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The Korean Rectal Cancer Multidisciplinary Committee Clinical Practice Guidelines for Rectal Cancer version 2.0

Hyo Seon Ryu[1], Hyun Jung Kim[2,3], Dong Hyun Kang[4], Yoo-Kang Kwak[5], Han Deok Kwak[6], Yoon-Hye Kwon[7], Dalyong Kim[8], Baek-Hui Kim[9], Jae Hyun Kim[10], Ji Hun Kim[11], Jin Won Kim[12], Tae Hyung Kim[13], Hae Young Kim[14], Soo Min Nam[15], Gyoung Tae Noh[16], Jun Woo Bong[17], Nak Song Sung[18], Seon Hui Shin[19], Kil-Yong Lee[20], Sung Chul Lee[21], Sea-Won Lee[22], Jung Won Lee[23], Jong Min Lee[24], Myung Hoon Ihn[25], Joo Han Lim[26], Woong Bae Ji[27], Dae Hee Pyo[28], Young Ki Hong[29], Jung-Myun Kwak[1]; on behalf of the Korean Rectal Cancer Multidisciplinary (KRCM) Committee

Full list of author information is available at the end of the article.

Rectal cancer, which accounts for approximately 40% of colorectal cancers, remains a major clinical concern. Recent advances in diagnostic imaging, surgical techniques, radiotherapy, and systemic treatment have steadily improved rectal cancer outcomes. Considering this, the Korean Rectal Cancer Multidisciplinary (KRCM) Committee has aimed to provide clinicians and policymakers with up-to-date, evidence-based clinical practice guidelines to support optimal decision-making, reflecting current evidence, the Korean healthcare context, and patient values and preferences. The Clinical Practice Guidelines for Rectal Cancer version 2.0 were developed through multidisciplinary collaboration with related academic societies, building upon and updating the KRCM Clinical Practice Guidelines version 1.0 (titled "Multidisciplinary guidelines for the management of rectal cancer"). These consensus guidelines of the KRCM were established based on a comprehensive literature review, evidence synthesis, with recommendation development guided by the GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology, and consideration of applicability in real-world clinical practice under the national health insurance system. Each recommendation has been presented with its strength and level of evidence.

Keywords: Rectal neoplasms; Diagnosis; Neoadjuvant therapy; Surgery; Clinical practice guidelines

INTRODUCTION

Colorectal cancer is a common malignancy in Korea, accounting for approximately 12% of all newly diagnosed cancers, with rectal cancer constituting 40% of these cases [1]. A marginal decline in rectal cancer incidence has been observed in recent years; however, its early onset in patients aged <50 years continues to rise, highlighting the need for improved screening and treatment strategies in younger populations [2]. The 5-year relative survival rate of colorectal cancer in Korea has markedly improved, from 54%

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Correspondence to: Jung-Myun Kwak, MD, PhD
Division of Colon and Rectal Surgery, Department of Surgery, Korea University Anam Hospital, Korea University College of Medicine, 73 Goryeodae-ro, Seongbuk-gu, Seoul 02841, Korea
Email: jmkwak@korea.ac.kr

in the early 2000s to 74% in recent years [1]. However, survival outcomes differ widely by stage, and 20% to 35% of patients with stage II or III locally advanced disease experience recurrence or distant metastasis after surgery, underlining the need for more intensive treatment strategies [3].

Imaging, pathology, surgical techniques, chemotherapy, and radiotherapy have witnessed considerable advances in recent years. Total neoadjuvant therapy (TNT) has reshaped the treatment paradigm for locally advanced rectal cancer (LARC) by improving tumor downstaging and pathologic complete response (pCR) while reducing recurrence [4]. Furthermore, the remarkable efficacy of immunotherapy for microsatellite instability-high (MSI-H)/mismatch repair-deficient (dMMR) rectal cancer has enabled organ preservation strategies in select patients [5].

Nevertheless, the safety, effectiveness, and optimal application of these evolving approaches remain uncertain, and variations in clinical practice persist. To address these gaps and support consistency in evidence-based care, the Korean Rectal Cancer Multidisciplinary (KRCM) Committee established under the Korean Society of Coloproctology and composed of colorectal surgeons, gastroenterologists, medical and radiation oncologists, radiologists, pathologists, and methodology experts led the development of this guideline through a structured, multidisciplinary collaboration. Therefore, these updated, evidence-based multidisciplinary guidelines aim to provide standardized, patient-centered recommendations, reflecting the latest evidence and the Korean healthcare setting.

METHODS

Methodology

The development of this guideline followed a hybrid approach that combined updating of previously developed evidence-based recommendations and *de novo* development of new recommendations. Eight key questions (KQs) from the prior evidence-based guideline (version 1) [6], originally created using a structured methodology by the Korean Society of Coloproctology, were systematically updated with new literature searches to incorporate the most recent evidence. In addition, 5 KQs that were not addressed in version 1 were developed *de novo*.

Evidence appraisal and determination of strength of recommendations (SORs) were conducted according to the Cochrane principle [7] and the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) framework [8]. All recommendations were formulated through multidisciplinary discussion within the KRCM Committee, taking into account patient values and preferences, clinical feasibility, and resource implications at each stage of the decision-making process.

Key clinical terms and outcome definitions used in this guideline are summarized in the supplementary materials to ensure consistency across KQs (Supplementary Table 1).

Synthesis of evidence

Literature search

A comprehensive literature review was conducted in 4 databases (MEDLINE via PubMed, Embase, the Cochrane Library, and KoreaMed) using predefined search strategies for each KQ, finalized via consultation with methodology experts (final search date: October 2024) (Supplementary Material 1). No language or publication status restrictions were applied. The retrieved studies were screened by at least 2 independent reviewers per KQ, according to the inclusion and exclusion criteria structured in a PICO (population, intervention, comparator, and outcomes) format (Supplementary Tables 2–14). The selection process adhered to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [9] (Supplementary Figs. 1-1–13-1).

Risk of bias assessment

Risk of bias was assessed by at least 2 independent reviewers using validated tools: RoB 2 (the revised Cochrane Risk of Bias tool) for randomized controlled trials (RCTs) [10], ROBINS-I (Risk of Bias in Nonrandomized Studies of Interventions) for nonrandomized studies (NRS) [11], and QUADAS-2 (the revised Quality Assessment of Diagnostic Accuracy Studies tool) for diagnostic accuracy studies [12]. Discrepancies were resolved by consensus. Eligible study designs were predefined according to the nature of each KQ. For intervention-related KQs, RCTs were preferentially included. When RCT evidence was limited or unavailable, NRS and observational studies were also considered. Diagnostic accuracy KQs included diagnostic test accuracy studies. The results are summarized in Supplementary Figs. 2-2–13-3.

