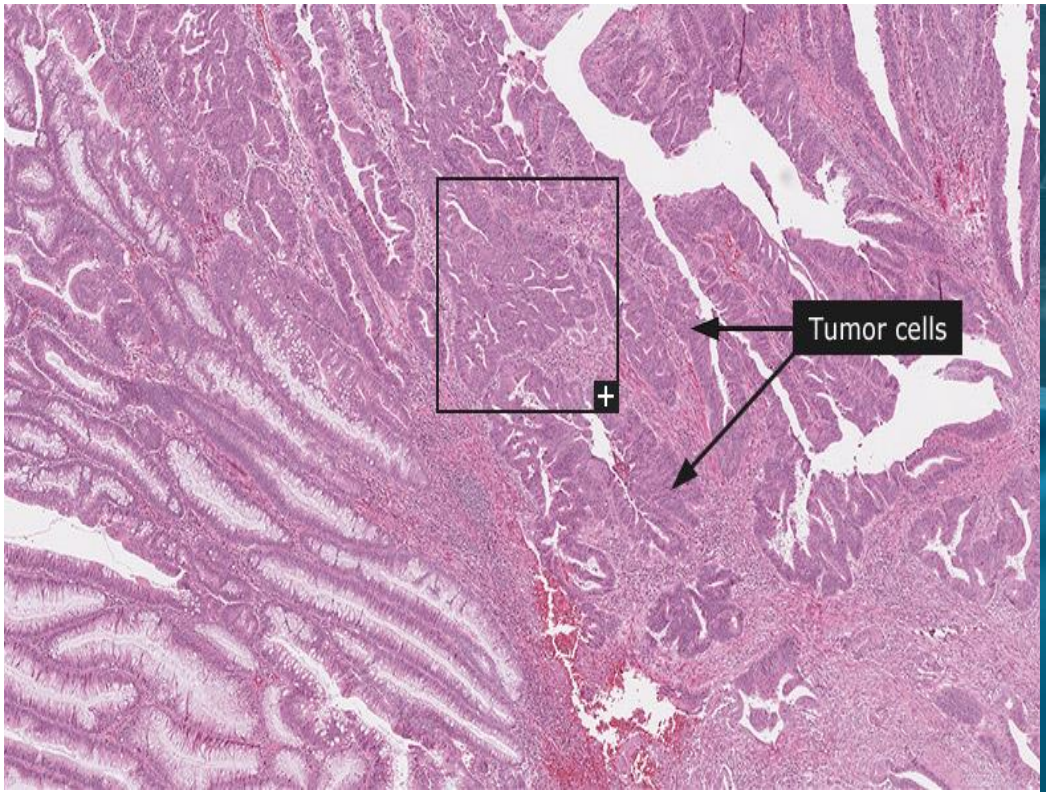
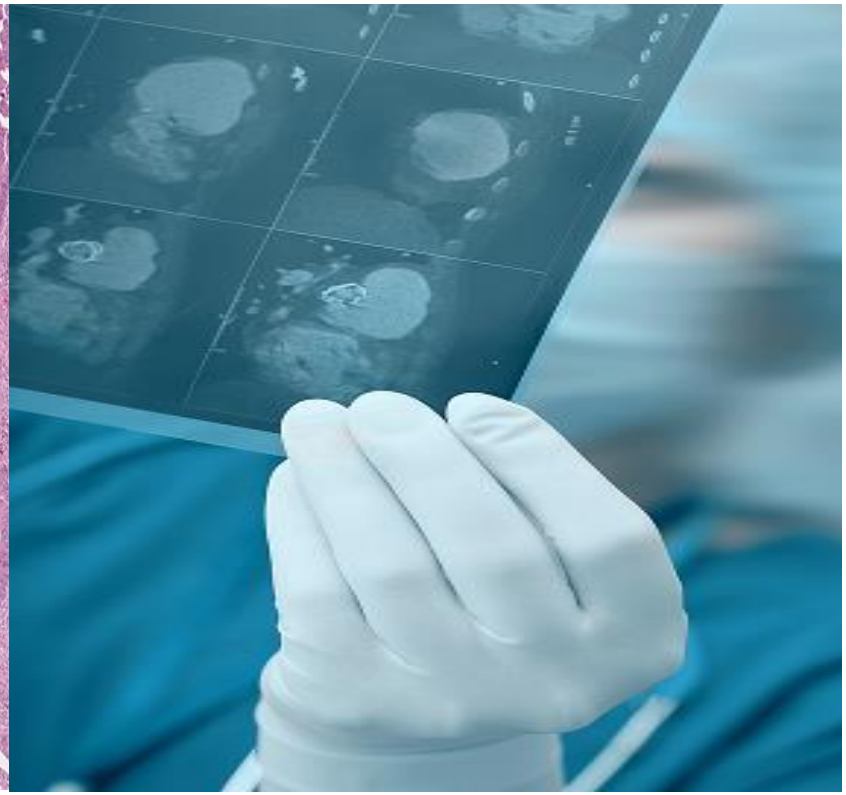
KCE REPORT 260CS

