

# A New Rectal Ultrasonographic Method for the Staging of Rectal Cancer

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**PURPOSE:** Radial transrectal ultrasound is the most frequently used method for preoperative staging of rectal cancer. Accuracy rates of transrectal ultrasound have fallen significantly to 64% and 70% for tumor and node staging, respectively. The use of a frontal probe may overcome the drawbacks of radial transrectal ultrasound. This study was designed to compare the accuracy of frontal transrectal ultrasound performed with a frontal probe with the classic procedure, which uses a radial probe, in the preoperative T and N staging of rectal cancer.

**METHODS:** Seventy-four patients with rectal adenocarcinoma underwent both techniques. Thirty patients had a neoadjuvant treatment. The staging accuracy of both methods was determined by comparing the results of each with the findings of surgical histopathologic evaluation.

**RESULTS:** Forty-six men and 28 women were recruited. Frontal transrectal ultrasound was performed in all patients. Staging was amenable in only 58 patients with the radial transrectal ultrasound because the tumors were either stenotic or too proximal. Frontal transrectal ultrasound was accurate in the T staging of 89% of the tumors, whereas radial transrectal ultrasound was accurate in only 69% ( $P = 0.004$ ). The difference was even more significant when we compared accuracy among the 58 patients in whom both examinations were completed ( $P = 0.002$ ). Both methods had similar accuracy for lymph node staging. Neoadjuvant treatment

had no influence on accuracy. No overstaging of the tumor occurred with the frontal transrectal ultrasound. Understaging was more frequently encountered with radial transrectal ultrasound than with frontal transrectal ultrasound (26% vs. 11%, respectively;  $P = 0.036$ ).

**CONCLUSION:** Compared with radial transrectal ultrasound, frontal transrectal ultrasound has a better accuracy for T staging of rectal cancer. Its advantage in overcoming the drawbacks of radial transrectal ultrasound may make this procedure the method of choice for rectal cancer staging.

**KEY WORDS:** Rectal cancer; Transrectal ultrasound; Rectum.

Colorectal cancer is the fourth most common non-cutaneous malignancy and the second most frequent cause of cancer-related death in the United States.<sup>1,2</sup> The treatment and prognosis of the tumor are based on preoperative staging. Therefore, the accuracy of tumor (T) and nodal (N) staging is essential. Patients with a T3 to T4 tumor will be scheduled for neoadjuvant treatment to reduce the rate of local recurrence. Spread of the tumor in the mesorectal fascia will determine whether the patient requires a total mesorectal excision.

Transrectal ultrasound (TRUS) is the method of choice for preoperative staging of rectal cancer.<sup>3</sup> The accuracy of T and N staging has been reported to range from 67% to 96% and 70% to 75%, respectively.<sup>4,5</sup> There are several reasons for these scattered figures: lack of uniformity in the TRUS technique, the procedure is operator-dependent, and difficulties in differentiating between desmoplastic or inflammatory changes and hypervascularization in the tumor. Furthermore, TRUS has a disadvantage when stenotic or high proximal rectal tumors are being staged, because the insertion of the rigid probe is limited to approximately 10 cm.<sup>6</sup> Because TRUS has been

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traditionally performed with 360° rotating transducers, radial plane scanning might not be possible. Using an end-fire probe (F-TRUS) may, theoretically, overcome these drawbacks. The probe may remain distal to the tumor because the field of examination is in the axis of the probe and not radial to it. Because the lateral resolution of the picture is a function of the aperture of the probe, a curved array may give sharper images than mechanically rotating transducers.

The purpose of the study was to compare the accuracy of F-TRUS, a new application of an end-fire transducer generally used for gynecologic ultrasound, with the accuracy of classic radial TRUS (R-TRUS) in T and N staging of patients with rectal cancer.

