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Endoscopic ultrasound and complete pathological response in rectal cancer

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Abstract: The possibility of preoperatively predict the complete pathological response in rectal cancer has been studied in order to identify patients who would respond to neoadjuvant and individualize therapeutic strategies. The endoscopic ultrasound of the rectum is an accurate method for the evaluation of the local invasion of the tumor and the lymph nodes. Aim. To evaluate the potential of endoscopic ultrasound as a predictor of the complete pathological response to neoadjuvant after surgery in patients with locally advanced rectal cancer. Material and methods. A retrospective study was realized in patients with rectal cancer from January 2014 to December 2016. Results. We obtained a statistical association between the stage of the T by endoscopic ultrasound and the complete pathological response ($p = 0.015$). Not so for N, sphincter involvement, circumferential involvement and maximum tumor thickness ($p = 0.723$, $p = 0.510$, $p = 0.233$ and $p = 0.114$, respectively). When applying the multivariate logistic regression analysis to assess the degree of influence of the predictor variables on the pathological response, none of these variables was associated with the complete pathological response. Conclusion. The prediction of the complete pathological response in rectal cancer has been considered as the crucial point on which treatments for rectal cancer could be individualized. So far, no imaging method has been able to demonstrate efficacy in predicting the complete pathological response, and in turn there is no direct association between an endosonography finding that can accurately predict it.

Key words: complete pathological response; rectal cancer; endoscopic ultrasound

1 Introduction

The treatment of choice for locally advanced, non-metastatic rectal cancer (stage II/III according to the American Joint Committee on Cancer) consists of multi-modal therapy based on preoperative chemoradiotherapy (CRT), total mesorectal excision (TME), and adjuvant chemotherapy [1,2,3].

A complete pathological response (pCR) to neoadjuvant CRT has been associated with reduced distant disease, improved local control, local recurrence rates below 1%, and 5-year overall survival exceeding 95%, when compared with patients who do not achieve pCR [4,5].

The possibility of predicting pCR preoperatively using clinical, pathological, radiological, and molecular methods has been studied [6,7,8,9]. The goal is to identify patients who would respond to neoadjuvant therapy, tailor treatment strategies, and avoid radical surgery and permanent stomas while preserving the rectum, without compromising patients'

oncological outcomes [4,10].

Results from three groups have found an association between the clinical T stage (TNM staging system) and the likelihood of achieving pCR: 58% for T1, 28% for T2, 16% for T3, and 12% for T4 [8]. In turn, pCR has been associated with good tumor differentiation, small tumor diameter, early T and N stages, non-circumferential, non-ulcerated tumors, and low pretreatment levels of carcinoembryonic antigen (CEA) [6,11,12]. However, these studies have low sensitivity and specificity, and other studies contradict these findings [6].

Endoscopic ultrasound (EUS) of the rectum is one of the most accurate methods for assessing local invasion of rectal cancer and perirectal lymph nodes [13]. Comparative studies show that the accuracy of EUS for T staging is 80−95% (Figure 1) compared with computed tomography (CT) (65–75%) and MRI (75–85%). For lymph node staging, accuracy is 70−75% (Figure 2), compared with CT (55−65%) and MRI (60−70%) [14]. EUS is recommended as an accurate staging method for selecting early-stage lesions suitable for endoscopic resection or transanal resection [13].

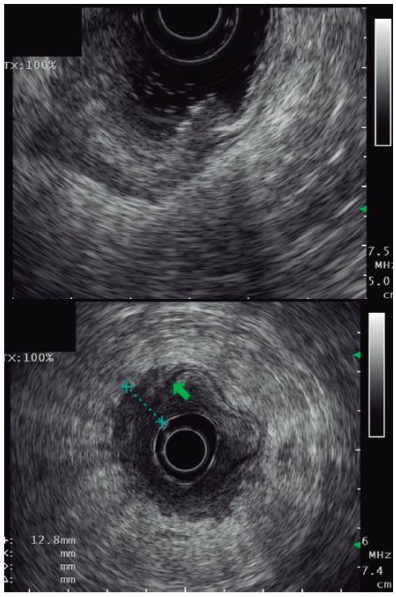

Figure 1. Endoscopic ultrasound assessment of the primary tumor (T) according to the TNM classification in rectal cancer. The tumor invades the pericolonic tissue through the muscularis propria (T3)