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

SUMMARY

GUIDELINE ON THE MANAGEMENT OF RECTAL CANCER





KCE REPORT 260CS
GOOD CLINICAL PRACTICE

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SUMMARY

GUIDELINE ON THE MANAGEMENT OF RECTAL CANCER

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FOREWORD

The first KCE guideline on rectum cancer already dates from 2007. It was developed in collaboration with, and in support of the PROCARE program. PROCARE was initiated by an inspired group of clinical experts aiming at improving clinical care for rectum cancer patients. In their preface, our predecessors stated: “PROCARE is unique and the first initiative of it’s kind in Belgium. KCE is proud to support this innovative program, in collaboration with the Cancer Registry and RIZIV/INAMI. Eventually, the patient’s outcomes will improve. And that is the essence of good cancer care.”

Meanwhile quality indicators, registration and feedback have been implemented. Naturally, eight years after its publication, an update of the 2007 guideline became necessary. A comprehensive update of the guideline was explicitly requested but not feasible due to limited resources. After deliberation, three research questions that urgently needed an update were selected.

The first two questions, on optimal staging and feasibility of local resection in early stages are very real since the screening programs are now well implemented in all regions of the country. As a consequence, an increasing number of cancers will be discovered in an early stage and it is crucial to prevent unnecessary mutilation without compromising the patient’s chances for survival. The third question on adjuvant therapy could unfortunately not be answered due to lack of evidence.

Throughout the whole research project, the expertise of the clinical specialists was of great value. Thanks to their thorough and realistic advices our recommendations undoubtedly became more convincing for clinical colleagues. We therefore wish to express our sincere gratitude and appreciation for their rich contribution. After all, a guideline is only valuable and useful when it is accepted and implemented in the field.

Christian LÉONARD
Deputy general director

Raf MERTENS
General director

SUMMARY

TABLE OF CONTENTS

ABBREVIATIONS

ABBREVIATION	DEFINITION
CT	Computed tomography
ERUS	Endorectal ultrasound
GDG	Guideline Development Group
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
MRI	Magnetic resonance imaging
PROCARE	Project on Cancer of the Rectum
RCT	Randomized Controlled Trial
SR	Systematic review
TAE	Transanal excision
TEM(S)	Transanal endoscopic microsurgery

1. INTRODUCTION AND SCOPE OF THE GUIDELINE

Despite a decrease in incidence of colorectal cancer following screening and detection programs it remains the third most common cancer in men and the second in women.[1] The Surveillance, Epidemiology and End Results (SEER) database reports an incidence of 42.4 per 100 000 men and women per year based on age-adjusted 2008-2012 cases and deaths. The number of deaths was 15.5 per 100 000 men and women per year during the same time period.[2] For the year 2012 the Belgian Cancer Registry reported 970 women and 1 494 men with rectal cancer.[3]

The Belgian Health Care Knowledge Center (KCE) published a guideline on good clinical practice for rectal cancer in 2007,[4] followed by two reports on quality indicators in 2008[5] and 2011.[6] The 2007 KCE guideline on rectal cancer[4] coincided with a 'Project on Cancer of the Rectum' (PROCARE) including a registry operated by the Belgian Cancer Registry for cases and quality indicators[a].