## MATERIALS AND METHODS

### Patients

In this retrospective study 74 patients (46 men and 28 women; mean age, 65 (range, 32–91) years) with biopsy-proven adenocarcinoma of the rectum were examined preoperatively with both TRUS techniques between March 2005 and September 2007. Rectal cancer was defined as a carcinoma within 15 cm from the anal verge. Forty-five patients had a mid rectal tumor (6–10 cm from the anal verge). Three tumors were located in the distal rectum (<5 cm from the anal verge), and 26 tumors were located in the proximal rectum (>10 cm). Thirty patients underwent the staging procedures after a fixed six-week protocol of neoadjuvant radiotherapy before surgical intervention. The decision to schedule these patients to preoperative neoadjuvant therapy was based on a previous TRUS staging performed either in our institution or elsewhere. These patients were referred for a second posttreatment, preoperative staging by the oncology department. The criteria for neoadjuvant therapy were consistently applied to all patients. These patients underwent a fixed protocol including 4,500 cGy of external radiotherapy, scheduled for five days a week with an additional boost of 540 cGy. The interval between imaging and surgery was <60 days for all patients. In all cases the results of TRUS staging were compared with the results of surgical staging. The depth of infiltration was classified according to the TNM staging.<sup>7</sup>

### TRUS Procedures

R-TRUS was performed with a B&K 3535 scanner (Diagnostic Ultrasound Systems, B&K Medical, Gentofte, Denmark) using a mechanically rotating probe (10 MHz) with a penetration depth of 2 to 4 cm, axial resolution of 0.4 mm, and lateral resolution of 1.0 mm. At the same session all patients also underwent F-TRUS. In our institution both probes are commonly used to examine these patients. Informed consent was obtained from all enrolled patients. For the great majority of patients the procedure was per-

formed by the same operator (MBG). The examination was performed with a Logiq 9 scanner (General Electric Medical Systems, GE Healthcare, Milwaukee, WI) using a conventional end-fire transducer of fundamental frequencies: 5, 6, and 8 MHz. All patients were given a sodium phosphate enema (Fleet enema, Dexxon Ltd., Hadera, Israel) two hours before the examinations. Patients laid on their left side. Both procedures were performed in random order. The rectal end of each probe was covered with a condom, and 60 ml of degassed water was injected into the rectal balloon around the B&K probe. One hundred milliliters of water was injected into the rectum during F-TRUS. The operator was aware of the results of the colonoscopy and biopsy but was blinded to the results of other imaging studies, such as prior CT, magnetic resonance imaging, and the prior TRUS in patients who underwent the procedure before a neoadjuvant treatment. After completing each TRUS technique, the diagnosis was defined in a separate report and reviewed at the end of the session. The TRUS classification corresponded to the pathologic TNM classification as described by Hildebrandt and Feifel,<sup>8</sup> whereby Stage T1 corresponds to infiltration of the mucosa and/or the hyperechoic submucosa, Stage T2 represents involvement of the hypoechoic muscularis propria, Stage T3 corresponds to extension of the tumor to the perirectal fat, and Stage T4 represents infiltration of other pelvic organs or the pelvic sidewall structures. For N staging, all visible lymph nodes >5 mm were considered indicative of nodal involvement. Preoperative TRUS results (obtained with both methods) were compared with the results of surgical staging.

### Statistical Analysis

Ultrasound T and N staging using each modality separately (*i.e.*, R-TRUS and F-TRUS) was compared with pathologic staging. Separate analyses were conducted for the accuracy of sonographic staging performed with and without preoperative neoadjuvant therapy. All frequencies were compared by the two-tailed Fisher's exact probability test. A *P* value of <0.05 was considered statistically significant.

## RESULTS

### Patients

Figure 1 shows the flowchart of the participating patients. Seventy-four consecutive patients were included. The procedure was performed in 30 patients after neoadjuvant treatment and in 44 patients without neoadjuvant treatment. All patients underwent F-TRUS. Sixteen patients did not have a concomitant R-TRUS and were considered as failures of this technique. In 7 of 16 patients, the tumor obstructed the lumen, and the radial probe could not be inserted through the stenosis. In the other nine cases the tumor was too proximal, so staging was possible for only the most distal part of the tumor.

