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Impact of Body Mass Index and Tumor Site on The Staging of Rectal Cancer with Endorectal Ultrasound

*(**Running title:** Effect of BMI and tumor site on ERUS)*

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Abstract

Purpose: Showing how the accuracy of endorectal ultrasound (ERUS) is reduced in overweight individuals and in lower rectal tumors because there is more perirectal fat tissue present causing more difficulty in checking T depth & LN. The aim of the present study was to evaluate the accuracy of the endorectal ultrasound scan during preoperative staging of rectal cancer and the effects that body mass index (BMI) and the tumor's distance have on its accuracy.

Methods: We reviewed the charts of 436 patients whose ERUS was done for them by the Division of Colon and Rectal Surgery at King Faisal Specialist Hospital and Research Centre from 2003 to 2012. Our analysis excluded 213 patients for various reasons. Accuracy and concordance between the ultrasonographic and clinical stages using magnetic resonance image will be determined. The effect of BMI, tumor distance, gender and the operator on the accuracy of endorectal ultrasound staging was evaluated. A student t-test and Chi square test were used for statistical analysis. $P<0.05$ was considered significant.

Results: The accuracy of endorectal ultrasound for the depth of invasion for BMI <20, 20-25, >25.1 were 66%, 72% and 79% respectively. The difference between them was highly significant $P<0.0001$ and $P<0.0001$ respectively. The accuracy for lymph node stage was 52%, 30% and 40% respectively for the same categories of BMI. It was highly significant only for BMI >25.1 $P<0.0001$.The distance of the tumor from the anal verge was associated with the following accuracy for the depth of the invasion 72%, 85% and 66% for the distance < 6 cm, 6-12 cm and >12 cm respectively. The accuracy was significantly better for the tumors located in midrectum $P< 0.0001$. The accuracy for the lymph node stage was 33%, 45% and 50% for the tumor distance < 6 cm, 6-12 cm and >12 cm respectively. It was significant for the tumor in the upper third of the rectum $P<0.0002$.The operator or gender of the patient did not affect the accuracy for the depth of invasion and lymph node stage.

Conclusion: The accuracy of endorectal ultrasound is affected by the BMI and the depth tumor's invasion and location during the lymph node stage.

Keywords: rectal cancer, ultrasound, body mass index, staging.

Introduction

The preoperative staging is crucial for the treatment of rectal cancer. Although, no method is completely reliable in establishing the preoperative extent of the penetration of the rectal wall and the lymphatic spread, endorectal ultrasonography was shown to be superior compared with clinical assessment or other imaging techniques in assessing neoplastic infiltration [1-5]. During the last decades, endorectal ultrasound (ERUS) has become the most common diagnostic modality for local staging of rectal cancer [6,7]. These therapeutic strategies that attempt to tailor treatment to the tumors stage require a precise knowledge of the depth of tumor's invasion in the rectal wall and the presence of the tumor in the regional lymph node [8]. The accuracy of (ERUS) in assessing the depth of tumor invasion particularly for early cancer is 69% and for assessing lymph node involvement is 64% [8]. However, rectal anatomy seems to affect staging accuracy in the lower rectum because the structure of the ampulla recti renders endosonographic examination more difficult [4]. Moreover, there is little data available on the association of tumor location and the accuracy of preoperative staging by ERUS

and the result of these studies are conflicting [9, 10]. No study has so far evaluated the effect of Body Mass Index on accuracy of ERUS. The aim of this study was to evaluate the accuracy of ERUS in overweight individuals compared to those with normal weight.

Aims

The aim of the present study was to evaluate the accuracy of the endorectal ultrasound scan during preoperative staging of rectal cancer and the effects that body mass index (BMI) and the tumor's distance have on its accuracy.

