

High practice variation in risk stratification, baseline oncological staging, and follow-up strategies for T1 colorectal cancers in the Netherlands



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ABSTRACT

Background and study aims Based on pathology, locally resected T1 colorectal cancer (T1-CRC) can be classified as having low- or high-risk for irradicality and/or lymph node metastasis, the latter requiring adjuvant surgery. Reporting and application of pathological high-risk criteria is likely variable, with inherited variation regarding baseline oncological staging, treatment and surveillance.

Methods We assessed practice variation using an online survey among gastroenterologists and surgeons participating in the Dutch T1-CRC Working Group.

Results Of the 130 invited physicians, 53% participated. Regarding high-risk T1-CRC criteria, lymphangio-invasion is used by 100%, positive or indeterminable margins by 93%, poor differentiation by 90%, tumor-free margin ≤ 1 mm by 78%, tumor budding by 57% and submucosal invasion $> 1000 \mu\text{m}$ by 47%. Fifty-two percent of the respondents do not perform baseline staging in locally resected low-risk T1-CRC. In case of unoperated high-risk patients, we recorded 61 different surveillance strategies in 63 participants, using 19 different combinations of diagnostic tests. Endoscopy is used in all schedules. Mean follow-up time is 36 months for endoscopy, 26 months for rectal MRI and 30 months for abdominal CT (all varying 3–60 months).

Conclusion We found variable use of pathological high-risk T1-CRC criteria, creating risk for misclassification as low-risk T1-CRC. This has serious implications, as most participants will not proceed to oncological staging in low-risk patients and adjuvant surgery nor radiological surveillance is considered. On the other hand, oncological surveillance in patients with a locally resected high-risk T1-CRC who do not wish adjuvant surgery is highly variable emphasizing the need for a uniform surveillance protocol.

Introduction

Due to implementation of colorectal cancer screening programs, detection of submucosal invasive colorectal cancers (T1-CRCs) has increased [1,2], with additional opportunities for local excisions.

Based on several pathological criteria, T1-CRCs can be divided into low risk or high risk for residual intramural cancer or lymph node metastases (LNM). However, there is variation between models using various pathological criteria contributing to a high-risk status (► **Table 1**). Availability of these significantly different models could lead to practice variation. In high-risk T1-CRC, adjuvant oncological resection should be discussed

► **Table 1** Available pathological risk criteria and the use in various definitions.

	Lymphan- gio-inva- sion	Poor or signet cell dif- ferentiation	Grade 2–3 tumor budding	≥ 1 mm submucosal invasion	Resection margin not free or inde- terminable	Margin free, but tumor-free margin < 1 mm
Dutch guideline [11]	x	x			x	uncertain
Scottish model [12]	x				x	
French model [13]	x				x	x
Japanese guideline [14]	x	x	x	x	x	

"x" confers high-risk status.

with the patient. On the other hand, in low-risk T1-CRC, baseline oncological staging is often considered unnecessary, as is additional oncological resection, due to a very low recurrence rate of 0.8% [3–5]. As a consequence, (mis)classification as low-risk has important implications for the patient.

In patients with high-risk T1-CRC, there is an increasing trend towards "wait and see" with surveillance chosen by the patient on the basis of shared decision-making. This is because risk of residual cancer in the bowel wall and lymph node metastasis is 3% to 8% [3, 6–8] and 12% to 16% [4–6], respectively. Accordingly, more than 84% of these patients have additional surgery without clear benefit while being exposed to surgical risks of morbidity (20%–30%), ostomy (5%–10%), and mortality (2.5%) [9, 10]. However, no guideline is available with advice on a specific oncological surveillance strategy as an alternative for these patients [11].

Various definitions and applications of pathological high-risk criteria may contribute to practice variation with potential consequences for treatment, baseline oncological staging, and surveillance of patients after local excision of T1-CRC. We investigated variations in personal daily practice about T1-CRC among dedicated gastroenterologists and surgeons.

Methods

Survey development and participants

We developed a structured online survey regarding current clinical practice of patients after local excision of a T1 CRC, with the focus on four main topics: use of pathological high-risk criteria, baseline oncological staging before local excision of suspected T1-CRC, oncological staging after local excision and surveillance of unoperated high-risk T1-CRC patients. The patient's situation was only globally addressed in the survey, for instance as a hypothetical patient, being fit for surgery, but we could not focus on individual patient details as this would render the survey impractical to fill out and difficult to analyze. This study was not intended to provide statistics on the type of local excision and the occurrence of rectal versus colonic locations. We asked the participants to answer the questions according to their own habits, which usually included counseling of the multidisciplinary oncological meeting. The survey consisted of 15 multiple choice and two open questions with exam-

ples of clinical cases (supplementary Appendix), based on guidelines and gastroenterologist's expert opinion.

