoneal rectal cancer surgery and thence provide clinical practice guidelines.

Methods

The EAES scientific committee commissioned the planning group in Cologne to take over the organisation of the guideline development and to undertake a systematic literature search.

Selection of topics and experts

An international expert panel was invited to appraise the current literature and to develop evidence-based

recommendations. An expert panel constituted for a consensus development conference (CDC) in May 2010 consisted of surgeons, oncologists, radiotherapist and research scientists. Experts were selected according to their scientific and clinical expertise as well as geographical location.

The key topics were formulated, consented and adopted by the guideline development group. For every key topic a coordinator was nominated, being responsible for literature appraisal and evidence synthesis for the assigned topic. Three or four selected subgroup members supported the coordinator.

Literature searches and appraisal

A systematic literature search was conducted in the electronic databases MEDLINE (Pubmed) and Cochrane Library for the years 2000–2010 (for some research questions also from 1990 to 2010) to identify clinical studies on endoscopic rectal cancer surgery with focus on randomised controlled trials and systematic reviews. Searches were carried out using medical subject headings (MeSH) and free-text words. The search was limited to studies published in English or German language.

The results of the literature search were sent to the expert panel for assessment of relevance for the clinical practice guidelines (CPG) and critical appraisal.

According to the hierarchy of research evidence [6], we tried to locate randomised controlled trials (RCT, level 1b) or systematic reviews (SR, level 1a) dealing with the key questions. When RCTs were of low quality or completely lacking, non-randomised controlled clinical trials (CCT, level 2) were included. Whenever evidence classified as level 1 or level 2 was scarce, case–control studies or case series (level 3 or level 4) were included.

Formulating recommendations and consensus process

All recommendations were graded according to the quality and quantity of the underlying scientific evidence, the risk–benefit balance and the values expressed by the panellists. The grades of recommendations ranged from A (high-quality evidence, usually from RCTs, demonstrating clear benefits) over B (medium-quality evidence and/or disputable risk–benefit ratio) to C (low-quality evidence and/or unclear risks and benefits). In case of limited or lacking data to support a recommendation the panel decided that the grade of recommendation (GoR) could be higher than the evidence in usual cases would allow. Furthermore, for some recommendations there was a need to modulate and weigh the evidence locally according to value judgements, priorities and local conditions [7].

Based on the identified studies the subgroups formulated draft recommendations. The recommendations were discussed

and consented in a consensus conference and thereafter presented at the annual congress of the EAES in Geneva, June 17, 2010 in a 90-min plenary session by members of the panel. Notes were taken from the audience after a lively discussion and considered in the further process. A second consensus process (Delphi process) of the recommendations with the explanatory text was necessary due to the changes after the consensus conference. After two Delphi rounds, consensus or strong consensus was reached for the majority of recommendations [8].

Classification of consensus

Strength of consensus	Percentage of agreement
Strong consensus	>95% of participants
Consensus	75–95% of participants
Majority	50–75% of participants
No consensus	<50% of participants

After final consensus of the recommendations a guideline draft for each topic was written by the subgroups of the expert panel. The manuscripts were collected and completed to a full guideline draft. Finally, the full guideline was consented and adopted by the expert panel. The results are given in the text below.

Recommendations

Tumour diagnosis and staging

Tumour biopsy with histopathological processing must be conducted prior to start of treatment. (100% [Strong consensus]; GoR A: 100% [Strong consensus])

Rectal cancer is diagnosed on the histopathological result of tumour biopsy. In presence of high clinical suspicion (and previous negative biopsy results) core biopsy under general anaesthesia is recommended. Benign pathology may not exclude further surgery in individual cases. Radio- and/or chemotherapy will not start without confirmed pathology.

Preoperative (and pretherapeutic) staging for precise localisation of the tumour must include digital examination and rigid rectoscopy. (100% [Strong consensus]; GoR A: 100% [Strong consensus])

Digital rectal examination (DRE) will allow the assessment of tumours within the lower third of the rectum and should be clinically staged according to Mason [9]. DRE is important to evaluate the function of the sphincter and the distance to the anorectal ring in order to evaluate

the possibility of doing a sphincter-preserving procedure. Rigid rectoscopy provides a more correct determination of tumour localisation than flexible colonoscopy [10], with an accurate assessment of the distance between the distal edge of the tumour and the dentate line, or alternatively the anal verge.

Assessment of tumour infiltration and local lymph nodes (TN-staging) must be performed prior to any treatment. Endorectal ultrasound and high-resolution magnetic resonance imaging are recommended. (92.9% [Consensus]; GoR A: 92.9% [Consensus])

Depth of invasion and lymph node involvement are both important factors for prognosis. In addition, involvement of the mesorectal fascia and tumour invasion of the mesorectal vessels predicts high risk of local recurrence and poor survival [11]. Decision on therapy, especially preoperative treatment, is dependent on accurate tumour staging.

Tumour T- and N-stage are reliably assessed by both endorectal ultrasound (EUS) and high-resolution magnetic resonance imaging (MRI). Both EUS and MRI have high sensitivity for evaluating T-stage. EUS is superior in discrimination of T1 and T2 tumours, and MRI better to evaluate involvement of the mesorectal fascia. Sensitivity for lymph node involvement is lower, but neither of the modalities is significantly superior to the other [12]. A meta-analysis comparing the accuracy of EUS, MRI and computed tomography (CT) was published in 2004 and included 90 studies between 1985 and 2002 [13]. The results demonstrated that EUS and MRI had similar sensitivities for muscularis propria invasion (94%), but specificity of EUS (86%) was significantly higher than that of MR imaging (69%). Identification and accurate assessment of lymph nodes remains a major challenge. In the meta-analysis, sensitivity estimates for EUS, CT and MR imaging were comparably low (EUS 67%, MRI 66% and CT 55%); specificity values were also comparable (78% for EUS, 76% for MRI and 74% for CT). An advantage of MRI is the ability to delineate the tumour and its relationship to the mesorectal fascia. High-resolution MRI predicted mesorectal fascia involvement with 92% agreement [14]. According to the results of the prospective MECURY trial, high-resolution MRI has sensitivity of 94% and specificity of 92% for predicting negative circumferential margins (CRM) after surgery [15]. MRI has been shown to be superior compared with CT in local staging of rectal cancer and prediction of mesorectal fascia involvement (MFR) [16].