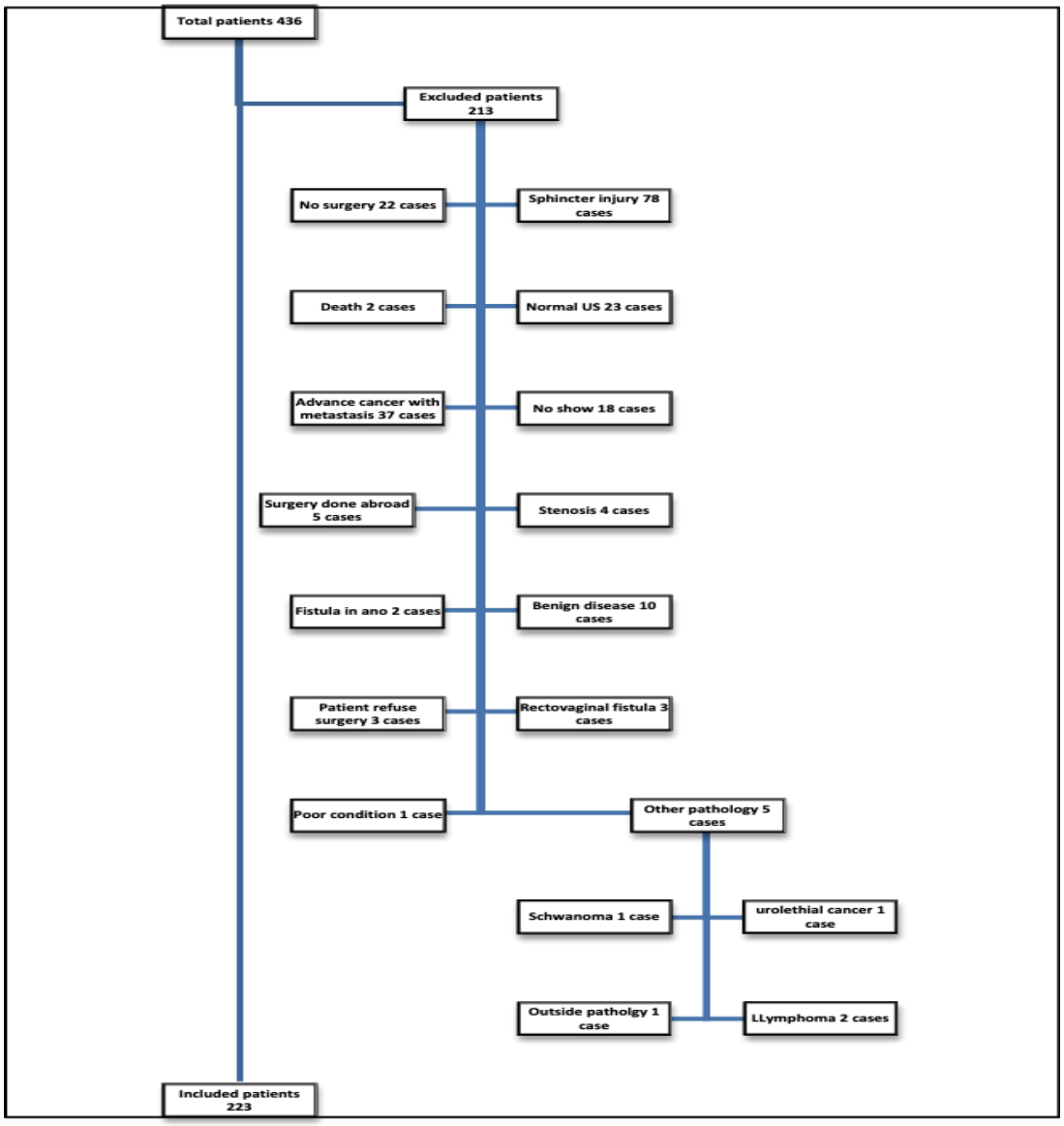
Patients and methods

We reviewed the charts of 436 patients whose rectal adenocarcinoma were staged by ERUS and who were operated on by the Division of Colon and Rectal Surgery at King Faisal Specialist Hospital and Research Centre from 2003 to 2012. Our institutional review board approved this study. Our analysis excluded 213 patients for various reasons and 223 patients were included in our study. Apart from the staging of all the tumors according to the TNM classification by Hildebrandt and Feifel, tumor height was recorded preoperative [11]. Our study exclusion criteria is shown in (Table 1). Four board certified experienced colorectal surgeons performed the ERUS examination. T1 lesions infiltrated the mucosa and submucosa, which is the first hypo-echoic layer. The T2 lesion infiltrated the muscularis propria, which is the second hypo-echoic layer. The T3 lesions infiltrated the perirectal tissue which is the hyper-echoic line delineating the outer limit of rectal wall. The T4 tumors infiltrated surrounding organs or the serosa in tumors above the peritoneal reflection. To establish the tumor height, the rectum was subdivided into three parts, the lower third (0-6 cm from the anocutaneous junction), the middle part (extending from 7-12 cm), and the upper third (above 12 cm). Pathological lymph nodes were defined as circular or oval shaped structures often with irregular borders and with echogenicity similar to the tumors as proposed by Beynon et al. [12]. Each patient was examined with a triad of diagnostic modalities: digital examination, proctoscopy, and ERUS. The patient was prepared for the examination with a fleet enema one hour before the ERUS. The patient was examined in a left lateral position. A B-K 7-MHz or a 10-MHz endosonographic probe was introduced through the anal verge. The probe was covered with a rubber balloon and passed carefully from anal verge to upper rectum. The balloon was then filled with variable amounts of water to achieve optimal contact with the rectal wall then the probe was slowly retracted to the level of the tumor. All patients underwent curative surgery and most of them had preoperative chemo-radiotherapy. The surgeon decided the treatment strategy based on the tumor and patients' characteristics. The surgical specimens were sent for pathologic examination and staging according to pTNM classification. The perirectal lymph node was classified as free from metastatic disease pN0 or as positive for metastatic disease pN1. Body mass index was calculated for each patient preoperatively. BMI > 35 cm/m^2 was considered morbid obesity, BMI 30-35 cm/m^2 was obesity, BMI 25-30 cm/m^2 was overweight and BMI 20-25 cm/m^2 was considered normal. The clinical stage using magnetic resonance image was compared with preoperative endosonographic staging (uT, uN). For each T and N-stages, the accuracy values were calculated. Calculations were repeated for combined stages. Overall accuracy rates of the three different levels and concordance were analyzed. The effect of body mass index, tumor location, gender and operator on accuracy of ERUS result were analyzed. Statistical significance was assessed using a student t- test and Chi-square test. P value of less than 0.05 which was considered significant.