Quantitative synthesis

Quantitative synthesis was performed for all KQs. Meta-analyses were conducted using random-effects models to account for anticipated between-study heterogeneity. Effect measures included hazard ratio for time-to-event outcomes and risk ratios or odds ratios for dichotomous outcomes, each with corresponding 95% confidence intervals (CIs). Statistical heterogeneity was assessed using the I^2 statistic. All meta-analyses were performed using Review Manager (RevMan) ver. 5.4.1 (The Cochrane Collaboration) (Supplementary Tables 2–14).

Level of evidence

The level of evidence (LOE) was graded as "high," "moderate," "low," or "very low," based on the GRADE criteria [13]. The LOE assessment was performed in consultation with a methodology expert, considering the risk of bias associated with each body of evidence (Table 1).

Recommendation formulation

Investigation of the values and preferences of the target population

A 19-item questionnaire was used to investigate health outcome priorities and preferences among patients diagnosed and treated for rectal cancer across all stages. In total, 48 patients participated in the survey. The results were reviewed by the committee and integrated into the evidence-to-decision framework when determining the direction and strength of each recommendation.

Strength and consensus of recommendations

Each draft recommendation and its strength were proposed by the designated KQ members using the GRADE grid method to support multidisciplinary agreement during recommendation process, considering the equipoise of benefits and harms, quality of evidence, patient values and preferences, feasibility, and cost/resources (Table 2) [14]. The draft statements were discussed at full committee meetings, and a consensus was reached via a blind vote, requiring at least 70% participation and 70% agreement for adoption. In case of nonconsensus, revisions were undertaken, and a second vote was conducted. The final recommendations were expressed using the standard GRADE terminology (strong or conditional, for or against).

Endorsement process

External expert review

To enhance the quality and validity of the guidelines, 28 external experts, endorsed by the participating academic societies, reviewed the content and assessed the acceptability of the recommendations among stakeholders. In addition, 3 independent methodology experts, unaffiliated with the guideline development, reviewed the document to verify methodological rigor. Feedback from all reviewers was incorporated into the final version of the guidelines.

Public hearing

Feedback regarding the direction, clarity, and applicability of the recommendations was collected from professional societies and stakeholders during public hearings. These comments were reviewed by the committee and integrated into the final recommendations as appropriate.

Guideline update plan

When new, high-quality evidence emerges on diagnostic modali-

Table 1. Level of evidence

Level of evidence	Definition
High	We are very confident that the true effect lies close to that of the estimate.
Moderate	We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate.
Very low	We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

Table 2. Strength of recommendations and clinical practice implications

Strength of recommendation	Definition
Strong for	Strongly recommended in most clinical situations, considering treatment benefits and harms, level of evidence, patient values and preferences, and resources.
Conditional for	Use of these treatments may depend on the clinical situation or patient/societal values. They might be used selectively or conditionally.
No preference	When ≥2 interventions have similar level of evidence and clinical effectiveness, either option may be appropriate depending on individual clinical circumstances and patient values or preferences.
Conditional against	In some situations or conditions, implementation is not recommended because the treatment harms may outweigh its benefits based on the clinical situation and/or patient/social value.
Strong against	Not recommended in most clinical situations because the harms of the treatment outweigh the benefits, considering the clinical situation and/or patient/social value.

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ties, therapeutic agents, or treatment strategies, the guidelines will be revised by adding new or updating the existing recommendations. In case of strong evidence contradicting or strengthening current recommendations, the committee will reassess the evidence and accordingly modify the content. When new data with a similar direction, albeit higher quality, becomes available, the committee will consider upgrading the LOE for the corresponding recommendation.

Recommendation	SOR	LOE	Context/key condition	Method
Diagnosis				
KQ 1. In patients with rectal cancer, is magnetic resonance imaging (MRI) appropriate for assessing complete response (CR) after preoperative chemoradiotherapy (CRT)?				
MRI may be considered for clinical assessment of CR after preoperative CRT in patients with rectal cancer.	Conditional for	Moderate to low	Multimodal assessment Watch-and-wait (W&W) candidates MRI expertise	Updated
KQ 2. In patients with suspected early colorectal cancer, are dye-based chromoendoscopy (DBC), virtual chromoendoscopy (VCE), or endoscopic ultrasonography (EUS) recommended for evaluating invasion depth?				
DBC, VCE, or EUS are recommended for the pre-resection assessment of invasion depth in patients with suspected early colorectal cancer.	Strong for	Moderate to low	Pre-resection decision Operator expertise Equipment availability	Updated
Endoscopic intervention				
KQ 3. In patients with submucosal invasive rectal cancer, is endoscopic resection alone curative?				
Endoscopic resection may be selectively performed in patients with submucosal invasive rectal cancer, considering the patient's condition and preferences.	Conditional for	Low	Low-risk tumors Medically unfit patients Shared decision-making	*De novo*
Neoadjuvant treatment				
KQ 4. In patients with locally advanced rectal cancer (LARC), are the clinical outcomes of preoperative short-course CRT (SCRT) comparable with those of long-course CRT (LCRT)?				
Preoperative LCRT or SCRT+delayed surgery may be considered for patients with LARC; however, SCRT+immediate surgery is not recommended because of its lower pathologic CR (pCR) rate.	No preference	Low	Tumor-downstaging goals Patient preference	Updated
KQ 5. Is preoperative CRT necessary for resectable upper LARC?				
Preoperative CRT is not routinely recommended for resectable upper LARC.	Conditional against	Very low	Resectable disease Selective high-risk use	*De novo*
KQ 6. Does prolonging the interval between radiotherapy and surgery improve the pCR rate?				
When the goal is to increase the pCR rate, extending the interval between LCRT completion and total mesorectal excision (TME) to ≥ 8 weeks may be considered; however, no significant difference in long-term oncologic outcomes has been demonstrated.	Conditional for	Low	pCR priority Organ preservation intent	Updated
KQ 7. Does total neoadjuvant therapy (TNT) improve pCR rate and survival in LARC?				
TNT may be considered for improving the pCR rate, overall survival, and disease-free survival in LARC.	Conditional for	Moderate	Medically fit patients Systemic therapy tolerance Survival priority	Updated
KQ 8. In patients with microsatellite instability-high (MSI-H)/mismatch repair-deficient (dMMR) LARC, can immunotherapy be considered?				
Considering the high CR rate, immunotherapy may be considered as a treatment option for patients with MSI-H/dMMR LARC.	Conditional for	Very low	MSI-H/dMMR Not reimbursed in Korea Equity considerations	*De novo*