The survey was published as a Google Form between January and February 2019 and tested and improved by dedicated gastroenterologists for applicability, clarity and content. We collected data on demographics of participants and their institutes, but no data which could identify the participant or the center of employment to guarantee anonymity. Participants received an e-mail with a cover letter and a link to the online survey, with a reminder after 2 weeks. Responses were accepted up to 4 weeks from the initial e-mail. Participants comprised all gastroenterologists and surgeons who are members of the Dutch T1 CRC Working group. This is a group of Dutch specialists in the field of T1 CRC, with joint research efforts and regular meetings.

Because the survey was based on voluntary participation and information disclosure, the study protocol did not need to undergo a formal review by an Ethics Committee. Survey return was taken as consent.

Follow-up investigations were grouped as: carcinoembryonic antigen (CEA); endoscopy; perirectal imaging (rectal endo-ultrasonography and magnetic resonance imaging [MRI]); abdominal lymph node imaging (abdominal computed tomography [CT] scan); liver imaging (abdominal CT scan or liver ultrasound) and lung imaging (chest x-ray and thoracic CT scan).

Statistics

We used descriptive statistics to analyze the results using counts and proportions for categorical data and means and standard deviations for continuous variables. Missing values were not imputed. The answers to most questions regarding stage determination and surveillance were tested against the type of hospital, specialty, age group and gender using chi-square. Statistical analysis was performed with IBM SPSS version 25.

Results

The survey was sent to 130 physicians and returned by 69 (53% participation grade). ► **Table 2** lists baseline characteristics of the participants. Eighty-seven percent of the participants were gastroenterologists (60/69), 16% were employed in an academic center. Ninety-six percent of physicians reported dis-

► **Table 2** Demographic characteristics of the participants.

Variable	n (%)
Specialist	
▪ Surgeon	8 (12%)
▪ Gastroenterologist	60 (87%)
▪ Physician Assistant gastroenterology	1 (1%)
Type of hospital	
▪ University hospital	11 (16%)
▪ General hospital, <6 gastroenterologists	6 (9%)
▪ General hospital, 6–10 gastroenterologists	34 (49%)
▪ General hospital, >10 gastroenterologists	16 (23%)
▪ Private hospital	2 (3%)
Sex	
▪ Male	49 (71%)
▪ Female	20 (29%)
Age group	
▪ 30–40 years	21 (30%)
▪ 40–50 years	29 (42%)
▪ 50–60 years	15 (22%)
▪ >60 years	4 (6%)

curring every patient with a T1 CRC in a regular multidisciplinary oncological meeting. Only 21 of 69 (30%) of the physicians reported having a local T1 CRC protocol available in their hospital.

Risk stratification

Pathological criteria used for low-risk or high-risk classification are shown in ► **Fig. 1**. Undisputed criteria for high risk in the Netherlands are lymphovascular invasion, a resection margin that is not free or indeterminable, and poor differentiation or presence of signet cells [12]. Eighty-one percent of the respondents used all three criteria. Tumor budding is not currently standardly reported by pathology labs in the Netherlands and was used by half of the respondents. Contribution of both a tumor-free margin ≤ 1 mm and invasion depth to high-risk status are disputed and were less often used. Fifty percent of academic participants did not use a tumor-free margin ≤ 1 mm as a high-risk criterion, whereas 80% of non-academic specialists did ($P = 0.044$). The other criteria did not show significant differences between academic and non-academic specialists.

Only twelve (17%) of the participants used the exact criteria from the Dutch Guideline to determine high risk (► **Table 1**) [12]. The Scottish and French models [13, 14] were used by none of the participants, the Japanese guideline [15] by five (7.2%).

Criterion	
Lymphovascular invasion	100%
Resection margin not free/indeterminable	93%
Poorly differentiated or signet-cell containing adenocarcinoma	88%
Free resection margin ≤ 1 mm	75%
Tumor budding grade 2 or 3	55%
Submucosal invasion depth $> 1000 \mu\text{m}$ or sm3 invasion	49%

► **Fig. 1** Heat map of pathology criteria used by respondents to define risk status.