In conclusion, EUS is most suitable for evaluating early rectal cancer. MRI is recommended in locally advanced rectal tumours, especially to assess mesorectal fascia involvement. The limitations of EUS are a high degree of user dependence and no assessment of stenotic tumours.

Adequate pretreatment staging must include CT of the abdomen and chest X-ray to identify metastatic disease. (83.3% [Consensus]; GoR A: 85.7% [Consensus])

Complete staging in patients appropriate for resection (and neoadjuvant therapy) must include physical examination with assessment of performance status, and assessment of the liver and lungs to rule out metastatic disease. Chest X-ray (or alternatively CT scan) and CT of the liver and abdomen (or alternatively MRI or ultrasound) should be performed [17].

Routine use of positron emission tomography (PET) or PET-CT is not indicated unless there is suspicion of synchronous metastatic disease.

(Comment: All panel members recommend assessment of liver and lungs to identify metastatic disease. A majority of the panel favoured the above recommendation including CT of the abdomen instead of ultrasound only for an adequate staging.)

Complete colonoscopy is required to rule out synchronous tumours or other pathologic conditions of colon or rectum. (78.6% [Consensus]; GoR A: 85.7% [Consensus])

Pretreatment work-up should include complete colonoscopy to rule out synchronous adenomas and tumours. Synchronous tumours are expected in up to 4% of all patients presenting with colorectal cancer [18, 19]. Alternatively radiological imaging (e.g. CT colonography or barium enema) can be applied when endoscopy is technically not feasible or tumour stenosis does not allow complete colonoscopy [20, 21]. In these cases colonoscopy should be performed 3–6 months after surgery.

Pretreatment determination of the tumour marker carcinoembryonic antigen (CEA) should be considered. (92.9% [Consensus]; GoR B/C: at 50% [Majority])

According to the American Society of Clinical Oncology (ASCO) 2006 Update of Recommendation for the Use of Tumor Markers in Gastrointestinal Cancer as well as the European Group on Tumour Markers, CEA testing should be ordered preoperatively in patients with rectal cancer. CEA should not be used as a screening test [22, 23]. In rectal as well as in combined colon and rectal cancer population, CEA is an independent prognostic parameter [24, 25]. CEA determination is important as a baseline for postoperative surveillance. Especially an elevated preoperative CEA suggests that the marker would be useful for surveillance. Elevated preoperative CEA will not alter initial treatment strategy or surgical therapy of the primary tumour.

Patient selection and neoadjuvant therapy

There is no indication for preoperative treatment in International Union against Cancer (UICC) stage I tumours. (92.9% [Consensus]; GoR A: 92.9% [Consensus])

Outside clinical trials, preoperative treatment in UICC stage I tumours is restricted to very selective individual cases. Organ preservation in ultra-low tumours may be one option.

Neoadjuvant therapy should be provided for patients staged UICC II and III. (92.9% [Consensus]; GoR B: 85.7% [Consensus])

Preoperative (instead of postoperative) regimen should be considered in UICC stage II and III rectal cancer. Either combined chemoradiotherapy (CRT) or short-course radiotherapy (scRT) can be used. The main consideration for choosing either of these two options is dependent upon the preoperative MRI staging. If the mesorectal fascia is involved (MRF+), a downsizing effect is important, in which case either CRT or scRT with delayed surgery can be recommended. If the tumour is not at risk of being resected with a positive resection margin, but there is an estimated risk of developing local recurrence, again either of the two schedules can be used [26].

After the endorsement of postoperative adjuvant CRT by a National Cancer Institute consensus conference in 1990, several randomised studies reported lower rates of local failure with preoperative radiotherapy than with surgery alone [27–29]. In addition, a Swedish trial could demonstrate a long-lasting benefit in overall survival compared with surgery alone [30]. After the wide adoption of the concept of total mesorectal excision (TME) as the surgical standard, improvement in local control and survival has been achieved with surgery alone [31]. One of the few studies evaluating preoperative therapy together with documented quality-controlled TME surgery is the Dutch Colorectal Cancer Group study. Preoperative scRT with TME was superior to TME alone in terms of local recurrence, whereas overall survival was similar in the two groups [28, 32]. A Medical Research Council (MRC) trial including 1,350 patients demonstrated a significant reduction of local recurrence in patients receiving preoperative scRT compared with initial surgery with selective postoperative radiochemotherapy (4.4% versus 10.6% after 3 years). In addition, a relative improvement in disease-free survival has been shown, whereas overall survival did not differ between the groups [33]. A number of randomised trials demonstrated the effectiveness of CRT (either post- or preoperatively). To our knowledge, there has been no prospective study comparing preoperative CRT with quality-controlled TME surgery alone. Two trials have compared preoperative treatment with postoperative one. The Uppsala trial demonstrated superiority in reduction of local recurrence rate with scRT versus postoperative long-course irradiation [34]. Moreover, the German Rectal Cancer Study demonstrated the superiority of the neoadjuvant approach over postoperative treatment. Preoperative

therapy was associated with a significant reduction in local recurrence and treatment-associated toxicity [35].

Both preoperative scRT and neoadjuvant CRT provide increased local control of rectal cancer. Still, there is much debate in Europe about the two different approaches. The results from the small study of the Polish Colorectal Study Group comparing scRT and CRT showed no evidence of a difference in the rates of sphincter-preserving surgery or local recurrence, however this study was not statistically powered to address local recurrence [36]. Outcome data from an Australian trial as well as a recently closed German trial comparing both preoperative treatment strategies are still awaited, but preliminary data indicate similar results to the Polish trial [37, 38].

Patients with T4-staged disease where downsizing is an issue should be treated with preoperative combined radiochemotherapy.

Standard preoperative CRT combines radiation with a dose of 46–50.4 Gy with 5-fluorouracil (5-FU) chemotherapy given either as bolus injections with Leucovorin, prolonged continuous infusion (likely better than bolus) or oral capecitabine [39–41]. Combined CRT is followed by TME surgery 6–8 weeks later.

Preoperative scRT consists of single doses of 5.0 Gy in five fractions within 1 week up to a total dose of 25 Gy. TME surgery should be performed within 10 days from start of radiotherapy [42]. If this schedule is not possible to follow, surgery should be postponed to 8 weeks later [43].