Since the search date of the guideline was 2006 it was necessary to update recommendations.

In order to update the 2007 guideline[4] a scoping meeting was held with a large group of experts on February10th, 2015. Due to resource constraints, it was decided to limit the update to three research questions (RQ). The selection of RQs was made by the members of the Guideline Development Group (GDG), representatives of professional organizations and patient representatives (the Scoping Group).

Three RQs were retained.

1. RQ1: What medical imaging technique should be used for optimal staging?
2. RQ2: Can local resection or transanal endoscopic microsurgical resection be performed instead of radical resection without compromising the outcome in rectal cancer patients (T1, T2)?
3. RQ3: When should adjuvant chemotherapy be considered in patients who received neoadjuvant chemo(radio)therapy?

2. TARGET USERS

This guideline is intended to be used by all care providers involved in the management of patients with rectal cancer, including general practitioners, oncologists, gastroenterologists, surgeons, radiologists, pathologists and nurses. It should also be of interest to patients and their families, hospital managers and policy makers.

[a] http://procare.kankerregister.be/procare.aspx?url=Procare_statistics

3. METHODS

3.1. Systematic review of the literature

For each RQ a search for systematic reviews (SR) was conducted in MEDLINE, Embase and The Cochrane Library (Cochrane Database of Systematic Reviews, DARE and HTA database). If a recent high quality SR was available, a search for primary studies published after the search date of the review was performed in MEDLINE, Embase and CENTRAL. If no SR was available, primary studies were searched for in the databases. Members of the GDG were also consulted to identify additional relevant evidence that may have been missed by the search. Only articles published in English, German, Dutch and French were included.

For the diagnostic question, SRs, diagnostic accuracy studies and randomized controlled studies (RCTs) were searched; for the other research questions, SRs, RCTs or comparative observational studies were searched. The quality appraisal was performed using the AMSTAR checklist for SRs, Cochrane Collaboration's tool for assessing risk of bias for RCTs and comparative observational studies, and the QUADAS-2 checklist for diagnostic accuracy studies. Study limitations in observational studies were evaluated using GRADE criteria.

3.2. Patient preferences

Evidence-based practice involves decision-making, based not only on efficacy and effectiveness but also on patient characteristics and preferences. A patient with rectal cancer is faced with difficult and complex decisions that have a crucial impact on health-related quality of life and survival. Studies have shown that medical professionals and patients often place different emphasis on treatment end-points, including side-effects, and point out a gap between what both parties regard as most important.[7]

For this topic, a systematic search for SRs and meta-analyses on patient preferences for all colorectal cancers was performed, because the topic is relatively new and a search for patient preferences on rectal cancer alone would be too limited. Searches were performed on March 27th, 2015 in the following databases: Medline (through Ovid), Embase and the Cochrane Database of Systematic Reviews. These results were used to complete the GRADE assessment for each RQ, if applicable.

3.3. Formulation of recommendations

Based on the retrieved evidence, the first draft of recommendations was prepared by the KCE research team. This draft, along with the evidence tables, was circulated to the GDG prior to the face-to-face meetings. Based on the discussions with the GDG, a second draft of the recommendations was prepared and once more circulated to the GDG for final approval.

To determine the level of evidence and strength of each recommendation, the GRADE methodology was followed (Tables 1 and 2). The strength of a recommendation depends on the balance between all desirable and all undesirable effects of an intervention (i.e., net clinical benefit), the quality of available evidence, values and preferences, and the estimated cost (resource utilization). For this guideline, no formal cost-effectiveness study was conducted. Due to current methodological limitations of the GRADE system for diagnostic tests, GRADE was not applied to the recommendations for diagnosis (RQ1).

The recommendations prepared by the GDG were submitted to key representatives of the relevant stakeholders (see colophon), who acted as external reviewers of the draft guideline.

Finally, as part of the standard KCE procedures, the current guideline was reviewed prior to its publication by two independent validators (cf. names in the colophon).

Declarations of interest of GDG members, validators and stakeholders were formally recorded and listed in the colophon.