(Continued on the next page)

Recommendation	SOR	LOE	Context/key condition	Method
Surgery				
KQ 9. In patients with LARC who undergo TME after preoperative CRT, is lateral pelvic lymph node dissection (LLND) effective?				
Concurrent LLND with TME may be considered for patients with LARC who are at high risk of lateral pelvic lymph node metastasis after preoperative CRT.	Conditional for	Low	Radiologically suspicious lateral pelvic lymph node High-risk subgroup	Updated
KQ 10. In patients with LARC who achieve a clinical CR (cCR) after preoperative CRT, is the W&W strategy noninferior in oncologic outcomes and superior in quality of life?				
The W&W strategy may be considered for patients with LARC who achieve a cCR after preoperative CRT.	Conditional for	Very low	cCR Intensive surveillance	*De novo*
KQ 11. In patients with LARC, is transanal TME oncologically safe compared with transabdominal TME?				
Transanal TME may be considered as an alternative approach for patients with LARC.	No preference	High	Surgeon expertise Institutional experience Individual approach	*De novo*
KQ 12. In patients with LARC who undergo local excision after preoperative CRT, is additional TME required when the pathological stage is ypT0–T1?				
Additional TME may be omitted when the pathological stage is ypT0–T1 for patients with LARC who undergo local excision after preoperative CRT.	Conditional against	Low	No adverse pathology Shared decision-making	Updated
Adjuvant chemotherapy				
KQ 13. In patients with LARC who undergo preoperative CRT followed by TME, is adjuvant chemotherapy necessary? Is adjuvant chemotherapy necessary for patients with postoperative stage 0 or I?				
(1) In patients with LARC who undergo preoperative CRT and surgical resection, the benefit of adjuvant chemotherapy is unclear for those with postoperative stage 0 or I.	No preference	Very low	Uncertain benefit Toxicity concern Individualized decision	Updated
(2) In patients with LARC who undergo preoperative CRT and surgical resection and are found to have postoperative stage II or III, adjuvant chemotherapy with an oxaliplatin-based combination regimen is recommended rather than fluoropyrimidine monotherapy.	Conditional for	Low	High-risk disease Medically fit patients	Updated

RESULTS

Diagnosis

KQ 1. In patients with rectal cancer, is MRI appropriate for assessing complete response (CR) after preoperative chemoradiotherapy (CRT)?

Recommendation 1.

MRI may be considered for clinical assessment of CR after preoperative CRT in patients with rectal cancer.

SOR: Conditional for

LOE: Moderate (specificity) to low (sensitivity)

MRI is the preferred imaging modality for assessing treatment response to preoperative CRT in rectal cancer. Pooled analyses indicate that MRI can predict pCR with moderate sensitivity (point estimate of 59%) and high specificity (90%), suggesting reasonable accuracy in identifying patients with no residual disease (Supplementary Figs. 1-3) [15–51]. Accurate recognition of CR may help facilitate nonoperative management, including a "watch-and-wait" (W&W) approach, with potential oncologic, functional, and economic benefits [18, 52–54]. However, limited sensitivity of MRI implies that some patients with true CR may be misclassified as non-CR, potentially leading to underestimation of CR. Therefore, MRI-based assessment should be interpreted within a multidisciplinary context that integrates endoscopic and clinical findings. This recommendation was graded as conditional because, although MRI plays a central role in post-CRT response assessment and provides clinically valuable information, its sensitivity and specificity are not sufficient to determine CR in isolation. MRI-based assessment should be interpreted in conjunction with endoscopic and clinical findings and is most applicable in centers with expertise in rectal MRI interpretation, particularly when nonoperative management strategies are being considered.

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KQ 2. In patients with suspected early colorectal cancer, are dye-based chromoendoscopy (DBC), virtual chromoendoscopy (VCE), or endoscopic ultrasonography (EUS) recommended for evaluating invasion depth?

Recommendation 2.

DBC, VCE, or EUS are recommended for the pre-resection assessment of invasion depth in patients with suspected early colorectal cancer.

SOR: Strong for

LOE: Moderate (specificity) to low (sensitivity)

Accurate assessment of the invasion depth of suspected early colorectal cancer is essential for selecting the appropriate treatment approaches: endoscopic or surgical resection. Meta-analyses of 51 studies revealed that the noninvasive DBC, VCE, and EUS approaches demonstrate acceptable diagnostic performance in predicting deep submucosal invasion (≥1,000 μm), with respective pooled sensitivities of 0.81, 0.75, and 0.78, and specificities of 0.96, 0.97, and 0.92 (Supplementary Figs. 2-3) [55–105], with no additional procedural harm being reported. False-negative results may lead to incomplete resection or delayed surgery in high-risk lesions, and false-positive results to unnecessary surgery [106–108]. However, these diagnostic modalities can improve overall diagnostic accuracy, reducing the likelihood of unfavorable events. Considering both diagnostic performance and potential clinical implications, the expected benefits of these modalities are presumed to outweigh the potential harm. Overall, DBC, VCE, and EUS are valuable tools for pre-resection invasion depth assessment and are strongly recommended for early colorectal cancer management. This recommendation was graded as strong because assessment of invasion depth directly determines treatment strategy and is highly valued by patients to avoid both undertreatment and unnecessary surgery. Given the high diagnostic reliability of DBC, VCE, and EUS, their minimal procedural burden, and broad feasibility in routine practice support consistent use across clinical settings where appropriate equipment and operator expertise are available.

Endoscopic intervention

KQ 3. In patients with submucosal invasive rectal cancer, is endoscopic resection alone curative?

Recommendation 3.

Endoscopic resection may be selectively performed in patients with submucosal invasive rectal cancer, considering the patient's condition and preferences.