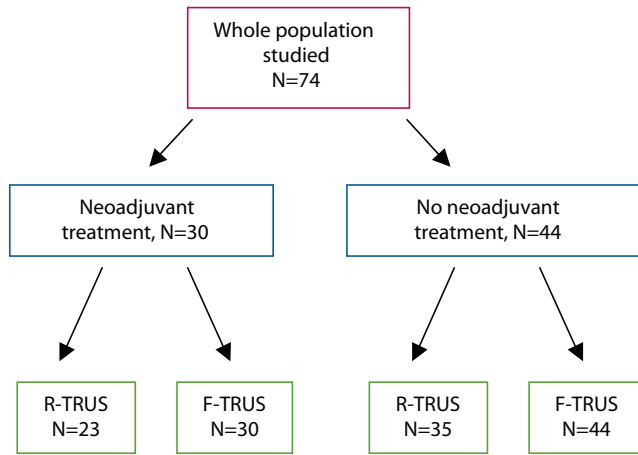


FIGURE 1. Study population flowchart.

**T and N Staging**

Table 1 shows the accuracy of R-TRUS and F-TRUS in the T and N staging of the whole group of patients. Penetration of the tumor into the rectal wall was accurately diagnosed by F-TRUS in 66 of 74 patients (89%), compared with 40 of 58 patients (69%) by the R-TRUS technique. This difference was statistically significant ( $P = 0.004$ ). The difference was even more significant when we compared the 58 patients in whom both examinations were completed. Accurate T staging was achieved in 54 of 58 patients (93%) with the F-TRUS method and in 40 of 58 patients (69%) with R-TRUS ( $P = 0.002$ ). Table 2 shows the results of T and N staging among the group of patients who had preoperative neoadjuvant radiotherapy. The accuracy of F-TRUS reached 93% (28 of 30 patients), compared with 70% (16 of 23 patients) achieved with R-TRUS. This difference did not reach statistical significance. Similar accuracy rates, in favor of F-TRUS, were observed in the group of patients with no preoperative treatment (Table 3). Thirty-eight of 44 patients had an accurate diagnosis by F-TRUS (86%), compared with 24 of 35 patients (67%) by R-TRUS. In the group of 16 patients in whom R-TRUS could not classify the tumor because it was too proximal or stenotic, correct classification was obtained in 14 patients (88%) by F-TRUS. In these patients the agreement was 100% in cases of obstructing tumor (7 of 7 patients) and 78% in cases of proximal tumors. The accuracy of N staging was high with both methods, reaching 88% with R-

**TABLE 1.** Accuracy of transrectal ultrasound using a radial probe or an end-fire probe in the T and N staging of all patients

Pathologic stage	R-TRUS (n = 58)	F-TRUS (n = 74)	P value
T	40 (69%)	66 (89%)	0.004
N	51 (88%)	67 (90%)	0.78

F-TRUS = transrectal ultrasound using an end-fire transducer probe; R-TRUS = transrectal ultrasound using a radial probe.

**TABLE 2.** T and N staging of transrectal ultrasound using a radial probe or an end-fire probe as compared with surgical staging in patients who had received neoadjuvant treatment

Pathologic stage	R-TRUS <sup>a</sup> (n = 23)			F-TRUS <sup>b</sup> (n = 30)		
	T1	T2	T3	T1	T2	T3
T1	1	2	0	5	0	0
T2	1	5	0	0	7	0
T3	0	4	10	0	2	16
	N0	N1		N0	N1	
N0	18	0		23	0	
N1	2	3		3	4	

F-TRUS = transrectal ultrasound using an end-fire transducer probe; R-TRUS = transrectal ultrasound using a radial probe.

<sup>a</sup>Accuracy of R-TRUS for T staging, 16/23 (70%); for N staging, 21/23 (91%).

<sup>b</sup>Accuracy of F-TRUS for T staging, 28/30 (93%); for N staging, 27/30 (90%).

