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ORIGINAL CONTRIBUTION

Interrater Agreement of Height Assessment by Rigid Proctoscopy/Rectoscopy for Rectal Carcinoma

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BACKGROUND: Some guidelines for rectal carcinoma consider 12 cm, measured by rigid endoscopy, to be the cutoff tumor height for optional neoadjuvant chemoradiation therapy. Measuring differences of only a few centimeters may predetermine the choice of further therapy. However, rigid endoscopy may exhibit similar operator dependence to most other clinical examination methods.

OBJECTIVES: Evaluation of concordance of rigid rectoscopic tumor height measurements performed by 4 experienced examiners, 2 measuring with patients in the lithotomy position and 2 in the left lateral position. Assessment of tumor palpability and distance of the anal verge to the anocutaneous line were also evaluated.

DESIGN: This study used a prospective observational design.

SETTING: This study was conducted at an academic teaching hospital that is a referral center for colorectal surgery.

PATIENTS: There were 50 patients, of whom 35 were men (70%). The median age was 72.5 years (53–88 years).

MAIN OUTCOME MEASURES: Interrater agreement of tumor height assessment and tumor height of less than or greater than the 12-cm height limit.

RESULTS: With an intraclass correlation coefficient of 0.947 (95% CI, 0.918–0.967, $p < 0.001$), interrater reliability of tumor height assessment was statistically rated "excellent." Despite this, in 26% of patients, there was no agreement regarding the allocation of the tumor <12- or >12-cm height limit. Furthermore, there was also considerable disagreement concerning tumor palpability and the distance of the anal verge to the anocutaneous line. Patient positioning was not found to influence results.

LIMITATIONS: Single-center study.

CONCLUSIONS: Rigid rectal endoscopy may not be a sound pivotal basis for the consideration of optional chemoradiation therapy in rectal carcinoma. Application of a universally valid height limit ignores biological variability in body frame, gender, and acquired pelvic descent. Eligibility for neoadjuvant therapy should not rely on height measurements alone. Uniform MRI or CT imaging protocols, based on agreed upon terminology, including factors such as tumor height relative to the pelvic frame and peritoneal reflection, may be an important diagnostic addition to such a decision. See **Video Abstract**.

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ACUERDO ENTRE EVALUADORES EN LA EVALUACIÓN DE LA ALTURA MEDIANTE PROCTO-/ RECTOSCOPIA RÍGIDA PARA EL CARCINOMA DE RECTO

ANTECEDENTES: Algunas guías para el carcinoma de recto consideran que 12 cm, medidos mediante endoscopia rígida, es la altura de corte del tumor para la quimiorradiación neoadyuvante opcional. Por lo tanto, una diferencia de medición de sólo unos pocos

centímetros puede predeterminar la elección de una terapia adicional. Sin embargo, la endoscopia rígida puede presentar una dependencia del operador similar a la de la mayoría de los demás métodos de examen clínico.

OBJETIVOS: Evaluación de la concordancia de las mediciones de la altura del tumor rectoscópico rígido realizadas por cuatro examinadores experimentados, dos en litotomía y dos en posición lateral izquierda. También se evaluó la evaluación de la palpabilidad del tumor y la distancia del borde anal a la línea anocutánea.

DISEÑO: Estudio observacional prospectivo.

LUGAR: Hospital universitario, centro de referencia para cirugía colorrectal.

PACIENTES: 50 pacientes, 35 varones (70%), mediana de edad 72,5 años (53-88 años).

PRINCIPALES MEDIDAS DE RESULTADOS: Acuerdo entre evaluadores en la evaluación de la altura del tumor y la asignación del tumor por debajo o más allá del límite de altura de 12 cm.