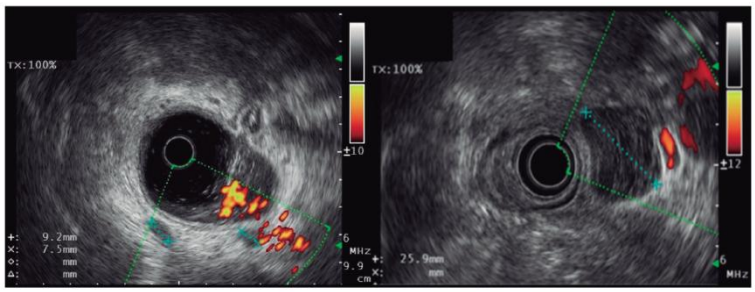

Figure 2. Endoscopic ultrasound assessment of regional lymph nodes in rectal tumors

The accuracy of staging after neoadjuvant radiation therapy decreases significantly due to edema, necrosis, and fibrosis caEUSd by radiation therapy; for this reason, the diagnostic accuracy of endoscopic ultrasound (EUS) for T staging decreases to 50% in the post-radiation therapy setting [15,16]. No imaging modality has been shown to be the most accurate for restaging after preoperative therapy and before surgery [17].

However, the EUS of EUS as a predictor of pCR has not been extensively evaluated. The study by Li et al. is the first

to propose serial measurements of EUS and tumor thickness after CRT as predictors of pCR, and in turn, of improved survival [18].

2 Objective

The objective of this study is to evaluate the potential of endoscopic ultrasound as a predictor of complete pathological response to neoadjuvant therapy following surgery in patients with locally advanced rectal cancer.

3 Materials and methods

A retrospective study was conducted on patients with rectal cancer enrolled between January 2014 and December 2016 at the National Cancer Institute of Mexico, with approval obtained from the Institute's Ethics Committee.

3.1 Inclusion criteria

Patients with locally advanced rectal cancer (American Joint Committee on Cancer stage II/III) confirmed by physical examination, chest X-ray, or CT scan, and who had not received prior treatment, were included. Patients underwent colonoscopy with histopathological confirmation of adenocarcinoma, with tumor location below the rectosigmoid junction or within the first 15 cm from the pectineal line.

Patients were staged prior to treatment using endoscopic ultrasound of the rectum, received neoadjuvant CRT, underwent surgical resection with TME, and had post-treatment pathological staging.

3.2 Exclusion criteria

Patients were excluded if they had stenosing tumors that could not be traversed by colonoscopy or endoscopic ultrasound, or if they had unresectable or synchronous tumors.

Pre-treatment staging was determined by endoscopic ultrasound using an Olympus GF-UE160 radial echoendoscope with frequencies of 7.5–12 MHz; with the patient in the left lateral decubitus position, scanning was performed from the aortic bifurcation until the anal sphincters were identified. The following variables were described: maximum tumor thickness (> 10 and ≤ 10 mm), sphincter involvement, circumferential tumor involvement (> 50% and ≤ 50%), and clinical stage by EUS according to the AJCC 7th edition TNM classification.

Demographic, clinical, and pathological data were collected from the patients, including age, sex, and pretreatment carcinoembryonic antigen (CEA) levels, with cutoff values of > 10 and ≤ 10 ng/ml. Neoadjuvant treatment consisted of a long course of intensity-modulated radiation therapy plus concomitant chemotherapy.

Analysis of the pathological specimens was performed by the Pathology Department and retrieved from the electronic medical record. The quality of mesorectal excision, the extent of surgical resection of the tumor, the pathological stage (ypTNM), and the degree of pathological response were evaluated.