Table 1 – Levels of evidence according to GRADE[$]

Quality level	Definition	Methodological Quality of Supporting Evidence
High	We are very confident that the true effect lies close to that of the estimate of the effect	RCTs without important limitations or overwhelming evidence from observational studies
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies
Low	Our confidence in the effect estimated is limited: the true effect may be substantially different from the estimate of the effect	RCTs with important limitations or observational studies or case series
Very low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect	

[$] *Balshem H, Helfand M, Schunemann HJ, Oxman AD, Kunz R, Brozek J, et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol. 2011;64(4):401-6.*

Table 2 – Strength of recommendations according to GRADE[$]

Grade	Definition
Strong	The desirable effects of an intervention clearly outweigh the undesirable effects (the intervention is to be put into practice), or the undesirable effects of an intervention clearly outweigh the desirable effects (the intervention is not to be put into practice).
Weak	The desirable effects of an intervention probably outweigh the undesirable effects (the intervention probably is to be put into practice), or the undesirable effects of an intervention probably outweigh the desirable effects (the intervention probably is not to be put into practice).

[$] *Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A, et al. Going from evidence to recommendations.[Erratum appears in BMJ. 2008 Jun 21;336(7658): doi:10.1136/bmj.a402]. BMJ. 2008;336(7652):1049-51.*

4. CLINICAL RECOMMENDATIONS

The details of the evidence used to formulate the recommendations below are available in the scientific report and its supplements. The tables follow the same sequence as the chapters of the scientific report.

4.1. What medical imaging technique should be used for optimal staging?

This section addresses the role of magnetic resonance imaging (MRI), computed tomography (CT) and endorectal ultrasound (ERUS) in T staging and N staging of rectal cancer. M staging was not included because primary studies usually pool colon and rectum cancer, and an extensive review on this issue was presented in the KCE report on colon cancer.[8] As it is important that MRI is conducted in a proper way, consensus-based standards on how to conduct MRI were also put forward by the GDG. A protocol for staging using MRI was proposed by a smaller group of clinicians specialized in MRI and can be found in the Scientific Report.

Recommendations

- **Perform MRI to assess the risk of local recurrence, as determined by anticipated circumferential resection margin, tumour and lymph node staging and extramural venous invasion, in all patients with rectal cancer, unless it is contraindicated.**
- **Offer endorectal ultrasound to patients with rectal cancer in cases where MRI shows disease amenable to local excision, additional clinical information is needed or MRI is contraindicated.**

4.2. Can local resection or transanal endoscopic microsurgical resection be performed instead of radical resection without compromising the outcome in rectal cancer patients (T1, T2)?

Stage I rectal tumours extend either into the submucosa (T1) or into, but not beyond, the muscularis propria (T2), without any evidence of spread into the lymph nodes (N0) nor metastases (M0). Radical resection, which includes the mesorectum and thereby resects lymphatic tissue, is considered curative since a five year cancer specific survival of >95% is observed.[9] The subject is controversial but recent guidelines do not recommend local resection, transanal excision (TAE) or transanal endoscopic microsurgical resection (TEMS) instead of a radical resection in patients with Stage I rectal cancer. In current practice however, indication for local resection is based on risk stratification. The strongest independent predictors are lymphatic invasion, submucosal invasion ≥ 1 mm, budding and poor histological differentiation.[10] The overall risk for nodal involvement in pT1 rectal cancer is about 15%[11] and was observed in 3% of pT1sm1, 8% of pT1sm2 and 23% of pT1sm3 lesions.[12]

Obviously, local resection of any type carries an inherent oncologic risk as nodes are not removed. It is therefore unclear whether more invasive radical resection should be advised in those cases. To address this uncertainty we undertook a SR of the clinical studies to answer the question whether local resection (any type, TAE or TEMS) can be performed instead of a radical resection without compromising the outcomes. Critical outcomes were disease free survival, metastasis free survival, local recurrence free survival, overall survival and quality of life.