RESULTADOS: Con un coeficiente de correlación intraclase de 0,947 (IC del 95%: 0,918-0,967, p < 0,001), la confiabilidad entre evaluadores de la evaluación de la altura del tumor se calificó estadísticamente como "excelente". A pesar de esto, en el 26% de los pacientes no hubo acuerdo sobre la asignación del tumor por debajo o por encima del límite de 12 cm de altura. Además, también hubo un considerable desacuerdo con respecto a la palpabilidad del tumor y la distancia del borde anal a la línea anocutánea. No se encontró que la posición del paciente influyera en los resultados.

LIMITACIONES: Estudio unicéntrico.

CONCLUSIONES: La endoscopia rectal rígida puede no ser una base sólida y fundamental para considerar la quimiorradiación opcional en el carcinoma de recto. La aplicación de un límite de altura universalmente válido obviamente ignora la variabilidad biológica en la constitución corporal, el género y el descenso pélvico adquirido. La elegibilidad para la terapia neoadyuvante no debe depender únicamente de las mediciones de altura. Los protocolos uniformes de imágenes por resonancia magnética o tomografía computarizada, basados en una terminología acordada, incluidos factores como la altura del tumor en relación con la estructura pélvica y la reflexión peritoneal, pueden ser una adición diagnóstica importante para tal decisión. *(Traducción—Yesenia Rojas-Khalil)*

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KEY WORDS: Interrater agreement; Rectal carcinoma; Rectoscopy; Rigid endoscopy; Staging.

In patients with rectal carcinoma, tumor height is a major criterion in deciding for or against optional neoadjuvant chemoradiation therapy. In most guidelines,[1,2] 12 cm is considered to be the height threshold, irrespective of body frame and gender. Additionally, guidelines vary in the definition of the point of reference for measurements (anal verge [AV][2,3] or anocutaneous line [ACL][1]) or are ambivalent.[4] To measure tumor height, rigid endoscopy (rectoscopy) is considered the criterion standard.[1,2] However, differences in measurements of only a few centimeters may have fundamental consequences for the choice of further therapy.

The almost exclusive reliance on rectoscopy assumes that rectoscopic measurements are universally valid and reproducible. So far, this assumption has not been proven. Rigid rectoscopy may exhibit a similar operator dependence, as do most other clinical examination methods, and may be influenced by examination conditions, such as positioning of the patient (left lateral [LL] position vs lithotomy [LIT] position).

This study prospectively assessed interobserver reliability and concordance of rectoscopic tumor height assessments by comparing measurements performed by 4 experienced examiners: 2 performing assessments of patients in the LIT position and 2 performing assessments of patients in LL position.

PATIENTS AND METHODS

This prospective observational study included 50 patients with histologically verified rectal carcinoma who were referred to our department's coloproctological outpatient clinic who were willing to participate. Patients with very low carcinoma (lower border <2 cm from the inner anal ring, n = 12), frail patients (patients with significant cognitive impairment or mobility limitation), and/or patients with very advanced disease (symptomatically obstructing tumor or clinically notable metastatic disease, n = 16) were excluded. The recruitment period was prolonged (May 2019–July 2022) because many patients (n = 37) were unwilling to undergo the demanding diagnostic protocol. Recruitment was further complicated by the fact that the study took place during the COVID-19 pandemic.

Within our usual clinical routine, patients referred with rectal carcinoma are seen by a senior surgeon (attending or senior attending level) who assesses tumor morphology and height by rectoscopy with the patient in the LL position, which is the standard patient positioning used in the department. Patients were examined after rectal cleansing with an enema. A repeat enema was administered in cases where a reliable assessment was deemed not possible due to fecal remnants in the rectum. Tumor height was defined as the distal border of the tumor.

Following informed consent, a repeat rectoscopy was then performed by a second senior surgeon. A second series of rectoscopies was performed by a third and fourth surgeon with the patient placed in the LIT position. Surgeons were asked to assess tumor palpability (by digital rectal examination [DRE]); to measure the distance of the ACL to the AV, which was routinely measured laterally; and to determine the distance of the lower border of the tumor from the AV. All examiners were blinded to the previous measurements, which were recorded by a study nurse. Standard 30-cm rigid rectoscopes (Karl Storz, Tuttlingen, Germany) were used for all examinations. Results were noted by a study nurse. A total of 7 surgeons participated in this study as examiners, all of whom were experienced colorectal surgeons familiar with rectoscopy. Examiners were assigned haphazardly according to availability, reflecting the clinical "real-life" scenario.