Table 1

Exclusion criteria
• Metastatic rectal cancer. • Unresetable rectal tumor. • Incomplete clinical information. • Incomplete evaluation (stenotic/inaccessible) • Poor medical condition which make surgery difficult. • Associated pathology (crohn's disease, FAP, fistula in ano)

Figure 1: Algorithm of the patients.



Results

Of the 223 patients in our study, 184 underwent open surgeries, 39 underwent laparoscopic surgeries, 155 underwent anterior resection (70%), 62 underwent abdominperineal resection (28%), 3 underwent transanal excision (3%), and 3 underwent other type of surgeries (3%). Neoadjuvant therapy was given to 211 patients. There were 134 males and 89 females; the mean age was 57.4 (range, 20-94) years. The mean BMI was 27 (range, 13.7-48) kg/m^2, the mean distance from the anal verge was 6.3 (range, 1-15) cm, the mean tumor diameter was 2.6 (range, 0-11) cm, the mean positive lymph nodes was 1.1 (range, 0-11), the mean negative lymph node was 12 (range, 0-66), and the mean total lymph nodes was 13.2 (range, 0-66).

There were 141 tumors in the lower rectum (0-6 cm), 64 of them were in the midrectum (7-12 cm) and 18 were in the upper rectum (> 12 cm). Twenty-one patients were underweighted (BMI <20 kg/m^2), 69 patients were normal weight (BMI 20-25 kg/m^2), 72 patients were overweight (BMI 25.1-30 kg/m^2), 44 patients were obese (BMI 30.1-35 kg/m^2), 17 patients were morbidly obese (BMI>35.1kg/m^2) and the total patients with BMI >25.1 were 133. Applying the uT/uN classification by Hildebrandt and Feifel, there were 2 uT0, 5 uT1, 10 uT2, 197 uT3, 9 uT4, 1 uN0, 126 uN1 and 33 uN2 tumors. Utilizing the pelvic MRI for clinical stage there were 1 cT0, 5 cT1, 34 cT2, 165 cT3, 18 cT4, 47 cN0, 59 cN1and 117 cN2 tumors. Overall accuracy of ERUS in assessing the depth of invasion in the rectal wall (T Stage) was 76%, with 9% of the tumors understaged and 15% of the tumors overstaged. The overall accuracy of ERUS in the diagnosis of lymph node metastasis (N stage) was 38%, with 49% of all the tumors understated and 13% of the tumors overstaged. All ERUS assessment scans were done before neoadjuvant treatment.

The accuracy of ERUS in assessing the depth of invasion for BMI (<20, 20-25, >25.1 kg/m^2) was 66%, 72% and 79% respectively. The difference in staging accuracy between tumors of patients with BMI <20/ 20-25 kg/m^2 and BMI >25.1/20-25 kg/m^2 was strongly significant (P<0.0001 and P<0.0001 respectively). The accuracy for lymph node stage was 52%, 30% and 40% respectively for the same categories of BMI. The difference was highly significant only for BMI>25.1 kg/m^2 (table 2).

The distance of the tumor from the anal verge was associated with the following accuracy for the depth of invasion (T stage) 72%, 85% and 66% for the distance < 6 cm, 6-12 cm and >12cm respectively. The difference in staging accuracy was strongly significant for the tumor located in the midrectum (P< 0.0001). The accuracy for the lymph node stage (N stage) was 33%, 45% and 50% for the distance < 6 cm, 6-12 cm and > 12 cm respectively. The difference was strongly significant for the tumor located in the upper rectum (P < 0.0002). (Table 3).