The latter was classified according to the 2010 AJCC tumor regression grade (TRG) (modified Ryan classification) as follows: TRG0, complete response (no viable tumor cells); TRG1, moderate response (small group of tumor cells or individual cells); TRG2, minimal response (residual cancer with fibrosis); and TRG3, poor response (with minimal or no elimination of tumor cells).

Furthermore, for the purposes of this study, the pathological response was classified into the group with complete pathological response (TRG0) and all others with no response or a variable response as the group without complete pathological response (TRG1, TRG2, TRG3) [19].

For this study, sphincter involvement was defined as tumor infiltration of one or both rectal sphincters; circumferential tumor involvement was defined as circumferential compromise when the tumor extends over more than 50% of the rectal circumference; tumor thickness was defined as the maximum measured thickness in millimeters of the rectal wall at the tumor site; degree of surgical resection, defined as R1 if the circumferential resection margin is positive

for neoplasia or if the resection margin is less than 1 mm, and R0 if the circumferential resection margin is negative for neoplasia [4]; complete pathological response (pCR), the absence of adenocarcinoma cells in the rectal wall or in regional lymph nodes (ypT0N0M0), classified as TRG0 [20,4]; without a complete pathological response, indicating the absence of a complete pathological response or a variable degree of response (TRG1, TRG2, TRG3).

3.3 Statistical analysis

Possible differences in clinical and pathological variables between patients who had pCR and those who did not were evaluated using the chi-square test. Logistic regression analysis was performed to predict pCR. The Stata/MP 13.0 software (Stata, College Station, TX) was EUSd for statistical analysis, with p-values < 0.05 considered statistically significant.

Differences between the groups were assessed using the chi-square test. Logistic regression analysis was performed to predict the dependent variable. A p-value < 0.05 was considered statistically significant. The Stata/MP 13.0 software (Stata, College Station, TX) was EUSd for statistical analysis.

4 Results

A total of 78 patients were included, all of whom met the established inclusion criteria. All patients underwent rectal endoscopic ultrasound (EUS), received neoadjuvant chemotherapy, underwent surgical resection with total mesorectal excision (TME), and postoperative pathological staging.

The included patients received intensity-modulated radiation therapy at a dose of 50.4 Gy in 28 fractions. The concomitant chemotherapy regimen EUSd was capecitabine 2.5 g/m² on days 1–14 every 3 weeks for 4 cycles in 87.2% of the patients, and capecitabine plus oxaliplatin in 12.8%.

The demographic characteristics of the patients and the variables associated with pCR are shown in Table 1. Women (n = 32) accounted for 41.0%, and men (n = 46) for 59.0%, with a median age of 60.5 years (range: 32–83). Pre-treatment ACE levels had a median of 3.28 ng/ml (range: 0.39–3321). The clinical stages determined by endoscopic ultrasound ranged from stage I to stage IIIC. Based on endosonographic findings regarding tumor invasion of the rectal wall, 10.3% (n = 8) corresponded to T2, 65.4% to T3 (n = 51), and 24.4% to T4 (n = 19). For lymph node staging, 33.3% (n = 26) were classified as N0, and 66.7% (n = 52) had positive lymph nodes. Sphincter involvement was present in 30.7% (n = 24), and circumferential tumor involvement of the rectum affecting >50% of the lumen was present in 67.9% of cases (n = 53). Regarding the measurement of maximum tumor thickness, this was assessed in 56 of the 78 patients. The median maximum tumor thickness was 15.7 mm (range: 8–34.6); for this parameter, cutoffs of > 10 mm and ≤ 10 mm were established based on the data distribution. As for the histopathological results following neoadjuvant therapy and surgery (Table 2), the tumors were staged as T0 in 16.7% (n = 13), Tis in 2.6% (n = 2), T1 in 10.2% (n = 8), T2 30.7% (n = 24), T3 33% (n = 26), and T4 6.4% (n = 5).