Statistical Analysis

Statistical analyses were performed using the software IBM SPSS Statistics version 28.0 (IBM, Armonk, NY). Data were described by standard statistics, using absolute and relative frequencies for categorical variables and median, range, and interquartile range (IQR) for continuous variables. The normal distribution of data was analyzed by the Kolmogorov-Smirnov test and Mann-Whitney *U* test and *t* tests were used as appropriate for continuous variables and the χ^2 test for categorical variables.

Reliability between measurements was shown with the ICC. A 1-way random model, single measures ICC (1.1) was used. ICC of <0.5 was interpreted according to Koo and Li as "poor," 0.5 to 0.75 as "moderate," >0.75 to 0.90 as "good," and >0.90 as "perfect" in terms of reliability.[5]

Kappa analysis was performed to determine the agreement between categorical variables. The κ value of ≤0.2 was evaluated as "slight," 0.21 to 0.4 as "fair," 0.41–0.6 as "moderate," 0.61 to 0.8 as "substantial," and >0.80 as a "perfect" fit according to Landis and Koch.[6] When evaluating the agreement between the different examiners, ≤2 mm deviation in the ACL–AV measurement and ≤1 cm in the assessment of tumor height were accepted. Tumor height measurements of ≥12 cm from the AV were considered to be in the proximal rectum and of <12 cm to be in the mid/distal rectum.

Patients with missing information for 1 variable were only excluded from the corresponding statistical analyses but not from the entire study. A probability value of <0.05 was considered statistically significant throughout the whole analysis.

Ethics Approval, Study Registration

This study was approved by the regional ethics committee (2017-282-f-S, Ethikkommission der Ärztekammer Westfalen-Lippe) and registered as a clinical study with the German national database (DRKS00012758, Deutsches Register Klinische Studien). In addition, this study was accredited by the German Cancer Society (registration number ST-D406, Deutsche Krebsgesellschaft).

RESULTS

A total of 50 patients were included in the study and had a median age of 72.5 years (53–88 y). Seventy percent were men (n = 35) and 30% were women (n = 15).

Tumor Palpability

The interrater agreement regarding the palpability of the tumor on DRE was substantial with a Fleiss κ of 0.629 (95% CI, 0.510–0.749, $p < 0.001$) for the whole collective (Tables 1 and 2). A total agreement of all 4 examiners was reached in 66% (n = 33) of cases, 75% agreement in 28% (n = 14), and 50% agreement in 4% (n = 2). One case was only evaluated by 3 examiners with an agreement of 66% (n = 1).

There was no significant correlation between the amount of agreement and patients' gender ($p = 0.177$) or age ($p = 0.723$).

The interrater agreement in the subgroup of patients examined in the LIT position was moderate with a Cohen of 0.533 ($p < 0.001$) and in the LL position was substantial with a Cohen κ of 0.750 ($p < 0.001$).

Distance Between the ACL and AV

Assessment of the distance between the ACL and AV showed moderate interrater reliability with an intraclass correlation coefficient [ICC] of 0.532 (95% CI, 0.258–0.723, $p < 0.001$; Tables 1 and 3). A total agreement (≤2 mm differences in measurements) of all 4 investigators was reached in 20% of cases (n = 10) of cases, 75% agreement in 22% (n = 11), and 50% agreement in 50% (n = 25). Three cases were evaluated by 3 examiners with an agreement of 66% (n = 3). In 1 case (2%), there was no agreement at all.

There was no significant correlation between the amount of agreement and patients' gender ($p = 0.613$) or age ($p = 0.315$).