Overall accuracy of ERUS by the surgeons is shown in figure 2. The differences between surgeons for T staging and N staging were statistically insignificant. The accuracy was not influenced by patients'x gender and the difference was not statistically significant figure 3.

Figure 2: Effect of operator on accuracy of ERUS.

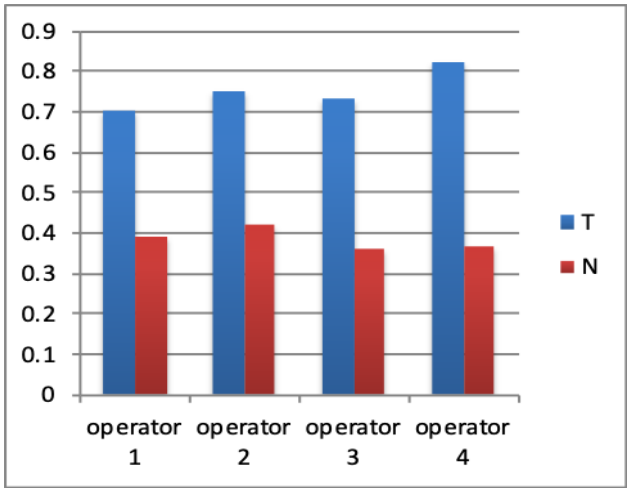
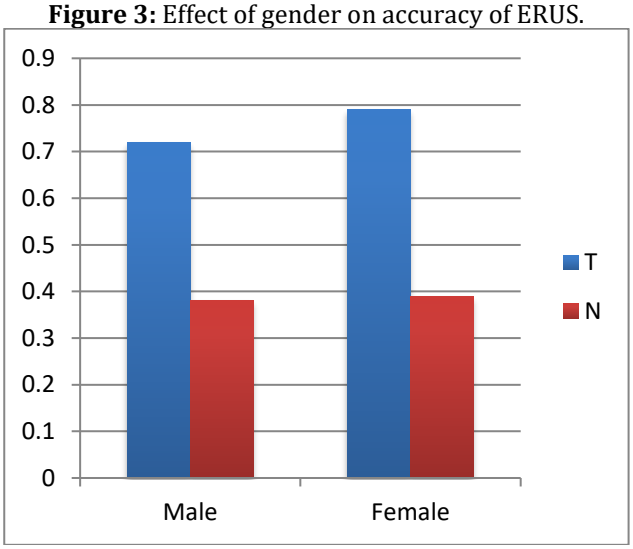


Figure 3: Effect of gender on accuracy of ERUS.



	T stage				N stage			
Distance	T understage	T overstage	Total	Accuracy	N understage	N overstage	Total	Accuracy
<6 cm	14 (9%)	25 (17%)	141	102 (72%)	75 (53%)	19 (13%)	141	47 (33%)
6-12 cm	5 (7%)	4 (6%)	64	55 (85%)	29 (45%)	6 (9%)	64	29 (45%)
>12 cm	2 (11%)	4 (22%)	18	12 (66%)	6 (33%)	3 (16%)	18	9 (50%)

Table 2: Effect of tumor distance on accuracy of ERUS.

	T stage				N stage			
BMI	T understage	T overstage	Total	Accuracy	N understage	N overstage	Total	Accuracy
<20	1 (4%)	6 (28%)	21	14 (66%)	6 (28%)	4 (19%)	21	11 (52%)
20-25	6 (8%)	13 (19%)	69	50 (72%)	41 (59%)	7 (10%)	69	21 (30%)
>25.1	13 (9%)	15 (11%)	133	105 (79%)	62 (47%)	18 (14%)	133	53 (40%)

Table 3: Effect of BMI on accuracy of ERUS.

Discussion

The therapeutic approach for rectal cancer depends on how accurate the preoperative stage is. The goal of any staging method of the rectum is to predict the depth of the invasion and nodal involvement [9]. Currently, ERUS appears to be the most accurate staging method [1-3, 12]. ERUS has been shown to alter clinical decision-making in 57 percent of patients with early neoplastic lesions and 40 percent with advanced neoplastic lesions [13]. The overall staging accuracy for ERUS is in the range of 75 to 94 percent for tumor invasion and 72 to 83 percent for lymph node metastasis [2, 14-20]. Others, had observed a greater percentage of overstaging than understaging [9,19,21,22]. In our study, we found that tumor invasion and lymph node metastasis were under-staged in 9, and 40 percent respectively and over-staged in 15, and 19 percent respectively. The overall accuracy in our study for tumor invasion and lymph node metastasis was 76 and 73 percent respectively, and this compared well with the published reports [2, 9, 12, 14-16, 23, 24].