SOR: Conditional for

LOE: Low

Endoscopic resection for T1 rectal cancer is less invasive than radical surgery, thus avoiding surgery-related morbidity (Supplementary Fig. 3-3) [109–119]. However, it is associated with procedural adverse events such as delayed bleeding and perforation (Supplementary Fig. 3-4) [113, 115–121], and its long-term oncologic efficacy remains uncertain. Endoscopic resection has been reported to have higher recurrence and mortality rates than surgery, whereas no significant differences were noted for overall and disease-free survival rates (Supplementary Figs. 3-5) [109–138]. Considering both short-term safety and long-term outcomes, endoscopic resection may be selectively considered for patients with T1 low-risk rectal cancer or for older patients or those who are medically unfit for radical surgery. Regarding patient values and preferences, prioritization of less invasive treatment with preservation of bowel function and quality of life supports the selective use of endoscopic resection through shared decision-making for appropriately chosen patients. This recommendation was graded as conditional because the balance between oncologic safety and treatment burden varies substantially according to tumor risk and patient condition, and the certainty of evidence for long-term outcomes remains low. While avoidance of radical surgery and preservation of function are highly valued by selected patients, particularly those with low-risk tumors or limited surgical tolerance, concerns regarding recurrence limit routine application, supporting use based on patient preferences and clinical context.

Neoadjuvant treatment

KQ 4. In patients with locally advanced rectal cancer (LARC), are the clinical outcomes of preoperative short-course CRT (SCRT) comparable with those of long-course CRT (LCRT)?

Recommendation 4.

Preoperative LCRT or SCRT+delayed surgery may be considered for patients with LARC; however, SCRT+immediate surgery is not recommended because of its lower pathologic CR (pCR) rate.

SOR: No preference

LOE: Low

Meta-analyses indicated the comparable oncologic outcomes of preoperative SCRT and LCRT in overall survival, local recurrence, and postoperative morbidity in patients with LARC (Supplementary Figs. 4-4–4-6) [139–154]. When stratified by surgical timing, SCRT with delayed surgery had pCR rates similar to those of LCRT, whereas SCRT with immediate surgery had significantly lower pCR rates (Supplementary Figs. 4-4–4-6). Late or chronic grade ≥3 complications were less frequent with SCRT with de-

layed surgery, although the certainty of evidence was "low" (Supplementary Fig. 4-6). The patient survey indicated the likelihood of achieving pCR (77.6%) primarily influenced treatment choice among SCRT with immediate surgery, SCRT with delayed surgery, and LCRT. Considering the comparable oncologic efficacy and potential reduction in treatment duration and toxicity, either LCRT or SCRT with delayed surgery may be appropriate options, whereas SCRT with immediate surgery is not recommended when tumor downstaging or organ preservation is prioritized. Therefore, the panel issues a conditional recommendation with no preferred option for LCRT and SCRT with delayed surgery. This recommendation was issued with no preference because both LCRT and SCRT with delayed surgery represent acceptable treatment options with similar oncologic outcomes, while the choice between them is strongly influenced by patient priorities regarding tumor response, treatment duration, and potential toxicity. Given the low certainty of evidence, the absence of a clearly superior strategy, and minimal barriers to implementing either approach in routine practice, the committee supported individualized selection based on clinical context and patient values, while discouraging SCRT with immediate surgery when tumor downstaging is desired.

KQ 5. Is preoperative CRT necessary for resectable upper LARC?

Recommendation 5.

Preoperative CRT is not routinely recommended for resectable upper LARC.

SOR: Conditional against

LOE: Very low

Meta-analyses indicated no significant survival benefit of preoperative CRT versus upfront surgery in patients with resectable upper LARC. Overall and recurrence-free survival were similar between both groups (overall survival: relative risk [RR], 1.03 [95% CI, 0.96–1.10]; recurrence-free survival: RR, 1.01 [95% CI, 0.94–1.09]) (Supplementary Fig. 5-4) [154–163]. Although subgroup analyses of RCTs revealed that preoperative CRT significantly reduced local recurrence (RR, 0.56; 95% CI, 0.34–0.92), this benefit did not translate into improved overall survival (Supplementary Fig. 5-4). Conversely, preoperative CRT was associated with higher diverting stoma formation rates (RR, 1.98; 95% CI, 1.39–2.81) and a greater incidence of Clavien-Dindo grade I–II complications (RR, 1.31; 95% CI, 1.01–1.70) (Supplementary Fig. 5-5). The patient survey indicated that "cure and recurrence prevention" was the most important factor influencing preoperative CRT decision-making (77.6%), followed by avoidance of temporary stoma (8.2%), and minimization of postoperative complications (2.0%). None of the respondents prioritized shorter treatment duration or lower costs. These findings indicate that patients value long-term oncologic outcomes more than short-term convenience or treatment burden. Considering that preoperative CRT offers limited survival benefit, modest local control improvement, and increased postoperative morbidity, its routine use is not justified in resectable upper LARC. Therefore, the panel issues a conditional non-recommendation for preoperative CRT, acknowledging that it may be selectively considered for patients with T4 disease or those with radiologic concern for incomplete resection. This recommendation was graded as conditional against because routine preoperative CRT does not align with patients' primary goal of improving long-term survival in resectable upper rectal cancer and introduces additional treatment burden without clear survival benefit. Given the low certainty of evidence, increased postoperative morbidity, and limited facilitators for routine use in this setting, the committee supported omission of preoperative CRT in most patients, while allowing selective use in high-risk situations where concerns about local control or resectability outweigh potential harms.

KQ 6. Does prolonging the interval between radiotherapy and surgery improve the pCR rate?

Recommendation 6.

When the goal is to increase the pCR rate, extending the interval between LCRT completion and total mesorectal excision (TME) to ≥8 weeks may be considered; however, no significant difference in long-term oncologic outcomes has been demonstrated.

SOR: Conditional for

LOE: Low

In patients with rectal cancer who received preoperative LCRT, a longer interval (>8 weeks) between radiotherapy completion and TME was associated with a higher pCR rate without compromising oncologic safety. Meta-analyses of 5 randomized studies and 19 retrospective studies revealed that delaying surgery by ≥8 weeks increased the likelihood of achieving pCR compared with that for surgery within 8 weeks (RR, 1.38; 95% CI, 1.04–1.83) (Supplementary Fig. 6-4) [164–188]. However, no significant differences were observed in overall survival (hazard ratio [HR], 1.14; 95% CI, 0.80–1.63), disease-free survival (HR, 1.27; 95% CI, 0.91–1.78), or recurrence rate (RR, 0.88; 95% CI, 0.36–2.15) between both groups (Supplementary Figs. 6-4, 6-5). Postoperative complication rates were comparable as well (RR, 0.99; 95% CI, 0.80–1.21) (Supplementary Figs. 6-6). These findings suggest that

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extending the waiting period moderately improved tumor regression and pCR without increasing postoperative risks. The patient survey indicated that achieving a CR was the most valued outcome regarding surgical timing after radiotherapy (71.4%). Only a few patients prioritized shorter treatment duration or reduced cost. Considering the potential improvement in pCR and comparable long-term oncologic and safety outcomes, delaying surgery to ≥8 weeks after the completion of LCRT may be considered for maximizing tumor downstaging or organ preservation. This recommendation was graded as conditional because prolonging the interval after LCRT primarily affects tumor response rather than long-term oncologic outcomes and the certainty of evidence remains low. Given that patients place high value on achieving CR and organ preservation, and major barriers such as increased surgical risk are not evident, the committee supported extension of the interval when treatment goals prioritize downstaging, while not endorsing routine delay for all patients.