Besides oncological limitations, there are no contraindications for laparoscopic surgery compared with open surgery. Morbid obesity or cardiopulmonary impairment is not a contraindication to laparoscopic rectal cancer surgery but may require additional perioperative evaluation and monitoring. (92.9% [Consensus]; GoR B: 92.9% [Consensus])

The panel refers to the previous EAES clinical practice guidelines on laparoscopic resection of colonic cancer (2004, update 2006) and on pneumoperitoneum for laparoscopic surgery (2002, update 2006) [44].

Perioperative management

Explicit data on bowel preparation before laparoscopic TME—either in favour or against—do not exist. (100% [Strong consensus]; GoR C: 100% [Strong consensus])

For colon cancer, there is some evidence that bowel preparation does not reduce complications (e.g. anastomotic leakage, surgical-site infections etc.) In addition, there is a trend for increased complications for patients undergoing bowel preparation [45–47]. The largest meta-analysis, including almost 5,000 patients, demonstrated with a high level of evidence that all kinds of mechanical

bowel preparation should be omitted before colonic surgery [46].

For rectal cancer alone, explicit data do not exist. However, in any case after low anterior resection where a deviating stoma is performed, bowel preparation seems to be a logical prerequisite. The necessity of a protective stoma in patients undergoing low anterior resection with TME is still discussed. A randomised controlled trial conducted by Ulrich et al. evaluated the need for diverting ileostomy in those patients. Even if the number of patients included in this study was quite small, they could demonstrate a significantly higher number of symptomatic anastomotic leakages in the non-stoma group compared with the stoma group [48]. The results of a larger randomised trial by Matthiesen et al. strongly support a diverting stoma after low anterior resection [49]. As there are many more arguments in favour of a deviating stoma after low rectal resection in open surgery, bowel preparation can be considered in these cases.

However, data from a subgroup analysis of a large multicentre trial did not show an influence of bowel preparation for cancer of the mid rectum [50]. These data are supported by Bretagnol, even if not significant [51].

Epidural catheter can be considered for pain management. (100% [Strong consensus]; GoR C: 100% [Strong consensus])

For open colon surgery, there is quite some evidence in favour of epidural analgesia, but for the laparoscopic approach it is still discussed [52]. Use of epidural or i.v. patient-controlled analgesia (PCA) has been extensively investigated in open surgery, but there is a paucity of data comparing the various analgesic regimes available in laparoscopic surgery. The enhanced recovery program (ERP) has increasingly been used for laparoscopic surgery in its unmodified form with thoracic epidural. While some centres are using this modality, other units are using PCA, and alternative forms of postoperative pain control are being investigated. Results of a systematic review have highlighted the relative lack of evidence comparing outcomes between differing analgesic regimes. At present, there is no convincing evidence to suggest the superiority of either PCA or epidural in terms of length of hospital stay for laparoscopic colorectal surgery. In the short term, no significant difference has been identified in terms of adverse events, although postoperative pain appears better controlled in the epidural group [53].

See also www.postoppain.org, and the PROSPECT study group.

Opioid-like drugs should be avoided. (100% [Strong consensus]; GoR B: 100% [Strong consensus])

While opioids still remain the mainstay for postoperative analgesia worldwide, their use can be associated with adverse effects, including ileus, which can prolong hospital

stay. A number of studies have investigated the use of non-opioid-like analgesics and regimens. A systematic review by McCarthy et al. determined the overall efficacy of different analgesic regimens on postoperative analgesia and recovery from surgery in patients undergoing various surgical procedures. Relevant data such as return of bowel function, length of hospital stay, intraoperative anaesthetic requirement and adverse effects were also compared. Patients receiving non-opioid-like drugs had more rapid return to normal bowel function and decreased length of hospital stay. Thus, opioid-like drugs, even if highly efficient in pain control, should be avoided due to their negative effect on bowel function [54, 55].

Currently, there are no evidence-based recommendations for a distinct perioperative volume management. “Fast-track” concepts should be considered. (100% [Strong consensus]; GoR C: 85.7% [Consensus])

The main goal of perioperative volume management is to keep homeostasis normal. Although the ideal volume and content of solutions for perioperative intravenous infusion are still unknown, there is evidence that excessive intravenous fluid administration in the perioperative phase has a negative impact on postoperative outcome [56–59]. According to the meta-analysis of Rahbari et al., restrictive rather than standard fluid amount reduces morbidity after colorectal resection [60].

Patients undergoing rectal surgery must receive antibiotic prophylaxis. The antibiotic must be administered before surgery (single dose) and should cover against both aerobic and anaerobic bacteria. (100% [Strong consensus]; GoR A: 100% [Strong consensus])

Research shows that administration of prophylactic antibiotics before colorectal surgery reduces the risk of postoperative surgical wound infection (SWI). The best antibiotic choice, timing of administration and route of administration remain undetermined [61]. The Cochrane review by Nelson et al., including 182 trials (30,880 participants) and 50 different antibiotics, demonstrated a statistically significant difference in postoperative SWI when prophylactic antibiotics were compared with placebo/no treatment [relative risk (RR) 0.30, 95% confidence interval (CI) 0.22–0.41]. No statistically significant differences were shown when comparing short- and long-term duration of prophylaxis (RR 1.06, 95% CI 0.89–1.27), or single-dose versus multiple-dose antibiotics (RR 1.17, 95% CI 0.67–2.05). Additional aerobic coverage and additional anaerobic coverage both showed statistically significant improvements in SWI rates (RR 0.41, 95% CI 0.23–0.71 and RR 0.55, 95% CI 0.35–0.85, respectively), as did combined oral and intravenous antibiotic prophylaxis when compared with intravenous alone (RR 0.55, 95% CI 0.41–0.74) or oral alone (RR 0.34, 95% CI 0.13–0.87). Established gold-standard regimens were no less effective

than any other antibiotic choice. Therefore, antibiotics covering aerobic and anaerobic bacteria must be delivered orally and/or intravenously prior to colorectal surgery, and one dose is sufficient [61].

Currently, there are no evidence-based recommendations for a distinct postoperative diet. “Fast-track” concepts should be considered. (100% [Strong consensus]; GoR C: 92.9% [Consensus])

Several randomised, controlled trials showed that early oral/enteral feeding at will did not increase morbidity and did reduce length of stay (LOS). Nausea and vomiting can be more frequent but do not lead to increased morbidity as well [62, 63].

See also the *Consensus Review of Optimal Perioperative Care in Colorectal Surgery* [64].