For pathological staging of lymph nodes, N0 accounted for 70.5% (n = 55), and when all stages with positive lymph node metastases due to malignancy were grouped together, they accounted for 29.5% (n = 23).

Table 1. Baseline patient characteristics and variables associated with pCR (n = 78)

Characteristic	n (%)
Age (years), median (range)	60.5 (32–83)
Sex	
Female, n (%)	32 (41)
Male, n (%)	46 (59)
Pre-treatment CEA (ng/ml), median (range)	3.28 (0.39–3321)
Clinical stage by EUS	
I	2 (2.6)
IIA	18 (23.1)
IIB	4 (5.1)
IIC	2 (2.6)
IIIA	5 (6.4)
IIIB	32 (41.0)
IIIC	15 (19.2)
Clinical T stage by EUS	
T2	8 (10.3)
T3	51 (65.4)
T4	19 (24.4)
Clinical N stage by EUS	
N0	26 (33.3)
N1A	15 (19.2)
N1B	20 (25.6)
N1C	1 (1.3)
N2A	9 (11.5)
N2B	7 (9.0)
Sphincter involvement	
Yes	24 (30.8)
No	54 (69.2)
Circumferential involvement	
> 50%	53 (67.9)
≤ 50%	25 (32.1)
Tumor thickness (mm), median (range)	15.7 (8–34.6)

Table 2. Post-treatment histopathological findings (n = 78)

Variable	n (%)
ypT Stage	
T0	13 (16.7)
Tis	2 (2.6)
T1	8 (10.2)
T2	24 (30.8)
T3	26 (33.3)
T4	5 (6.4)
ypN Stage	
N0	55 (70.5)
N1A	8 (10.2)
N1B	6 (7.7)
N1C	3 (3.8)
N2A	3 (3.8)
N2B	3 (3.8)
Tumor resection grade	
R0	72 (92.3)
R1	6 (7.7)
Total mesorectal excision	
Complete	63 (80.8)
Incomplete	15 (19.2)
Tumor Regression Grade (AJCC)	
0 (Complete)	13 (16.6)
1 (Moderate)	24 (30.8)
2 (Minimal)	24 (30.8)
3 (Poor)	17 (21.8)
Grouped pathological response	
Complete	13 (16.7)
Non-pCR	65 (83.3)

AJCC: American Joint Committee on Cancer; pCR: complete pathological response.

For the resection grade, R0 was 92.3% (n = 72) and R1 was 7.7% (n = 6). In 80.8% (n = 63) of cases, TME was performed, and in 19.2% (n = 15), mesorectal excision was incomplete. Finally, the achieved pCR (GRT0) was 16.7% (n = 13), and when moderate, minimal, and no responses (TRG1, TRG2, and TRG3) were grouped together, the rate was 83.3% (n = 65). Within the group of patients with pCR, 30.7% were T2 (n = 4), 38.5% were T3 (n = 5), and 30.7% were T4 (n = 4). For the group without pCR, we found that T2 accounted for 6.1% (n = 4), T3 for 70.8% (n = 46), and T4 for 23.1% (n = 15).

In accordance with the study's objective—to evaluate the potential of endoscopic ultrasound as a predictor of pCR—when analyzing the factors we identified as possible predictors using the chi-square test, we found a statistical association between the T stage determined by endoscopic ultrasound and pCR ($p = 0.015$). This was not the case for N stage by EUS, sphincter involvement, circumferential involvement, and maximum tumor thickness ($p = 0.723$, $p = 0.510$, $p = 0.233$, and $p = 0.114$, respectively) (Table 3).

Furthermore, when we applied multivariate logistic regression analysis to assess the degree of influence of the predictor variables on the pathological response, none of these variables was associated with pCR (Table 4).