KQ 7. Does total neoadjuvant therapy (TNT) improve pCR rate and survival in LARC?

Recommendation 7.

TNT may be considered for improving the pCR rate, overall survival, and disease-free survival in LARC.

SOR: Conditional for

LOE: Moderate

In patients with LARC, TNT demonstrated superior tumor response and survival outcomes compared with standard preoperative LCRT. Meta-analyses of 19 RCTs revealed that TNT significantly improved 3-year disease-free survival (HR, 0.83: 95% CI, 0.74–0.93) and overall survival (HR, 0.75; 95% CI, 0.62–0.89) compared with LCRT alone (Supplementary Fig. 7-3) [3, 189–206]. The pCR rate was significantly higher with TNT than with LCRT (RR, 1.78; 95% CI, 1.53–2.07), regardless of the chemotherapy delivery approach (induction or consolidation sequence) (Supplementary Fig. 7-4). The R0 resection rate was similar between groups (Supplementary Fig. 7-4). Although TNT increased the incidence of grade ≥3 preoperative toxicity (RR, 1.78; 95% CI 1.29–2.46), postoperative grade ≥3 complications were comparable between the groups (RR, 1.08; 95% CI, 0.55–2.14) (Supplementary Fig. 7-5). These findings indicate that TNT enhances tumor regression and long-term outcomes with an acceptable increase in short-term toxicity. The patient survey indicated that improvement in survival outcomes (33.3%) and willingness to tolerate adverse effects for greater efficacy (31.2%) highly influenced decision-making, whereas avoidance of toxicity (10.4%) and treatment cost (4.2%) were less frequently prioritized. These results suggest that most patients value potential cure and long-term outcomes over treatment burden, supporting the use of TNT in appropriately selected candidates. Considering the consistent improvement in pCR, disease-free survival, and overall survival, with acceptable treatment-related toxicity, TNT may be considered for patients with LARC who are medically fit to receive systemic chemotherapy. This recommendation was graded as conditional because, although TNT provides meaningful improvements in tumor response and survival, its use entails increased treatment intensity and short-term toxicity that may not be acceptable or feasible for all patients. Given the moderate certainty of evidence, patients' strong prioritization of long-term oncologic benefit over treatment burden, and the need to consider medical fitness and tolerance to systemic chemotherapy, the committee supported TNT as a preferred option for appropriately selected patients rather than as a universal standard.

KQ 8. In patients with microsatellite instability-high (MSI-H)/mismatch repair-deficient (dMMR) LARC, can immunotherapy be considered?

Recommendation 8.

Considering the high CR rate, immunotherapy may be considered as a treatment option for patients with MSI-H/dMMR LARC.

SOR: Conditional for

LOE: Very low

In patients with MSI-H/dMMR LARC, immune checkpoint inhibitor (ICI) monotherapy has demonstrated remarkably high CR rates and favorable safety profiles, suggesting its potential as an alternative to conventional CRT (CCRT) in select cases. Meta-analyses of 4 single-arm NRS demonstrated a pooled CR rate of 87% (95% CI, 0.71–1.03) with ICI monotherapy (Supplementary Fig. 8-3) compared to 24% (95% CI, 0.09–0.38) with CCRT (Supplementary Fig. 8-3) [5, 207–209]. The incidence of grade ≥3 treatment-related toxicity was markedly lower with immunotherapy (1%; 95% CI, 0.02–1.13) than with CCRT (34%; 95% CI, 0.14–0.54) (Supplementary Fig. 8-3), and most immune-related adverse events were mild and manageable. These findings suggest that neoadjuvant immunotherapy provides substantial tumor regression and potential organ preservation with minimal toxicity. The patient survey indicated that 71.4% of respondents expressed willingness to receive immunotherapy despite the lack of insurance coverage and high out-of-pocket costs, reflecting strong expectations for cure and functional preservation. Considering the high CR rate, favorable safety profile, and strong patient preference for organ-preserving and less invasive treatment despite financial

burden, neoadjuvant immunotherapy may be used as an alternative strategy for managing MSI-H/dMMR LARC. The panel issues a conditional recommendation (LOE, very low), acknowledging the small sample sizes, NRS designs, and limited long-term data. This recommendation was graded as conditional because, although immunotherapy demonstrated very high CR rates and a favorable safety profile, the certainty of evidence remains very low due to limited sample sizes and lack of long-term outcome data. In addition, the absence of national insurance reimbursement in Korea raises substantial concerns regarding cost, accessibility, and equity, which precludes a strong recommendation despite strong patient preference for organ-preserving and less invasive treatment. Therefore, the committee supported cautious and selective use of immunotherapy in patients with MSI-H/dMMR LARC.

Surgery

KQ 9. In patients with LARC who undergo TME after preoperative CRT, is lateral pelvic lymph node dissection (LLND) effective?

Recommendation 9.

Concurrent LLND with TME may be considered for patients with LARC who are at high risk of lateral pelvic lymph node metastasis after preoperative CRT.

SOR: Conditional for

LOE: Low

In patients with LARC who received preoperative CRT, concurrent LLND with TME reduced local and distant recurrence without significantly affecting overall or disease-free survival. Meta-analyses of 1 RCT and 10 NRS indicated that TME with LLND significantly lowered local recurrence (HR, 0.31; 95% CI, 0.13–0.50) (Supplementary Fig. 9-4) and distant metastasis (HR, 0.63; 95% CI, 0.44–0.83) (Supplementary Fig. 9-5), without improvement in overall or disease-free survival (Supplementary Fig. 9-6) [210–220]. The benefit was most evident in patients with pretreatment lateral nodes ≥5–7 mm on imaging, suggesting selective application in high-risk cases. Postoperative morbidity was comparable between both groups, although urinary and sexual dysfunction occurred more frequently with TME with LLND (Supplementary Fig. 9-7). The patient survey indicated that cure and recurrence prevention were the most valued treatment goals, whereas concerns about postoperative complications remained less important. These findings support selective LLND for patients with radiologically suspicious lateral nodes where the potential oncologic benefit outweighs functional impairment risk. This recommendation was graded as conditional because the potential oncologic benefit of LLND is limited to a well-defined high-risk subgroup and the certainty of evidence remains low. Given patients' strong prioritization of cure and recurrence prevention, balanced against concerns regarding urinary and sexual dysfunction, the committee supported selective use of LLND in patients with radiologically suspicious lateral nodes through multidisciplinary decision-making rather than routine application.