Operative techniques

Patient must be well fixed and placed in lithotomy position with legs in padded, adjustable stirrups. (92.9% [Consensus]; GoR A: 85.7% [Consensus])

Patient should be placed in modified lithotomy position. The legs are placed in padded, adjustable stirrups. The thighs have to be at the level of the abdominal wall with the knees slightly flexed. Higher elevation may cause difficulties in manoeuvring instruments. The patient is positioned so that the perineum is reachable from between the legs. This allows the surgeon free access to the anus and rectum for intraoperative endoscopy, pelvic manipulation, perineal resection or transanal anastomosis. These are sound principles based on experience, although not tested by randomised trial.

It is important to place the patient carefully on the operating room (OR) table, fixed according to local regulations and in such a way that introduction of the circular stapler through the anus can be safely performed.

Operating table has to be capable of steep Trendelenburg and reverse Trendelenburg positions and right and left rotation. (100% [Strong consensus]; GoR A: 85.7% [Consensus])

Again there is no evidence from any randomised trial; the recommendation is based on the experience of the panel. The Trendelenburg position is used to keep the small bowel out of the operating field during the procedure. Both arms are tucked, padded and protected along the patient's side.

A catheter is introduced into the bladder. (85.7% [Consensus]; GoR A: 78.6% [Consensus])

As an alternative to transurethral catheterization, suprapubic catheterization may be used. There is no evidence that one is better than the other [65].

Positioning of the surgeon and assistants as well as trocar position are based on the experience and the

preference of the individual surgeon. (100% [Strong consensus]; GoR C: 100% [Strong consensus])

The most commonly used OR setting is a set of two monitors; one is placed at the level of the patient's left shoulder and the other at the left foot level of the patient. The surgeon and the first assistant stand at the patient's right side, and the nurse is positioned between the patient's legs. A second assistant stands at the left side of the patient.

After insufflation, four or five ports are used: one for the laparoscope, held by the first assistant; two for the operating surgeon, introduced in the right lower abdomen for instruments and endo-staplers. The fourth port is introduced left laterally at the level of the umbilicus, and a fifth trocar will be introduced in the left upper abdomen to mobilize the splenic flexure. During dissection of the rectum deep in the pelvis, another trocar may be introduced above the pubis to assist the anterior aspect of dissection.

There is no clear recommendation for a distinct device, whether bipolar or ultrasonic. Ultrasonic and advanced bipolar devices as well as surgical stapling devices may reduce blood loss and shorten operating time. (100% [Strong consensus]; GoRA: 85.7% [Consensus])

Dissection may be performed by means of electrocautery, ultrasonic scalpel or bipolar electrothermal device.

Most data are derived from laparoscopic colon surgery, where it has been shown that high-energy power sources specifically adapted for endoscopic surgery reduce operative time and blood loss [66–69]. These data can be transferred to laparoscopic rectal cancer surgery. Morino et al. conducted a prospective randomised trial in patients undergoing laparoscopic colorectal surgery, comparing ultrasonic dissection (UC) with standard electrocautery. Forty of 146 randomised patients underwent low anterior resection. Operative time was less with UC, but did not differ significantly between the two groups, whereas intraoperative blood loss was significantly less with UC [70]. Zhou et al. studied 40 patients with rectal cancer scheduled for TME, randomly divided into ultrasonic scalpel or monopolar electrocautery shovel (ES). This study showed no significant difference in blood loss, but ES may generate heavy smog. Furthermore, ES can produce a higher surface temperature when managing tissues [71].

In all cases of low anterior resection the splenic flexure should be mobilized. (78.6% [Consensus]; GoR B: 71.4% [Majority])

This is a general rule, but in selected cases, the length of the sigmoid loop will influence the choice. A long loop may in some cases preclude mobilization. The splenic flexure should be mobilized when needed to ensure a tension-free anastomosis. Experience suggests that this is better done at the beginning of the operation; before dissection of the rectum, the left mesocolon and the sigmoid mesocolon are dissected from medial to lateral, starting

behind the inferior mesenteric vein. The underlying retroperitoneal structures, including gonadal vessels, left ureter and Gerota's fascia, are left in place. Dissection is continued orally up to the pancreas into the lesser sac and laterally along the fascia of Toldt on to the peritoneal attachments of the left colon. After dividing the inferior mesenteric vein under the pancreas and the inferior mesenteric artery (IMA), complete mobilization is achieved by lateral dissection and mobilization of the splenic flexure and the descending colon and freeing the greater omentum from the transverse colon. Dissection will proceed with medial dissection of distal sigmoid and rectum [2–15].

Unexpected locally advanced tumour (T4) should lead to conversion. (100% [Strong consensus]; GoRB: 85.7% [Consensus])

As in open surgery, oncological principles (resection margins, high vessels ligation, lymphadenectomy etc.) should be respected by the laparoscopic approach. (92.9% [Consensus]; GoRB: 92.9% [Consensus])

The main goal is a tumour-free margin. Whenever possible a free margin should be obtained. (92.9% [Consensus]; GoRB: 85.7% [Consensus])

Pelvic dissection and rectal mobilization must be performed according to TME principles. (100% [Strong consensus]; GoRA: 92.1% [Consensus])

These are universally accepted oncological statements and are common sense for both open and laparoscopic surgery [72–74]. T4 tumours have been excluded from all randomised studies in laparoscopic colon and rectal cancer surgery. In individual cases it may be possible to proceed with the laparoscopic approach, e.g. in limited T4 situation where en bloc resection with small bowel or tangential/partial resection of the bladder will allow safe resection with free margins.

From medial to lateral, the rectum is dissected free on its right side and posteriorly as far as possible. The pelvic autonomic nerve plexus, the superior hypogastric sympathetic nerves are carefully dissected from the mesorectum and preserved. Anteriorly, dissection will start at the level of the seminal vesicles in the male patient or recto-vaginal septum in the female patient, usually after traction of the uterus by a percutaneously introduced needle.

Pelvic dissection proceeds, according to TME principles, alternating posterior, lateral left and right and anterior dissection, along the seminal vesicles, Denonvillier fascia and the prostate in the male or along the recto-vaginal septum in the female patient. It is important is to preserve the parasympathetic sacral nerve roots from S2 to S4. Dissection proceeds down to the pelvic floor [75–88].