Herzog, U., et al. [9] found that most false negative diagnosis of the lymph node was when it was less than 11mm. They encountered high rates of false positive diagnosis and this was explained by the changing degree of inflammation and cross-sectioned vessels in the perirectal fat.

Garcia-Aguilar, J., et al. [8] correctaly staged most of the villous adenoma but less than half of T1 tumors with the same probabilty for overstaging and understaging. The accuracy of diagnosis T2 tumors was 68 percent, was worse than previously reported. ERUS correctly identified 77 percent of patients whose tumors where localized to the rectal wall and 70,50 percent of T3 and T4 tumors respectively. They found the accuracy of lymph node metastasis were 68, 52 percent for N0 and N1 respetively. In our study, the accuracy of T1,T2,T3 and T4 was 20,60,78 and 33 percent respectively with high accuracy was for T3 stage. The accuracy of lymph node metastasis for NO,N1 and N2 was 38,31 and 73 percent respectively (Table 4,5).

	cT0	cT1	cT2	cT3	cT4	Overstaged	Understaged	Total	Accuracy
uT0	0	0	0	2	0	0	2	2	0
uT1	0	1	2	2	0	0	4	5	20%
uT2	0	0	6	4	0	0	4	10	60%
uT3	0	4	25	154	14	29	14	197	78%
uT4	0	0	2	4	3	0	0	9	33%

Table 4: Accuracy of ERUS in tumor invasion.

	cN0	cN1	cN2	Overstaged	Understaged	Total	Accuracy
uN0	24	15	25	0	40	64	38%
uN1	19	39	68	68	19	126	31%
uN2	4	5	24	9	0	33	73%

Table 5: Accuracy of ERUS in lymph node stage

Whether tumor distance from the anal verge has an impact on the accuracy of ERUS staging has been controversial. Sentovich, S.M., et al. [10] reported a significant result for the tumors within 6 cm from the anal verge. However, they only examined 35 patients of whom 14 (40 percent) had low rectal lesions. Herzog, U., et al. [9] found a significantly poorer accuracy rate for tumors of the distal rectum. They included 125 patients, 54 (43 percent) who had low rectal neoplasms. Sailer, M., et al. [4] found the accuracy in the lower third of rectum was only 68 percent compared with 76 and 88 percent for the middle and the upper rectum , respectively. They agreed with Herzog and his colleagues [9] that the reason for the less accurate staging in the lower rectum is a technichal one, ie., difficulties in achieving uniform contact between the water balloon and the rectal wall and to the suboptimal delineation of the rectal wall immediately above the anorectal ring. Garcia-Aguilar, J., et al. [8] they found that the distance of the tumor from the anal verge did not influence the accuracy. In our study, we found that the accuracy of ERUS for the depth of invasion was 72, 85 and 66 percent for the lower, middle and upper third of rectum, respectively with statistical significance for the middle third of rectum (P< 0.0001). The accuracy of the lymph node metastasis was 33, 45 and 50 percent for the lower, middle and upper third of rectum, respectively with significance for the tumor in the upper third of rectum (P< 0.0002).

To date, no other group has analyzed the impact of body mass index on the accuracy of ERUS. In our study, we found that the accuracy of ERUS for the depth of invasion in underweight , normal weight and obese patients was 66, 72 and 79 percent, respectively with statistical significance for both normal and obese patients (P< 0.0001 and P< 0.0001 respectively). The accuracy of lymph node metastasis was 52, 30 and 40 percent for underweight, normal and obese patients, respectively. It was highly significant only for obese patients (P< 0.0001).We found that the accuracy of ERUS for the depth of invasion and lymph node metastasis was not affected by the operator or gender of the patient. The limitations of this study was that there is not enough data about the effect of body mass index on the staging using ERUS and the staging was compared with MRI not to the pathological stage due the effect of neoadjuvant chemoradiotherapy on the number of LN.

Conclusion

Our research has shown that he accuracy of ERUS is affected by the tumor's location and body mass index for the depth of invasion and lymph node metastasis.

Conflict of interest
The author declares that there is no conflict of interest.

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None.

Credit authorship contribution statement:
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-SAMAR ALHOMOUD (co-author)
-LUAI ASHARI (co- author)
-Rami sairafi (co-author)
-Alaa aljohani (data collector, editing)

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