KQ 10. In patients with LARC who achieve a clinical CR (cCR) after preoperative CRT, is the W&W strategy noninferior in oncologic outcomes and superior in quality of life?

Recommendation 10.

The W&W strategy may be considered for patients with LARC who achieve a cCR after preoperative CRT.

SOR: Conditional for

LOE: Very low

In patients with LARC who achieved a cCR after preoperative CRT, the W&W strategy demonstrated comparable oncologic outcomes with radical surgery, with superior functional preservation and quality of life. Meta-analyses of 13 NRS revealed no significant differences in overall survival (RR, 1.02; 95% CI, 0.98–1.06), disease-free survival (RR, 0.96; 95% CI, 0.86–1.06), or distant metastasis-free survival (RR, 0.99; 95% CI, 0.92–1.05) between W&W and surgical resection (Supplementary Fig. 10-3) [221–233]. However, local regrowth occurred more frequently in the W&W group (RR, 5.76; 95% CI, 2.26–14.63), emphasizing the need for meticulous surveillance and timely salvage surgery. Functionally, W&W exhibited markedly lower major low anterior resection syndrome rates (RR, 0.59; 95% CI, 0.38–0.92) and achieved higher sphincter preservation rates (RR, 1.40; 95% CI, 1.20–1.64), particularly in low rectal cancers within 3 cm from the anal verge (Supplementary Fig. 10-4). These findings highlight the substantial quality-of-life benefits when oncologic safety is maintained. The patient survey revealed that most respondents prioritized cure and recurrence prevention as the most important treatment goals, while a considerable proportion valued quality of life and avoidance of a permanent stoma even at the expense of an increased local recurrence risk. These diverse preferences require shared decision-making between clinicians and patients. Considering the comparable long-term survival, improved functional outcomes, and patient preference for organ preservation, the W&W approach may be selectively considered for patients with a cCR who can adhere to strict follow-up. This recommendation was graded as conditional because the LOE is very low and the oncologic safety of the W&W strategy depends heavily on rigor-

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ous surveillance and timely salvage surgery. Given the trade-off between functional preservation and the increased risk of local regrowth, as well as substantial variability in patient values regarding quality of life and stoma avoidance, the committee supported selective application of W&W through shared decision-making in patients who can adhere to intensive follow-up.

KQ 11. In patients with LARC, is transanal TME oncologically safe compared with transabdominal TME?
Recommendation 11.
Transanal TME may be considered as an alternative approach for patients with LARC.
SOR: No preference
LOE: High

In patients with LARC undergoing curative resection, transanal TME demonstrated comparable oncologic safety and postoperative outcomes with transabdominal TME. Meta-analyses of 4 RCTs and 41 NRS demonstrated no significant differences in overall survival (HR, 0.86; 95% CI, 0.72–1.00) or disease-free survival (HR, 0.71; 95% CI, 0.17–1.26) between transabdominal TME and conventional laparoscopic or robotic TME (Supplementary Fig. 11-4) [234–278]. The overall complication rate (RR, 0.96; 95% CI, 0.77–1.21) and severe complications of Clavien-Dindo grade III–IV (RR, 1.22; 95% CI, 0.82–1.82) were comparable as well (Supplementary Fig. 11-5). These findings indicate the equivalency of transanal and transabdominal TME in oncologic safety and perioperative outcomes. Transanal TME requires a high level of anatomical understanding, technical proficiency, and multidisciplinary coordination. Considering its steep learning curve, structured training, surgical mentoring, and institutional familiarity are critical for safe adoption. Transanal TME may be considered as a surgical option for LARC, particularly when performed by trained surgeons in high-volume centers. The choice of surgical approach may be individualized based on patient anatomy, tumor location, and surgeon expertise. The panel issues a recommendation with no preferred option for transanal and transabdominal TME. This recommendation was issued with no preference because transanal and transabdominal TME demonstrate comparable oncologic safety and perioperative outcomes, and neither approach offers a clear overall advantage across all patients. Given that the effectiveness and safety of transanal TME depend strongly on surgeon expertise, structured training, and institutional experience, and that patient anatomy and tumor characteristics further influence procedural suitability, the committee supported individualized selection of the surgical approach through multidisciplinary consensus rather than routine preference for either technique.

KQ 12. In patients with LARC who undergo local excision after preoperative CRT, is additional TME required when the pathological stage is ypT0–T1?
Recommendation 12.
Additional TME may be omitted when the pathological stage is ypT0–T1 for patients with LARC who undergo local excision after preoperative CRT.
SOR: Conditional against
LOE: Low

In patients with LARC who underwent preoperative CRT followed by local excision and were found to have ypT0–T1 tumors, omitting completion TME resulted in comparable oncologic outcomes with improved postoperative recovery and functional preservation. Meta-analyses of 3 RCTs and 9 NRS revealed no significant differences between the local excision-only and TME groups in overall survival (RCT: HR, 1.36 [95% CI, 0.36–5.17]; NRS: RR, 1.12 [95% CI, 0.35–3.54]), disease-free survival (RCT: HR, 1.20 [95% CI, 0.40–3.63]; NRS: RR, 1.19 [95% CI, 0.03–2.35]), local recurrence (RCT: HR, 1.34 [95% CI, 0.19–9.31]; NRS: RR, 0.68 [95% CI, 0.30–1.53]), or distant metastasis (RCT: HR, 0.88 [95% CI, 0.25–3.05]; NRS: RR, 0.71 [95% CI, 0.32–1.60]) (Supplementary Figs. 12-4, 12-5) [279–290]. However, the local excision-only group had a significantly lower incidence of postoperative complications (RR, 0.46; 95% CI, 0.32–0.76) and major lower anterior resection syndrome (RR, 0.39; 95% CI, 0.25–0.63) than the TME group, translating into better quality of life and functional outcomes (Supplementary Fig. 12-6). These findings suggest that omitting completion TME may be a reasonable organ-preserving option for carefully selected patients with ypT0–T1 without adverse pathologic features such as lymphovascular, perineural, or extramural venous invasion, positive resection margin, tumor budding, or poor differentiation. In contrast, additional TME should be considered when these high-risk features are present [291–295]. The patient survey indicated that younger patients prioritized functional preservation and stoma avoidance, whereas older patients prioritized reduced surgical risk and recovery burden. These findings highlight the importance of shared decision-making based on both oncologic risk and individual patient preference. Considering the comparable survival outcomes, lower postoperative morbidity, and meaningful functional benefit in select cases, the panel issues a non-recommendation for routine completion of TME after local excision in patients with ypT0–T1 (LOE, low). This recommendation was graded as conditional against routine completion TME because the certainty of evidence