If the tumour is located in the midrectum, the rectum should be transected at the level of the pelvic floor followed by a double-stapling anastomosis. (100% [Strong consensus]; GoRB: 100% [Strong consensus])

The rectum is transected at the level of the pelvic floor by means of a roticulating endostapler device [75–88], using as few cartridges as possible. Use of more than two cartridges has been reported to result in a higher anastomotic leakage rate [89, 90]. After rectal division, usually a port site in the right lower abdomen is extended to 5–7 cm, and adequately protected to deliver the specimen. Alternatively, a small Pfannenstiel incision is used. Once the specimen is exteriorised, division of the remaining mesentery and the marginal artery are completed and the anvil inserted. After closure of the wound or temporary closure of the protection device, pneumoperitoneum is re-established and a double-stapling anastomosis accomplished (after introduction of the stapler device transanally). Control of the anastomosis should always be performed by either endoscopy, methylene blue or instillation of air under saline solution. The presacral space should be drained [91] and a protective stoma created [92].

The difficulty of performing the transection is still a point of concern. Some authors argue that it is always possible to transect the rectum at this level, independently of the angle of the rectum and the abdominal wall. Eventually introduction of the endostapler through a suprapubic trocar may help to do this adequately at this level [79]. In a narrow male pelvis with a reasonably big tumour located in the mid or proximal low rectum, this action may be difficult to accomplish. Difficulties in achieving this are variable, being related to high body mass index (BMI), tumour size, distance from the anal verge and characteristics of the pelvic outlet. These factors may be considered to be related to anastomotic leakage and morbidity [93, 94]. Moreover, some authors argue that an optimal perpendicular transection of the rectum during laparoscopic TME is impossible or very demanding to achieve with the available 45° angulation roticulating stapling devices and that the optimal angulation for this ideal transverse transection will vary between 62 and 68° [95]. Some surgeons will, to achieve this at the proper place, prefer to palpate the tumour before transection. They will prefer at this stage to make a Pfannenstiel incision and to apply manually the conventional roticulator-contour device properly below the tumour [26]. Double-stapling anastomosis will be done as mentioned above. Use of a small Pfannenstiel incision to perform the anastomosis at this stage should not be considered as conversion [96, 97].

Laparoscopic intracorporeal dissection means that the dissection, the division of the vessels, the transection of the rectum and the anastomosis must be performed laparoscopically. (85.7% [Consensus]; GoR A: 85.7% [Consensus])

Intracorporeal dissection means that the dissection, the division of the vessels, the transection of the rectum and the anastomosis are all performed laparoscopically. If dissection of the rectum has to be completed through a

wide Pfannenstiel incision, this is considered conversion to laparotomy. Once dissection is completed laparoscopically, use of a small Pfannenstiel incision for performing the anastomosis is not considered as conversion.

Dissection is mostly performed medial to lateral. Dissection may be performed by means of electrocautery, ultrasonic scalpel or bipolar electrothermal device. After visualization of the left ureter, the IMA is dissected free and is divided between clips, endostapler or sealing device at high or low tie level. Low tie level will permit preservation of the left colonic artery and better protection of the hypogastric plexus on the aorta [71, 75–88].

For this laparoscopic procedure, there are alternatives such as hand-assisted ultra-low resection [98] one hand-size incision surgery [99] and robot-assisted rectum laparoscopic resection [100–102].

Some authors have used intraoperative radiotherapy during the laparoscopic TME in order to reduce the local recurrence rate in locally advanced rectal cancer [103]. Furthermore in cases of difficult dissection in which conversion is considered necessary, laparoscopic mobilization of the splenic flexure followed by rectal dissection through a Pfannenstiel incision will reduce operative trauma and decrease morbidity [104].

All these variations must be regarded as experimental and cannot be recommended until further evidence.

A continent patient with low rectal cancer, 3–4 cm from anal verge, with no infiltration into the pelvic floor and external sphincter can be approached by transanal intersphincteric dissection and coloanal anastomosis. (100% [Strong consensus]; GoR C: 100% [Strong consensus])

In a patient with incontinence a low Hartmann procedure should be considered. (100% [Strong consensus]; GoR C: 92.9% [Consensus])

In very distal rectal cancer, e.g. 3–4 cm from anal verge, with no in-growth of tumour in the pelvic floor or external sphincter and with good continence grade, a coloanal anastomosis should be considered. In this case, dissection of the rectum will be continued through the pelvic floor to reach the level of the sphincters [78, 84, 85].

Considering a low Hartman procedure in patients pre-operatively not continent for stool is a sound concept, although no studies investigating this subject exist [105].

Transanal intersphincteric dissection should be performed proximal from the dentate line and below the tumour. (92.9% [Consensus]; GoR B: 85.7% [Consensus])

Dissection should be performed proximal from the dentate line and below the tumour. Using the anal Scott spreading device (lone star) the anus and distal rectum are exposed, and the rectum transected proximal to the dentate line after intersphincteric dissection. The specimen can be retrieved through a small Pfannenstiel incision or through the anus, and an end-to-side or J pouch anastomosis is

performed [74, 85, 106, 107]. The presacral space should be drained and a defunctioning loop ileostomy created to protect the anastomosis [91, 92].

No recommendation concerning the construction of a colonic pouch can be made. There are no specific data for laparoscopic surgery. In open surgery the use of a colonic pouch guarantees better function in the first 12–18 months and in the long term. (92.9% [Consensus]; GoR C: 92.9% [Consensus])

Controversy exists about the type of anastomosis to use in low anterior resection and coloanal anastomosis: straight anastomosis, J pouch anastomosis, transverse coloplasty or end-to-side anastomosis [106–111]. One review concludes that probably end-to-side anastomosis will result in the same functional quality of life as pouch anastomosis [109].

The advantages of the construction of a colonic pouch after rectal resection in the laparoscopic setting should be the same as in open surgery. Construction of a pouch in the laparoscopic setting seems not to be more difficult than in open surgery [108].

Concerning a deviating stoma there are no specific data for laparoscopic surgery. In open surgery a deviating stoma reduces the rate of symptomatic leakage/fistula. (78.6% [Consensus]; GoR B: 85.7% [Consensus])

Data from open rectal cancer surgery demonstrate that a deviating stoma reduces the rate of symptomatic leakage/fistula. Metanalysis and review of currently published studies show the advantages of the ileostomy [48]. A large Swedish randomised trial showed a reduction in leak rate in patients with stoma and a better long-term outcome [49]. Therefore, a deviating stoma is recommended when performing TME in rectal cancer surgery. These data should be extrapolated to laparoscopic surgery. In laparoscopic surgery, results of comparative trials in similar clinical situation show a reduction in the intensity of peritonitis when the anastomosis is diverted or not [112]. Especially after neoadjuvant chemoradiotherapy a stoma (ileostomy or colostomy) is advisable in laparoscopic rectal cancer surgery.