Table 3. Predictors of pCR after neoadjuvant CRT and surgery (n = 78)

Variables	pCR n	Non-pCR n	p
Sex			
Male	8	38	0.837
Female	5	27	
Age (years)			
> 45	10	55	0.497
≤ 45	3	10	
Pre-treatment CEA (ng/mL)			
> 10	2	15	0.54
≤ 10	11	50	
Clinical T stage by EUS			
T2	4	4	0.015 *
T3	5	46	
T4	4	15	
Clinical N stage by EUS			
N0	6	20	0.723
N1a	2	13	
N1b	4	16	
N1c	0	1	
N2a	1	8	
N2b	0	7	
Sphincter involvement			
Yes	3	21	0.51
No	10	44	
Circumferential involvement			
> 50%	7	46	0.233
≤ 50%	6	19	
Tumor thickness (mm)			
> 10	8	38	0.114
≤ 10	4	6	

pCR: complete pathological response; CRT: chemoradiotherapy; CEA: carcinoembryonic antigen; EUS: endoscopic ultrasound. Chi-squared test * $p < 0.05$

Table 4. Multivariate predictors of pCR

Variables	p *
Sex	0.541
Age	0.362
CEA	0.426
T2 stage	0.895
T3 stage	0.393
Sphincter involvement	0.539
Circumferential involvement	0.147
Tumor thickness	0.159

pCR: complete pathological response; CEA: carcinoembryonic antigen. *Logistic regression analysis

5 Discussion

In our study, we reported a complete pathological response rate of 16.7%, which is consistent with reports in the literature ranging from 10% to 20% [4,6,21]. In the univariate statistical analysis, we found an association between the T stage as determined by EUS and pCR, but not with the other potential predictors (sphincter involvement, circumferential tumor involvement, or tumor thickness). However, in the logistic regression analysis, none of the p-values obtained were statistically significant. Therefore, we can conclude that there is no direct relationship between any pre-treatment

endoscopic ultrasound measurement and the prediction of pCR, and we cannot conclusively identify which patients would achieve a complete resection prior to treatment.

In the study by Ning Li et al., sequential measurements of the largest tumor diameter were performed using endoscopic ultrasound in 41 patients with stage II and III rectal cancer prior to the start of neoadjuvant treatment, 2 weeks after its initiation, and 6 to 8 weeks after the completion of chemoradiotherapy. They found a correlation between post-treatment maximum tumor thickness, as well as the ratio of post-neoadjuvant CRT tumor measurements to pretreatment diameter, with complete pathological response and tumor regression grade ($p = 0.001$ and $p = 0.026$, respectively).

Although previous studies have suggested that the accuracy and utility of endoscopic ultrasound (EUS) in restaging rectal cancer are compromised by the edema and fibrosis induced by neoadjuvant therapy, these results suggest that the correlation between post-neoadjuvant post-treatment and pre-treatment endoscopic ultrasound measurements, in addition to the maximum tumor thickness measurement in the post-neoadjuvant period, may predict therapeutic response in rectal cancer [18]. It is worth noting that, in addition to sample size, having only a single pre-treatment measurement may affect the results obtained in our study.

Various factors influence the pathological response to neoadjuvant therapy, ranging from varying sensitivity to chemoradiotherapy due to the individual nature of the tumor to the time interval between the completion of neoadjuvant therapy and surgical resection, among others [9,22,23].

Multiple prospective, uncontrolled studies report that the local recurrence rate and overall survival in patients with pCR who underwent surgical procedures without TME are similar to those in patients who did undergo TME [10,24].

Given the favorable oncological outcomes in patients with a complete pathological response, efforts to identify this group have become a challenge.

The main obstacle is that such a response can only be assessed using the surgical specimen. Clinical prediction of pathological response would allow for the selection of patients in whom surgery and TME could be avoided [3,25].

6 Conclusion

Predicting complete pathological response in locally advanced rectal cancer is a challenge that remains under investigation, as this issue has been considered the crucial factor upon which personalized treatments for locally advanced rectal cancer could be based. To date, no imaging method has proven effective in predicting complete pathological response, and there is no direct association between any that can accurately predict it [21].

Variable tumor responses to neoadjuvant chemoradiotherapy suggest a complex relationship with tumor biology, likely due to various molecular pathways that regulate sensitivity to chemoradiotherapy [6].

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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