The mean distance between the ACL and the AV was 13.295 mm (SD: 5.482 mm), with a range of 30 mm (5–35 mm). The median absolute difference from mean values was 2.5 mm (IQR: 2.5 mm). The difference between the highest and lowest measurements had a median of 8.5 mm (range, 24 mm [0–24 mm], IQR: 5 mm).

The interrater agreement in the subgroup of patients examined in the LIT position was moderate with an ICC of 0.525 (95% CI, 0.162–0.732; $p = 0.005$) and in the LL position was poor (did not reach statistical significance) with an ICC of 0.235 (95% CI, −0.386 to 0.579, $p = 0.187$).

TABLE 1. Interrater reliability between the different investigators for the whole collective and stratified into patient positioning (lithotomy position and left lateral position)

Parameter	*K*	*ICC*	*95% CI, p value*	*Level of interrater reliability*
Whole collective				
Tumor palpability	0.629	–	0.510–0.749, $p < 0.001$	Substantial
Distance between ACL and AV	–	0.532	0.258–0.723, $p < 0.001$	Moderate
Tumor height		0.947	0.918–0.967, $p < 0.001$	Excellent
Allocating tumor height	0.629		0.515–0.744, $p < 0.001$	Substantial
Left lateral position				
Tumor palpability	0.750	–	$p < 0.001$	Substantial
Distance between ACL and AV		0.235 (NS)	–0.386 to 0.579, $p = 0.187$	Poor (NS)
Tumor height		0.914	0.848–0.951, $p < 0.001$	Excellent
Allocating tumor height	0.657		$p < 0.001$	Substantial
Lithotomy position				
Tumor palpability	0.533	–	$p < 0.001$	Moderate
Distance between ACL and AV		0.525	0.162–0.732, $p = 0.005$	Moderate
Tumor height		0.909	0.840–0.948, $p < 0.001$	Excellent
Allocating tumor height	0.793		$p < 0.001$	Substantial

ACL = anocutaneous line; AV = anal verge; ICC = intraclass correlation coefficient; NS = not significant.

TABLE 2. Tumor palpable on digital examination

Tumor palpable (yes/no)	
Agreement	*n (%)*
100% (all 4 examiners)	33 (66)
75% (3/4 examiners)	14 (28)
66%[a] (2/3 examiners)	1 (2)
50% (2/4 examiners)	2 (4)

[a]One examination not documented.

TABLE 3. Distance between ACL to AV

Distance ACL to AV	
Agreement[a]	*n (%)*
100% (all 4 examiners)	10 (20)
75% (3/4 examiners)	11 (22)
50% (2/4 examiners)	28 (56)
0%	1 (2)
Measuring disagreement (highest to lowest measurement)	
Median: 8.5 mm (range, 0–24 mm)	

ACL = anocutaneous line; AV = anal verge.
[a]Measuring difference ≤2 mm.

Assessment of Tumor Height (Distance Between AV and Distal Tumor Margin)

Assessment of the tumor height showed excellent interrater reliability with an ICC of 0.947 (95% CI, 0.918–0.967, $p < 0.001$; Tables 1 and 4).

A total agreement (≤1 cm difference in measurements within a measurement corridor of ≤2 cm) of all 4 investigators was reached in 52% (n = 26) of cases, 75% agreement in 34% (n = 17), and 50% agreement in 14% (n = 7).

The difference between the highest and lowest height measurements had a median of 2 cm (range, 5 cm [0–5 cm]; IQR: 2 cm).

TABLE 4. Tumor height: measured distance of lower border of tumor from AV

Distance between lower border of tumor (from AV)	
Agreement[a]	*n (%)*
100% (all 4 examiners)	26 (52)
75% (3/4 examiners)	17 (34)
50% (2/4 examiners)	7 (14)
Measuring difference (highest to lowest measurement)	
Median 2 cm (range, 0–5 cm)	

AV = anal verge.
[a]Measuring difference ≤1 cm within a measurement corridor of ≤2 cm.