Very low rectal cancer, with infiltration into the external sphincter or pelvic floor, should be treated by APR. (85.7% [Consensus]; GoR B: 92.9% [Consensus])

Classical APR implies a laparoscopic mobilization of the rectum followed by perineal resection in lithotomy position. Prone position for the perineal cylindrical excision is proposed. (85.7% [Consensus]; GoR C: 92.9% [Consensus])

Mobilization of the rectum by laparoscopy has to be performed as deep as possible in the pelvic floor, to a level where there is no risk of compromising the surgical plane [113–118].

There are two different approaches for the perineal phase: the classical perineal resection between the legs in

lithotomy position, and the extralevator perineal resection performed in prone position [119]. During the first approach the perineal excision is performed, the specimen resected and retrieved (waist model), presacral space drained and wound approximated in layers, whereas in the extralevator excision the resected specimen has cylindrical shape. It is currently suggested that R0 resections and circumferential resection margins (CRM) involvement are improved in the extralevator resection [120].

The defect after perineal excision can be approximated, whereas after extralevator dissection it can be closed by means of a muscular flap. (92.9% [Consensus]; GoR C: 92.9% [Consensus])

In lithotomy position, closure methods to occlude the pelvis can include the use of the greater omentum, closure of the peritoneum or leaving the peritoneum and the pelvis open. To close a huge perineal defect after extralevator excision, reconstruction of pelvic floor will be accomplished by means of unilateral or bilateral m. gluteus maximus flap reconstruction, a vertical m. rectus abdominis flap or a transverse m. rectus abdominis flap [121]. Other possibilities of reconstruction such as use of prosthetic materials are considered as exceptional and routinely not recommended.

Quality and outcome analysis

Laparoscopic approach for curative rectal cancer must offer the same quality of the surgical specimen as in open surgery. Pathology analysis must include assessment of the following: completeness of the mesorectum, CRM, distal margin and number of lymph nodes. (100% [Strong consensus]; GoR A: 92.9% [Strong consensus])

Laparoscopic approach to TME is not inferior to the open in terms of disease-free survival (DFS), overall survival (OS) or local recurrence. (92.9% [Consensus]; GoR B: 85.7% [Consensus])

The final goal in rectal cancer surgery using total mesorectal excision is to reduce the incidence of local recurrence to a minimum rate. Current results of multiple single-centre and multicentre experiences in open surgery established a recurrence rate below 5–7% [32, 35]. The initial results obtained from single-centre experiences show the ability of laparoscopic approach to obtain mesorectal specimens that achieve the standards of pathology quality and a local recurrence rate below 6%. In a recent study analysing the Spanish registry of rectal cancer there were no differences in the quality of the mesorectum between the open and the laparoscopic approach. Six hundred four patients operated between 2006 and 2008 (209 laparoscopic and 395 open) were included. This study did not show differences in the number of lymph nodes retrieved, status of the CRM or in the quality of the mesorectum

(complete 77%, nearly complete 15%, incomplete 8%). However, the shortcomings of this study are diverse: it is a voluntary registry, not randomised and obviously selected, with more difficult cases included in the open group [122]. In a recent single-center prospective randomised trial Lujan et al. could not find any differences in the quality of the mesorectum or in the rates of local recurrence [88]. However, these trials still have the drawbacks of selection bias, and this topic should be analysed carefully in multi-center prospective randomised trials that would permit to demonstrate the safety of the laparoscopic approach to low rectal cancer.

The laparoscopic approach permits to obtain similar long-term outcome, in terms of disease-free or overall survival, as in open surgery. Table 1 presents the long-term outcome from the most important series observed up to now, showing DFS, OS and local recurrence similar to open surgery. Recently, Laurent et al. [123] presented outcome data from a comparative study including 500 patients (Tables 1, 2). The main results of this study were the absence of differences in relation to local recurrence (LR) and DFS. Additionally this study reported that the type of approach did not influence the cancer outcome, as well as that the conversion (36/238, 15%) did not have a negative impact on postoperative mortality, local recurrence or survival [123].

Laparoscopic resection is slightly superior to open in terms of short-term outcome (reduced hospital stay, improved bowel function and reduced pain). (92.9% [Consensus]; GoR B: 85.7% [Consensus])

Initial results show that laparoscopic approach to rectal cancer is followed by the accepted advantages of endoscopic surgery in terms of less pain, faster recovery and better immediate outcome compared with open cases. Breukink et al. [124] published in 2006 a metaanalysis of 48 studies including 4,224 cases. The quality of the trials included in this metaanalysis were diverse [3 grade 1b (individual randomised trial), 12 grade 2b (individual cohort study), 5 grade 3b (individual case–control study)

and 28 grade 4 (case series)]. This meta-analysis did not show differences in DFS, LR, mortality, morbidity, leakage, CRM or number of lymph nodes. Laparoscopic TME was associated with less blood loss, faster return to normal diet, less pain, less narcotic use and less immune response. On the other hand the laparoscopic approach was followed by longer operative time and higher costs. The conclusion of this analysis was that the laparoscopic approach appeared to have clinically short-term advantages in patients with primary resectable rectal cancer. The long-term impact on oncological endpoints awaits the findings from large ongoing randomised trials. Table 2 reports the results of the more important series published.