Baseline oncological staging

In the example case of a macroscopically recognized carcinoma during endoscopy, 13 (19%) would perform oncological staging prior to local excision, whereas five (7%) would only do so in case of rectal localization.

Of those who would not perform a priori staging (51 respondents), 53% would stage every patient if pathology confirms a T1-CRC (low-risk and high-risk), while 47% would do so only in case of one or more high-risk features.

When confronted with an unexpected carcinoma (“oops”-carcinoma) in a locally removed polyp, 49% would only stage in case of high-risk features, the remainder in every case. We examined associations between type of hospital, specialty, sex, age groups, and baseline staging practices. No statistically significant associations were found, although it was remarkable that staging of suspected lesions before embarking on endoscopic resection was not performed by any of the nine academic respondents. Taken together, approximately 50% will not perform baseline oncological staging in case of locally resected low-risk T1-CRC.

Surveillance after locally resected high-risk T1 CRC in patients who refrain from additional surgery

Details about surveillance strategies were returned by 63 participants; most participants (84%) indicated using the same surveillance strategies after local excision of T1 CRC by submucosal dissection or full-thickness local resection techniques (such as trans-anal endoscopic microsurgery, or endoscopic full-thickness resection). On closer look, we encountered 61 different schedules, with 19 different combinations of diagnostic tests. Endoscopy is used in all schedules. Endoscopic surveillance has a median duration of 48 months (IQR 24–48 months). Radiological surveillance (including rectal endoultrasonography) has a median duration of 36 months (IQR 12–48 months), and CEA monitoring time has a median duration of 48 months (IQR 24–48 months). A heat map of the time points and follow-up investigations is shown in ► **Fig. 2**. Significant differences

Month	3	6	12	18	24	30	36	42	48	54	60
Endoscopy	67%	76%	83%	33%	52%	13%	37%	11%	46%	2%	11%
Liver imaging	19%	49%	65%	21%	56%	6%	41%	6%	41%		14%
Perirectal imaging	35%	49%	56%	22%	38%	11%	29%	8%	25%	2%	13%
Serum CEA	29%	48%	52%	29%	45%	14%	38%	11%	37%	2%	9%
Lung imaging	9%	27%	27%	6%	27%	2%	25%	2%	23%		6%
Abdominal lymph node imaging	17%	24%	38%	10%	25%	2%	16%	3%	19%		10%

Investigation targets. Liver imaging: abdominal CT and/or ultrasound; perirectal imaging: pelvic MRI or rectal endosonography; lung imaging: chest X-ray or CT thorax; Abdominal lymph node imaging: abdominal CT.

► **Fig. 2** Heat map of investigation targets.

between academic and non-academic respondents are summarized in ► **Fig. 3**. In general, more follow-up investigations are performed by academic specialists, with higher use of CT-scans.

Most participants would proceed to surgery ($n=50$) when local recurrence or suspicious lymphadenopathy is demonstrated during follow-up, six of them suggested also performing this in case of limited metastasis, and two respondents in case of increasing CEA levels.

Discussion

In this study, considerable practice variation among Dutch hospitals was observed in risk classification used to predict lymph node metastasis and local recurrence, on baseline oncological staging and especially on follow-up after local excision of a T1 CRC with high-risk features, but while refraining from performing surgery.

It is well known that pathological criteria that contribute to a high-risk status of a locally resected T1-CRC are subject to interobserver variation by pathologists [16,17]. Indeed, a substantial percentage of these lesions are reclassified as high risk after revision by an expert pathologist [18]. However, in the Netherlands, a decision about T1-CRC risk status is made by the treating physician, and not by the pathologist, who merely reports on presence or absence of these risk factors. Thus, it is important to understand how treating physicians deal with this information. In our survey, directed at specialists with special interest in T1-CRC, we encountered considerable practice variation.