The mean tumor height was 9.52 cm (SD: 2.921 cm) with a range of 13 cm (3–16 cm).

Interrater reliability was excellent for both the subgroup of patients examined in the LL position (ICC: 0.914; 95% CI, 0.848–0.951, $p < 0.001$) and those examined in the LIT position (ICC: 0.909; 95% CI, 0.840–0.948, $p < 0.001$).

Allocating Tumor Height (Proximal Rectum ≥12 cm and Mid/Distal Rectum <12 cm)

The interrater agreement regarding the allocation of the tumor to the proximal and mid/distal rectum was substantial with a Fleiss κ of 0.629 (95% CI, 0.515–0.744; $p < 0.001$; Tables 1 and 5) for the whole collective. A total agreement of all 4 examiners was reached in 74% (n = 37) of cases, 75% agreement in 18% (n = 9), and 50% agreement in 8% (n = 4).

In 13 patients (26%), there was no agreement regarding the allocation of the tumor to proximal or mid/distal rectum (Table 5).

There was no significant correlation between the amount of agreement and patients' gender ($p = 0.824$) or age ($p = 0.922$).

Interrater agreement in the subgroup of patients examined in the LIT position was substantial with a Cohen

TABLE 5. Tumor allocation >12 cm or <12 cm from AV

Distance lower border of tumor (from AV)	
Agreement[a]	*n (%)*
100% (all 4 examiners)	37 (74)
75% (3/4 examiners)	9 (18)
50% (2/4 examiners)	4 (8)

AV = anal verge.
[a]Measuring difference ≤ 1 cm within a measurement corridor of ≤ 2cm.

κ of 0.793 ($p < 0.001$); interrater agreement was also substantial in the patients examined and in the LL position with a Cohen κ of 0.657 ($p < 0.001$).

Comparison of Tumor Height Assessment in LIT and LLP

See Table 1 for the comparison of tumor height assessment in the LIT and LL positions.

The mean tumor height in the LL position was 9.47 cm (SD: 2.97 cm) with a range of 11 cm (4–15 cm). It was 9.56 cm (SD: 2.89 cm) with a range of 13 cm (3–16 cm) in the LIT position ($p = 0.843$).

The median difference between the highest and lowest height measurements in the LL position was 1 cm (range, 4 cm [0–4 cm], IQR: 2 cm) with a median of 1 cm (range, 5 cm [0–5 cm], IQR: 2 cm) in the LIT position.

DISCUSSION

Tumor height assessment by rigid endoscopy is a major determinant for or against preoperative ("neoadjuvant") chemoradiation therapy. This study has shown that from a summary statistical point of view ("interrater agreement"), tumor height measurements by rigid endoscopy may be rated "excellent." This, however, does not correspond to the whole truth. Individual case analysis reveals considerable discrepancies in measurements, which in 26% of cases led to results on both sides of the 12-cm height limit,[1,2] largely considered to be the threshold for the option of chemoradiation therapy in rectal carcinoma. Accordingly, the level of interrater reliability for tumor height allocation to the proximal or mid/distal rectum (ie, >12 cm or <12 cm) is statistically rated somewhat more cautiously as "substantial." It must be pointed out that all surgeons involved in the present study were experienced colorectal surgeons. Rigid rectal endoscopy may, therefore, be overtaxed as the pivotal basis for the consideration of optional chemoradiation therapy.

According to preference, rigid rectosigmoidoscopy may be performed with the patient in the LL, LIT, or in the prone jackknife positions, with the latter being rarely used in this country in outpatient scenarios. Current guidelines are without specification in this respect. Patient positioning may potentially affect height measurement. In comparing LL and LIT positionings, our data do not statistically support this assumption. However, considerable deviations were observed in some cases, ranging from −3.5 to +2.5 cm from mean measurements comparing both positions. Despite this finding, the interrater agreement was again rated "excellent" for both subgroups. Also, no general trend of plus or minus deviation associated with patient positioning was observed.