Recommendations	Level of Evidence	Strength of Recommendation
In patients with T2 rectal cancer, radical resection should be performed.	**Very low**	**Strong**
In patients with pT1 sm1 rectal cancer confirmed by the pathology report and staging, 'en bloc' complete local resection is considered sufficient. Discussion by a multidisciplinary team and adequate surveillance is mandatory.	**Expert consensus**	**Strong**
In patients with pT1 sm2 sm3 rectal cancer, a multidisciplinary discussion is mandatory and if no contraindication, radical surgery is recommended.	**Expert consensus**	**Strong**

4.3. When should adjuvant chemotherapy be considered in patients who received neoadjuvant chemo(radio)therapy?

The aim of this RQ is to assess the effect of adjuvant chemotherapy in patients with rectal cancer who were previously treated with neoadjuvant chemoradiotherapy and surgery, compared with no adjuvant chemotherapy in terms of overall survival, disease free survival, and quality of life.

Recommendation

- **Based on the current available evidence, no recommendation can be made in favour or against the use of adjuvant chemotherapy in patients with rectal cancer who received chemo(radio)therapy.**

5. PATIENTS PREFERENCES

A recent review concluded that regarding adjuvant therapy "most patients judge a moderate survival benefit to be sufficient to make adjuvant therapy worthwhile". On the contrary the review concludes that patients "are willing to trade a potential reduction in life expectancy and survival to avoid unwanted surgical sequelae".[13] Another review concluded that "although colorectal cancer patients do have preferences regarding different treatment options and outcomes, these are not homogeneous and seem to also depend on personal factors, including age and gender". Additionally, the review concludes that "despite the existence of preferences the majority of patients prefer to take a passive role in the decision-making process, which in part may be explained by the severity of the disease".[14] The choice of a treatment should not only consider medical aspects but also patient preferences. Patients should always receive timely and comprehensive information about treatment options, advantages and disadvantages.

6. IMPLEMENTATION AND UPDATING OF THE GUIDELINE

6.1. Implementation

6.1.1. Multidisciplinary approach and patient-centred care

In this report we focused on the effectiveness of specific medical interventions, without taking into account the organization of health services. In clinical practice, a multidisciplinary approach by different health care professionals should be encouraged. This approach should not only cover the medical needs of the patient but also their psychosocial needs.

The choice of a treatment should not only consider medical aspects but also individual patient preferences. Patients should always receive timely and comprehensive information about treatment options, advantages and disadvantages.

6.1.2. Barriers and facilitators for implementation

During the stakeholders meeting, the potential barriers and facilitators related to the use of this guideline were discussed. In this particular case a significant barrier is the termination of the PROCARE program in December 2014. However the College of Oncology will pursue a new PROCARE plan and pursue further registration in the National Cancer Registry. In addition the Belgian Society of Radiology (http://www.bsr-web.be/) will publish the MRI protocol and organize training.

6.1.3. Actors of the implementation of this guideline

The implementation of this guideline will be facilitated/conducted by the College of oncology and the professional associations involved. Dissemination of this guideline is intended by scientific and professional organisations.

6.2. Monitoring the quality of care

This guideline should be considered as a starting point to develop quality improvement programs that targets all caregivers concerned. It can be used as a tool to support health policies to improve the quality of care, e.g. through the support of actions to increase caregivers' awareness and to improve their practice, or through the development (or revision) of sets of process and outcome quality indicators. KCE previously recommended to set up an integrative quality system in oncology, covering the development and implementation of clinical practice guidelines, the monitoring of the quality of care with quality indicators, feedback to health care providers and organizations and targeted actions to improve the quality if needed. In the present case a protocol for MRI was developed by the GDG.

6.3. Guideline update

In view of the rapidly evolving evidence, guidelines should be updated every five years. Important new evidence would become available in the meantime, this should be taken into consideration. Potential interest for groups of health practitioners is also considered in this process. This appraisal should lead to a decision on whether to update a guideline or specific parts of it to ensure the recommendations stay in line with the latest scientific developments.

POLICY RECOMMENDATION[b]

Recommendation to the medical community:

- **Guidance for adequate use of MRI in the initial evaluation of patients with rectal cancer should be developed.**

[b] The KCE has sole responsibility for the recommendations.

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COLOPHON

Title:	Guideline on the management of rectal cancer – Summary
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