Previous studies show conflicting results concerning the true value of submucosal invasion depth $\geq 1000\mu\text{m}$ and a tumor-free margin $< 1\text{ mm}$ as a high-risk pathological factor [8, 19–23]. Indeed, this survey found that submucosal invasion depth $\geq 1000\mu\text{m}$ is used by 49% of physicians and a tumor-free margin $< 1\text{ mm}$ by 75%. Although lymphangio-invasion, poor differentiation, and a positive or indeterminable resection margin are undisputed risk factors [6, 12, 19–22, 24–26], 19% of respondents do not use all three criteria. In the literature, high-

Investigation	Time point	Academic	Non-academic	P value
Endoscopy	18	67%	28%	0.022
Pelvic MRI	42	22%	2%	0.008
	48	56%	15%	0.005
CT abdomen	24	56%	20%	0.025
	30	11%	0%	0.014
	42	22%	0%	0.000
	48	44%	15%	0.036
CT thorax	24	22%	2%	0.008
	30	11%	0%	0.014
	36	22%	2%	0.008
	42	11%	0%	0.008
	48	22%	2%	0.008
X-ray thorax	18	22%	0%	0.000
CEA	42	33%	7%	0.019
Perirectal imaging	48	56%	20%	0.025
Liver imaging	24	89%	50%	0.030
	42	22%	4%	0.035
	48	78%	35%	0.016
Lung imaging	6	56%	22%	0.034
	18	33%	2%	0.000
	24	56%	24%	0.034
	30	11%	0%	0.013
	42	11%	0%	0.013
	48	56%	18%	0.014

Time point is in months. MRI, magnetic resonance imaging; CT, computed tomography; CEA, carcinoembryonic antigen

► **Fig. 3** Significant differences between academic and non-academic specialists in surveillance time points and investigations

grade tumor budding is a strong risk factor as well [19–21, 26], but this criterion was used by half of the respondents. This is probably explained by the fact that, in the Netherlands, reporting of tumor budding is currently not obligatory.

Taken together, incomplete use of pathological high-risk factors carries the risk of wrong low-risk classification of a locally resected T1-CRC.

Misclassification as low-risk T1-CRC has important consequences. Our study showed that half the physicians do not perform baseline oncological staging in these patients (which is theoretically defensible as risk of metastasized disease in true low-risk T1-CRC is only 0.8% [3–5]).

In addition, the option of adjuvant surgical resection will not be discussed in low-risk T1-CRC and surveillance is only performed according to the current polyp surveillance guideline using merely colonoscopy [27].

In the second part of the survey, we addressed surveillance practices of physicians in patients after local excision of a high-risk T1-CRC without adjuvant surgery.

We found enormous practice variation among physicians, which underscores the need for a uniform surveillance protocol.

We recognize, however, that such a protocol is difficult to conceive. Literature on surveillance of unoperated high-risk T1-CRC is scanty and retrospective. Asian studies describe use of CEA and thoraco-abdominal CT every 6 months for 3 years, thereafter every 12 months for 2 years, combined with annual colonoscopy [4, 28]. A less invasive strategy with CEA, CT of the chest, abdomen, and pelvis, and a colonoscopy every year for 5 years was used by Kouyama et al [25]. However, the benefit of these surveillance strategies has not been established. In particular, baseline radiological oncological staging of lymph nodes in colorectal cancer is hampered by moderate sensitivity and specificity of approximately 75% [29–36], and there exists no literature on the benefits of sequential imaging over time.

Our study has some limitations.

1. Only physicians participating in the T1-CRC working group were invited, which may create response bias towards experts in the field of T1-CRC. Accordingly, the reader should be aware of the fact that application of pathological high-risk criteria may be more incomplete in less involved physicians.
2. It should be noted that only some of the questions addressed the rectum and colon separately. Although this had no influence on our findings regarding application of pathological high-risk criteria and oncological staging, surveillance strategies differed between these tumor locations.
3. Each respondent provided his or her own opinion. Although reflecting the usual outcome of the multidisciplinary oncology meetings of the local hospital was encouraged, it is possible that the actual advice from a multidisciplinary meeting would have been different from the answers provided by the respondents. Nevertheless, the answers do reflect an overview of the respondents' personal habits.
4. We limited patient details in our questionnaires to the most important to improve generalization, for instance “fit for

surgery,” while realizing that patient-specific additional factors will play a role in daily practice.

Conclusion

In conclusion, we encountered considerable practice variation with regard to use of pathological high-risk T1-CRC criteria, with potential misclassification as low-risk T1-CRC. This has serious consequences, as a lot of these patients will not have baseline oncological staging and counseling about adjuvant surgery, or radiological surveillance. For the growing group of patients who do not wish to have adjuvant surgery in case of locally resected high-risk T1-CRC, a standardized oncological surveillance protocol is urgently needed.

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Competing interests

The authors declare that they have no conflict of interest.

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