Laparoscopic resection is superior to open in terms of reduced surgical-site infections. (92.9% [Consensus]; GoR B: 85.7% [Consensus])

Two recent studies [125, 126] have shown the definitive advantage of laparoscopic approach in terms of incidence and severity of postoperative surgical-site infection (SSI). Varela et al. [125] have recently observed in a large cohort of patients [laparoscopic ($n = 94,665$) or open ($n = 36,965$) appendectomy, cholecystectomy, antireflux surgery or gastric bypass between 2004 and 2008]. Overall, the incidence of SSI was significantly lower in laparoscopic (483 of 94,665, 0.5%) than in open (669 of 36,965, 1.8%) surgery ($p < 0.01$). The study permits to conclude that patients treated with laparoscopic procedures are less likely to experience SSI. After stratification by severity of illness, admission status and wound classification, laparoscopic techniques showed a protective effect against SSI. In another recent study [126] Dobson et al. analysed the need for emergency department evaluation, hospital readmission and re-operation after colorectal surgery in 603 laparoscopic versus 2,246 open patients prospectively recorded. Although SSI was identified in 5.8% of the laparoscopic group and 4.8% in the open group, emergency department evaluation for infection was needed in only 24% of the laparoscopic patients versus 42% in open surgery. Also hospital readmission (1% laparoscopic versus

Table 1 Laparoscopic rectal cancer surgery, long-term oncological outcome: follow-up, 5-year overall survival (OS), 5-year disease-free survival (DFS), local recurrence (LR) and type of study with level of evidence (LoE)

	<i>N</i>	Follow-up (months)	5-Year OS (%)	5-Year DFS (%)	LR (%)	Type of study	LoE
Anthuber [152] 2003	101	17	–	–	2	Individual cohort study	2b
Morino [78] 2003	70	45.7	74	63	4.2	Case series	4
Leroy [80] 2004	98	36	65	75	6	Case series	4
Tsang [153] 2006	105	26.9	76.9	64.4	8.9	Case series	4
Agha [154] 2008	225	46.4	69.2	85.7	5.8	Case series	4
Laurent [123] 2009	238/233	52	83/72	82/79	3.9/5.5	Individual case–control study	3b
Laparoscopy/Open							

Table 2 Laparoscopic rectal cancer surgery, short-term outcomes: operating time (OP-time), conversion rate, hospital stay, mortality, morbidity and type of study with level of evidence (LoE)

	N	OP-time (min)	Conversion (%)	Hospital stay (days)	Mortality (%)	Morbidity (%)	Type of study	LoE
Quah [151] 2002 Laparoscopy/Open	86/84	–	12	–	–	–	RCT	1b
Anthuber [152] 2003 Laparoscopy/Open	101/334	218/219	10.9	14.4/19.9	0/1.5	30.7/65	Individual cohort study	2b
Morino [78] 2003	100	250	12	16.6	2	36	Case series	4
Rullier [111] 2003	32	420	9.3	9	3.1	31.2	Individual cohort study	2b
Leroy [80] 2004	102	202	3	11.9	2	27	Case series	4
Tsang [153] 2006	105	170	1.9	10.1	0	24.7	Case series	4
Agha [154] 2008	225	217	10.2	13.8	1.3	35.6	Case series	4
Laurent [123] 2009 Laparoscopy/Open	238/233	–	15.1	9/16	0.8/2.6	32/37.7	Individual case–control study	3b

52% open) and re-operation (0% laparoscopic versus 12% open) were both significantly less common and permitted to conclude that laparoscopic colorectal surgery patients experienced less severe morbidity when they developed SSI and required fewer healthcare resources to manage their wounds compared with open colorectal surgery patients.

Postoperative morbidity rate after laparoscopic approach to the rectum seems to be similar/slightly lower than after open surgery. (85.7% [Consensus]; GoR B: 85.7% [Consensus])

Postoperative morbidity after laparoscopic approach to the rectum seems to be similar/slightly lower than after open surgery. This issue cannot be definitively assessed until the results of large multicenter RCT are available. A cautionary note should be commented in relation to the anastomotic leak rate, in relation to the difficulty observed for low rectal transection in the obese or in those with a narrow pelvis space. As commented before, surgical-site infections are expected to be lower when the laparoscopic approach is used.

The laparoscopic approach permits to obtain a similar sphincter-preservation rate, without impact on the number of definitive stoma. (92.9% [Consensus]; GoR B: 85.7% [Consensus])

The lack of adequately powered RCT does not permit to definitively conclude whether the laparoscopic approach to rectal cancer is associated with a similar rate of sphincter preservation or definitive stoma. Preliminary results from single series and RCT do not show any differences regarding the rate of definitive stoma, and due to the better visualization of the deep pelvis, the number of sphincter preservations may be increased.

There are no definitive data in relation of quality of life (QoL) after laparoscopic surgery of the rectum; however, data extrapolated from trials including rectosigmoid

resection seem to confer a slight short-term improvement of QoL after laparoscopic surgery. (92.9% [Consensus])

It is well established that, after colorectal laparoscopic surgery, immediate QoL is superior to that after open surgery [127–129]. This advantage may be extrapolated to low rectal cancer cases, mainly because some of these trials included rectosigmoid resections, but there are no data available in relation to rectal surgery. A logical inference is to assume that this improvement could be extrapolated to rectal surgery, but in this situation, the most detrimental to QoL are the existence of a stoma or poor anorectal function, aspects that are not related intrinsically to the laparoscopic approach. For all these reasons, further specific information regarding this clinical point is necessary.

Anorectal function has a similar outcome after laparoscopic and open surgery. Laparoscopic pelvic dissection may impair genitourinary function after rectal resection, like open surgery. Sexual function is a point of concern. (92.9% [Consensus])

Pelvic exploration is improved by the laparoscopic approach due to better visualization of the structures, but identification of the tiny nervous structures especially in the lower pelvis continues to be hazardous. On the other hand the need for retraction as well as energy sources used in laparoscopic surgery may impair/cause injury to deep pelvic structures. Laparoscopic pelvic dissection may impair bladder function after rectal resection, like in open surgery. Sexual function is a point of concern, and several studies have shown detrimental effects on postoperative sexual function, but without a clear consensus (Table 3).

There is a lack of information in relation to anorectal function after laparoscopic dissection of the rectum. Anorectal function is severely impaired by previous radiotherapy, but the laparoscopic approach does not seem to impair/improve this function. Further studies focussed on

Table 3 Laparoscopic rectal cancer surgery, post-operative urinary and sexual function: year of publication, type of study and level of evidence (LoE)

	Year of publication	Urinary function	Sexual function	Type of study	LoE
Quah [151]	2002	No significant deterioration	Impaired in male, but not in female	RCT	1b
Laparoscopy/ Open		No differences lap versus open	Subgroup of sexually active male significantly impaired in lap versus open		
Jayne [155]	2005	Bladder dysfunction (global) in 35%	Impaired	RCT	1b
Laparoscopy/ Open		No differences lap versus open	In male, overall sexual function + erectile function tended to be worse in lap versus open		
Liang [156]	2007	Voiding function—71.6% good, 23% fair, 5.4% poor	Female—53.6% good, 14.3% fair, 32.1% poor Male-ejaculation/potency—56.3/62.5% good, 18.7/14.3% fair, 25/21.9% poor	Case series	4
Breukink [157]	2008	Quality of life due to urinary symptoms significantly decreased With regard to specific symptoms, only frequency significantly worsened	No significant differences except of intercourse satisfaction	Case series	4
Asoglu [158]	2009	No differences	Significantly higher rate of sexual dysfunction in open versus lap (in both female and male)	Individual cohort study	2b
Laparoscopy/ Open					
Morino [159]	2009	No significant differences, except for a postoperative weak stream	Sexual desire was maintained by 55.6%, ability to engage in intercourse by 57.8%, and ability to achieve orgasm and ejaculation by 37.8% of the male patients	Case series	4

these important items are needed to identify the possible detrimental factors of the laparoscopic approach.