is low and no clear oncologic advantage has been demonstrated in patients with ypT0–T1 after local excision. Given the substantial functional benefit and reduced postoperative morbidity associated with omission of TME, balanced against the need to consider adverse pathologic features and heterogeneity in patient values regarding functional preservation and surgical risk, the committee supported selective omission of TME through shared decision-making rather than routine additional surgery.

Adjuvant chemotherapy

KQ 13. In patients with LARC who undergo preoperative CRT followed by TME, is adjuvant chemotherapy necessary? Is adjuvant chemotherapy necessary for patients with postoperative stage 0 or I?

Recommendation 13-1.

In patients with LARC who undergo preoperative CRT and surgical resection, the benefit of adjuvant chemotherapy is unclear for those with postoperative stage 0 or I.

SOR: No preference

LOE: Very low

Recommendation 13-2.

In patients with LARC who undergo preoperative CRT and surgical resection and are found to have postoperative stage II or III, adjuvant chemotherapy with an oxaliplatin-based combination regimen is recommended rather than fluoropyrimidine monotherapy.

SOR: Conditional for

LOE: Low

Meta-analyses of 1 RCT and 10 NRS revealed that adjuvant chemotherapy after preoperative CRT and curative resection did not significantly improve overall or disease-free survival in patients with ypStage 0–I. The pooled HR for overall survival and disease-free survival was 0.78 (95% CI, 0.54–1.02) and 0.69 (95% CI, 0.22–1.17), respectively, indicating no statistically significant advantage, although a potential benefit cannot be excluded (Supplementary Fig. 13-4) [296–306]. Approximately 30% of patients receiving adjuvant therapy experienced grade ≥3 toxicities (95% CI, 0.22–0.38), primarily fatigue, diarrhea, and neuropathy (Supplementary Fig. 13-5). Considering the absence of clear survival improvement and the non-negligible toxicity risk, the role of adjuvant chemotherapy in patients with ypStage 0–I remains uncertain. The patient survey indicated that 69.4% agreed with receiving adjuvant chemotherapy, 24.5% supported it only for stage ≥II disease, and only 6.1% disagreed. "Cure and recurrence prevention" were identified as the most important goals, followed by "maintenance of quality of life" and "minimization of adverse effects." Patients generally sought to balance efficacy and toxicity; however, they ultimately prioritized the possibility of cure and long-term disease control. In formulating this recommendation, the panel considered that while patients expressed conditional acceptance reflecting both anticipated benefit and toxicity concerns, the evidence of benefit remains uncertain. Therefore, because individualized decision-making that respects each patient's risk profile and preference is paramount, the panel issues a recommendation with no preferred option. This recommendation was issued with no preference because the certainty of evidence is very low and available data do not demonstrate a clear survival benefit of adjuvant chemotherapy in patients with postoperative stage 0–I, while treatment-related toxicity is non-negligible. Given the uncertainty regarding oncologic benefit and substantial variability in patient values concerning oncologic benefit versus quality of life, the committee supported individualized decision-making based on patient risk profile and preference rather than routine use.

Evidence from 1 RCT (ADORE trial) and 3 NRS indicated that oxaliplatin-based combination therapy (FOLFOX [fluorouracil, leucovorin, and oxaliplatin] or CAPOX [capecitabine and oxaliplatin]) improved disease-free survival compared with fluoropyrimidine monotherapy in patients with ypStage II or III [307–310]. The pooled HR for disease-free survival was 0.63 (95% CI, 0.43–0.93), corresponding to a 37% reduction in recurrence risk. Overall survival favored the combination regimen as well (HR, 0.79; 95% CI, 0.63–0.99) (Supplementary Fig. 13-6) [307–310]. Grade ≥3 toxicities, primarily hematologic toxicities and peripheral neuropathy, occurred more frequently with oxaliplatin-based therapy (RR, 1.25; 95% CI, 0.96–1.61) than with fluoropyrimidine monotherapy. However, they were generally manageable with supportive care (Supplementary Fig. 13-7). These data suggest that oxaliplatin addition provides a meaningful oncologic benefit that outweighs the incremental toxicity for most patients with ypStage II–III disease. The patient survey indicated that respondents at higher clinical risk expressed greater willingness to tolerate adverse events for improved survival, highlighting a value shift toward efficacy over comfort in advanced stages. Considering the consistent improvement in disease-free survival, acceptable toxicity, and alignment with patient priorities, the panel issues a conditional recommendation for oxaliplatin-based combination therapy as the preferred adjuvant regimen for ypStage II–III rectal cancer (LOE, low). This recommendation was graded as conditional because, although oxaliplatin-based combination chemotherapy shows a clinically meaningful improvement in disease-free survival in patients with ypStage II–III rectal cancer, with a favorable

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overall survival trend, the certainty of evidence remains low and the magnitude of benefit and tolerability may vary by patient. Given the manageable but non-negligible toxicity, along with variability in patient values and clinical fitness, the committee supports the use of oxaliplatin-based combination therapy through individualized decision-making and shared discussions regarding expected benefit and adverse effects.