Some authors have noted that, in many aspects, there are inconsistencies among guidelines.[7,8] For instance, some guidelines recommend 12 cm as the required height limit for optional neoadjuvant therapy,[1,2] whereas height is not mentioned in others.[3,4,9] Also, whereas most guidelines consider the AV as a point of reference for height measurements, others refer to the "ACL,"[1] or the "beginning of the hair-bearing skin,."[4] Although easily visualized in most cases, this landmark is not truly suitable for height measurements within the rectum. The transition from anoderm to perianal skin surrounds the anus, sometimes in a slightly undulating manner, about 1 to 2 cm lateral to the AV. There may be considerable variation following different degenerative and inflammatory proctologic disorders, such as perianal eczema or, in some cases of, anal prolapse as an accompanying feature of hemorrhoid disease. Direct measurements by rigid endoscopy are therefore not feasible, leaving the examiners to estimate the distance. This imprecision is reflected by the "modest" interrater agreement found in the present study. However, it may be assumed that for pragmatic reasons and despite the definition of the guideline, most examiners will use the AV as the measuring reference.

There are few studies comparing the methodology of height assessment for rectal cancer. No study was found assessing interrater agreement. Comparing retrospective data of 173 patients, Tanaka et al[10] found a good correlation between height assessment by flexible and rigid proctoscopy. However, the authors noted "occasional discrepancies." Yeom et al[11] retrospectively compared MRI, DRE, and flexible colonoscopy in 100 cases and found concordance to be low. Navarro et al[12] retrospectively analyzed 95 cases and found a strong statistical correlation between height assessment by MRI and clinical measurements (either DRE or rigid proctoscopy). Yet, almost 40% of their patients had a change in clinical trial eligibility depending on measuring modality, indicating a discrepancy between the measured statistical concordance and clinical reality, as was also the case in this study.

In current guidelines, tumor height predetermines consideration of neoadjuvant chemoradiation therapy in rectal carcinoma. However, it is not tumor height per se that limits the applicability and usefulness of radiotherapy. It is the risk of collateral radiation damage primarily due to overexposure of the small bowel and of diminished effectiveness.[13–17] Furthermore, the application of a strict height limitation ignores biological variability in body

frame and gender. It also neglects acquired anatomic variability such as pelvic descent, which regularly comprises the descent of the peritoneal reflection and the ensuing descent of the small bowel. This variability was exemplified by Wasserman et al,[18] who assessed the distance of the AV respective to the dentate line, puborectalis muscle, anterior rectal reflection, sacral promontory, and confluence of tenia. Distances were measured by rigid proctoscopy in 71 patients who underwent open pelvic surgery. All distances were found to be highly variable and associated with patient gender and body weight. The authors concluded that "the anthropometric definition of the rectum remains ill-defined."

This "nebulous"[18] definition of the rectum is further aggravated by examiner dependence on rigid endoscopic tumor height measurements shown in the present study.

Rectal cancer location lacks standardization and remains a matter of interpretation.[19] The present study has shown that rigid endoscopy, often used as the sole basis for such tumor height assessment, is fraught with sufficient uncertainty to warrant other means not only for uniform reporting and research but also for adequate patient selection for neoadjuvant therapy.

Therefore, rectal cancer height measurements should be correlated with detailed and preferably standardized CT or MRI. In this context, MRI has gained traction over the past years[4,20] and is, in many places, now considered an important addition to rectal cancer staging. If performed by dedicated experts, MRI can contribute to tumor staging and assessment of tumor height relative to the pelvic frame and circumferential resection margin.[20]

Modern rectal cancer treatment is based on a multidisciplinary approach within the framework of tumor boards. For sound therapeutic advice, detailed knowledge of normal pelvic anatomy and variations correlated to tumor morphology in the individual case are prerequisites, as are uniformity and agreement in description and nomenclature. This should be considered, and guidelines should be supplemented by incorporating more detailed mandatory assessment protocols for rectal cancer staging.

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