Direct costs after laparoscopic surgery of the rectum are similar or slightly higher than after open surgery. (85.7% [Consensus])

The scarce data from different studies show uniformly that costs of the laparoscopic approach are higher than after open surgery [130–134]. Arteaga [135] showed an increase in OR costs that balanced with a shorter hospital stay to make total hospital costs similar. All health economy analyses must be used with care, as differences in national health systems and reimbursement systems differ widely. In many systems the direct costs in OR can rarely be compensated in another budget.

Special and new surgical techniques

TEM and transanal local excision

Patients with T1 cancer and favourable histological features may undergo local excision alone. (85.7% [Consensus]; GoR B: 78.6% [Consensus])

When local excision is indicated, transanal endoscopic microsurgery (TEM) is the preferred technique. (92.9% [Consensus]; GoR B: 79.6% [Consensus])

Patient selection is the most important factor in successful local excision; however, specific criteria for

selecting patients have not been universally accepted. Local treatment of rectal cancer aims to decrease the morbidity and the functional sequelae associated with radical surgery without compromising local tumour control and long-term survival.

Patients with localised superficial tumour (uT1, uN0) may undergo local excision alone. Other additional criteria are tumour size less than 4 cm and well- or moderately well-differentiated histology. The probability of lymph node metastases for a T1 G1 (well-differentiated) tumour is around 0% compared with more than 10% for a T1 G3 (poorly differentiated) tumour [136].

Full-thickness excision of the tumour with lateral margin of 1 cm and clear margin to the perirectal tissue without tumour fragmentation is essential. This approach allows accurate assessment of histopathological parameters such as margin, differentiation, vascular involvement and depth of penetration [137, 138].

When a local excision is indicated, the minimally invasive endoscopic technique transanal endoscopic microsurgery (TEM) is the preferred technique. Gerhard Bueß originally developed TEM in the 1980s [139, 140]. Conventional transanal excision is mostly limited to low rectal lesions, whereas TEM is preferably used for lesions in the middle and upper third of the rectum that are inaccessible by conventional transanal excision. TEM has been proved to be safe and effective in several case series

[141, 142]. Although the evidence regarding TEM is limited, it does appear to result in fewer recurrences compared with conventional transanal excision [143, 144].

NOTES and single port

No recommendations were established at the consensus conference considering natural orifice transluminal endoscopic surgery (NOTES) and single-incision laparoscopic surgery (SILS). No available data with regard to SILS and NOTES on rectal cancer exist. (100% [Strong consensus])

According to the EAES recommendations on methodology of innovation management in endoscopic surgery, feasibility and preclinical safety must be established before innovations such as NOTES and SILS become subject of clinical research [145].

Within the last years, significant research efforts have focussed on developing safe and reproducible transluminal endoscopic approaches to perform various intra-abdominal procedures [146]. Recently a first clinical case of NOTES transanal resection for rectal cancer using TEM and laparoscopic assistance has been reported [147]. Improvements in NOTES instrumentation and careful patient selection may allow further clinical application within controlled clinical trials to evaluate safety and outcome of this approach.

Conclusions

Laparoscopic surgery for middle and low rectal cancer can be recommended under optimal conditions (expert surgeons, expert centres, selected patients, excluding T4). (85.7% [Consensus]; GoR B: 85.7% [Consensus])

The vast majority of the panel would recommend the laparoscopic approach for rectal cancer surgery. Still, upcoming results from large randomised trials are awaited to strengthen the evidence for improved short-term results and equal long-term results in comparison with open surgery.

After the recommendations above were presented, data from two randomised controlled trials have been published [148, 149]. These results strengthen our recommendations by confirming the safety of the laparoscopic approach and providing evidence for no difference in long-term outcome.

In July 2010, Kang et al. published the short-term outcomes of the comparison of open versus laparoscopic surgery for mid and low rectal cancer after neoadjuvant chemoradiotherapy (COREAN) trial, a randomised controlled, multicentre study. Analysis of the criteria associated with long-term oncological outcome such as quality of TME, CRM positivity and number of lymph nodes showed very good results similar to open surgery (incomplete TME in 4.7% of laparoscopic cases versus 6.5% in open surgery,

positive CRM of 2.9% in the laparoscopic group versus 4.1% in the open group, and median 17 lymph nodes versus 18). Furthermore, the authors report a very low conversion rate of 1.2% and confirmed the known recovery benefits of the laparoscopic approach such as fewer wound complications, less pain and better recovery of intestinal function. These results show that excellent outcomes can be achieved by the laparoscopic approach in expert hands [148].

The 5-year analyses of the Medical Research Council CLASICC trial of laparoscopically assisted versus open surgery for colorectal cancer were published online in July 2010. There was no difference in OS or DFS for patients with rectal cancer with respect to the randomised procedure. For rectal cancer, the 5-year OS rate was 52.9% for open versus 60.3% for laparoscopic surgery; the 5-year DFS rate was 52.1% for open versus 53.2% for laparoscopic surgery. In patients undergoing anterior resection, the previously reported differences in CRM positivity rates did not translate into a difference in the 5-year local recurrence rate: 7.6% for open versus 9.4% for laparoscopic surgery ($p = 0.740$) [149].

Recently, the COLOR II trial comparing laparoscopic and open rectal cancer surgery within a multicentre and multinational setting completed inclusion of more than 1,100 patients. When the panel members demonstrated the first consensus on these recommendations at the 18th International Congress of the EAES in Geneva, Jaap Bonjer presented the first data of the COLOR II trial after recruitment was closed some days before. As of May 2010, 1,103 patients with rectal cancer have been randomised in 30 sites in 8 countries. Valid short-term results from this trial should be released soon, whereas long-term results may be available in some years only [97, 150].

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