CONCLUSION

These updated guidelines emphasize an individualized, evidence-driven approach to rectal cancer management, delivered through multidisciplinary collaboration and attuned to patient values. Key recommendations include the use of high-resolution pelvic MRI for precise staging and treatment response assessment after neoadjuvant CRT, helping identify complete responders who may safely avoid surgery. Both LCRT and SCRT with delayed surgery are endorsed as acceptable neoadjuvant options with comparable oncologic outcomes. TNT is advised in select patients to improve pCR rates and long-term survival. Emerging evidence supports offering immunotherapy to patients with MSI-H/dMMR tumors, considering the CR rates observed in this subgroup. TME remains the cornerstone of surgical management, with a transanal TME approach available as a feasible alternative in experienced centers, without compromising oncologic safety. Concurrent LLND is recommended for cases at high risk of lateral nodal metastasis to ensure comprehensive clearance. Key organ-preserving strategies include a W&W strategy for patients achieving a clinical CR after neoadjuvant therapy, and if a patient who undergoes local excision after CRT has only a ypT0–1 residual tumor, a completion TME can be omitted. Adjuvant chemotherapy recommendations are tailored according to the pathologic stage. Adjuvant therapy is not routinely indicated for those downstaged to ypStage 0–I, as its benefit in this group is unclear, whereas patients with ypStage II–III disease can be offered adjuvant oxaliplatin-based combination chemotherapy to improve disease-free survival. Notably, most recommendations are conditional, reflecting the limits of current evidence and the need to individualize decisions contextually. Thus, these guidelines integrate the best available evidence with expert multidisciplinary consensus and patient preferences to support optimal care for rectal cancer. Ongoing research and emerging data will be critical for refining these recommendations, underlining the importance of future updates as new evidence accumulates.

ARTICLE INFORMATION

Author details

[1]Division of Colon and Rectal Surgery, Department of Surgery, Korea University College of Medicine, Seoul, Korea
[2]Institute for Evidence-based medicine, Korea University College of Medicine, Seoul, Korea
[3]Cochrane Korea, Seoul, Korea
[4]Department of Surgery, Soonchunhyang University Cheonan Hospital, Soonchunhyang University College of Medicine, Cheonan, Korea
[5]Department of Radiation Oncology, Incheon St. Mary's Hospital, Incheon, Korea
[6]Department of Surgery, Chonnam National University Hospital, Chonnam National University Medical School, Gwangju, Korea
[7]Division of Colorectal Surgery, Department of Surgery, Uijeongbu Eulji Medical Center, Uijeongbu, Korea
[8]Division of Hematology and Oncology, Department of Internal Medicine, Dongguk University Medical Center, Goyang, Korea
[9]Department of Pathology, Korea University Guro Hospital, Seoul, Korea
[10]Department of Internal Medicine, Kosin University College of Medicine, Busan, Korea
[11]Department of Pathology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea
[12]Division of Hematology/Medical Oncology, Department of Internal Medicine, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Bundang, Korea
[13]Department of Radiation Oncology, Nowon Eulji Medical Center, Eulji University School of Medicine, Seoul, Korea
[14]Department of Radiology and Research Institute of Radiology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea
[15]Department of Surgery, Ewha Womans University Mokdong Hospital, Seoul, Korea
[16]Department of Surgery, Ewha Womans University College of Medicine, Seoul, Korea
[17]Department of Surgery, Korea University Guro Hospital, Seoul, Korea
[18]Department of Surgery, Konyang University Hospital, Daejeon, Korea
[19]Department of Colon and Rectal Surgery, Kyungpook National University Chilgok Hospital, Daegu, Korea
[20]Department of Surgery, UiJeongbu St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Uijeongbu, Korea
[21]Department of Surgery, Dankook University Hospital, Cheonan, Korea
[22]Department of Radiation Oncology, Eunpyeong St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea
[23]Department of Internal Medicine, Samsung Changwon Hospital, Sungkyunkwan University School of Medicine, Changwon, Korea
[24]Department of Surgery, Yongin Severance Hospital, Yonsei University College of Medicine, Yongin, Korea
[25]Department of Surgery, Soonchunhyang University Seoul Hospital, Soonchunhyang University College of Medicine, Seoul, Korea
[26]Department of Internal Medicine, Inha University Hospital, Incheon, Korea
[27]Division of Colon and Rectal Surgery, Department of Surgery, Korea University Ansan Hospital, Ansan, Korea
[28]Department of Surgery, Eunpyeong St. Mary's Hospital, College of

Medicine, The Catholic University of Korea, Seoul, Korea
[29]Department of Surgery, National Health Insurance Service Ilsan Hospital, Ilsan, Korea

Conflict of interest

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Author contributions

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Supplementary materials

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tinence, peritonitis, pneumonia, pneumomediastinum, pneumothorax, presacral abscess, and stoma formation.

Supplementary Fig. 3-4. Forest plots of adverse events exploring the potential risks of endoscopic resection compared with surgery (A) overall bleeding events, (B) perforation, and post-polypectomy syndrome.

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Supplementary Fig. 9-3. Risk of bias assessment using ROBINS-I for KQ 9.

Supplementary Fig. 9-4. Forest plots of local recurrence and lateral local recurrence in patients who underwent LLND versus those who did not, presented separately for (A, C) HRs and (B, D) RRs.

Supplementary Fig. 9-5. Forest plots comparing distant metastasis in patients who underwent LLND versus those who did not.

Supplementary Fig. 9-6. Forest plots of (A) 3-year overall survival, (B) 5-year overall survival, (C) 3-year disease-free survival, and (D) 5-year disease-free survival in patients who underwent LLND versus those who did not.

Supplementary Fig. 9-7. Forest plots of (A) overall complications and anastomotic leakage, (B) urinary dysfunction and wound in-

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Supplementary Fig. 10-1. PRISMA flow diagram for KQ 10.

Supplementary Fig. 10-2. Risk of bias assessment using ROBINS-I for KQ 10.

Supplementary Fig. 10-3. Forest plots of oncologic outcomes of "W&W" versus surgery.

Supplementary Fig. 10-4. Forest plots of functional outcomes and recurrence of "W&W" versus surgery.

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Supplementary Fig. 11-2. Risk of bias assessment using RoB 2 for KQ 11.

Supplementary Fig. 11-3. Risk of bias assessment using ROBINS-I for KQ 11.

Supplementary Fig. 11-4. Forest plots of (A) overall survival and (B) disease-free survival of transanal versus transabdominal TME.

Supplementary Fig. 11-5. Forest plots of (A) overall complications and (B) Clavien-Dindo III–IV complications of transanal versus transabdominal TME.

Supplementary Fig. 12-1. PRISMA flow diagram for KQ 12.

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Supplementary Fig. 12-4. Forest plots of (A) overall survival and (B) disease-free survival of local excision versus TME.

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Supplementary Fig. 13-7. Incidence of grade 3–4 toxicities during adjuvant chemotherapy: FOLFOX versus FU monotherapy in patients with ypStage II–III rectal cancer after neoadjuvant chemoradiotherapy.

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