TRUS and 90% with F-TRUS. Preoperative neoadjuvant therapy had no impact on the accuracy rates.

Table 4 shows the rates of overstaging and understaging with both techniques. Understaging was more frequent with the R-TRUS than with the F-TRUS method. The majority of patients who were misclassified had a misdiagnosis of a T2 tumor that was later demonstrated to be a T3 tumor by surgical staging. There were no case of overstaging with the F-TRUS method, where three patients were overstaged by R-TRUS.

**DISCUSSION**

Colorectal cancer is a leading cause of cancer-related death in many parts of the world, being the second most frequent in the United States. The management of rectal cancer is based on locoregional staging. Endoscopic ultrasound has been shown to be a reliable tool for the staging of rectal cancer. Nevertheless, accuracy rates for staging rectal cancer vary among published studies. Although the earliest publications reported relatively high accuracy rates, the

**TABLE 3.** T and N staging results of transrectal ultrasound using a radial probe or an end-fire probe as compared with surgical staging in patients with no neoadjuvant treatment

Pathologic stage	R-TRUS <sup>a</sup> (n = 35)			F-TRUS <sup>b</sup> (n = 44)		
	T1	T2	T3	T1	T2	T3
T1	6	0	0	7	0	0
T2	2	9	1	2	14	1
T3	1	7	9	1	2	17
	N0	N1		N0	N1	
N0	29	2		34	3	
N1	3	1		1	6	

F-TRUS = transrectal ultrasound using an end-fire transducer probe; R-TRUS = transrectal ultrasound using a radial probe.

<sup>a</sup>Accuracy of R-TRUS for T staging, 24/35 (69%); for N staging, 30/35 (86%).

<sup>b</sup>Accuracy of F-TRUS for T staging, 38/44 (86%); for N staging, 40/44 (91%).

**TABLE 4.** Errors in staging by transrectal ultrasound using a radial probe and an end-fire probe

	R-TRUS (n = 58)	F-TRUS (n = 74)	P value
Downstaging	15 (26%)	8 (11%)	0.036
Overstaging	3 (5%)	0 (0%)	NS

F-TRUS = transrectal ultrasound using an end-fire transducer probe; NS = not significant; R-TRUS = transrectal ultrasound using a radial probe.

most recent studies show considerably less accurate results. In this retrospective study we compared the accuracy of two TRUS methods in staging rectal cancer. The accuracy of the F-TRUS method for T staging was better than the conventional R-TRUS method in the whole group of patients. Preoperative neoadjuvant therapy did not change the results. Both ultrasound methods were equally and highly accurate in diagnosing lymph node metastatic involvement when a 5 mm cutoff was used. There was no case of overstaging by F-TRUS in the whole group of patients.

TRUS is the most common technique used to stage rectal cancer. However, its accuracy varies between studies, fluctuating between 63% and 93% for T staging and between 65% and 85% for N staging.<sup>9–11</sup> In addition, lately less impressive overall accuracy rates have been reported. T staging was correctly diagnosed in 66% of the cases of rectal cancer in the study of Ptok *et al.*<sup>12</sup> Similar relatively low rates of correct staging (69% for T staging and 64% for N staging) were reported by Garcia-Aguilar *et al.*<sup>13</sup> In our series an accuracy rate of 69% for T staging was achieved with the R-TRUS method. These results are comparable to those of the aforementioned studies, in which a similar modality of rectal ultrasound was used. However, significantly better results for T staging (93% overall accuracy rate) were obtained with the use of the F-TRUS technique. There are several possible reasons for these better results. First, in the F-TRUS technique, we injected approximately 100 ml of degassed water in the rectum. The use of water enables better rectal distention, and the contact of the water with the rectal mucosa sharpens the accuracy and may also prevent a potential blurring effect in the deep structures. Optimal transmission of the ultrasound waves can be obtained by water penetration between the irregularities of the tumor surface.<sup>14,15</sup> The water-filled balloon around the radial probe is less adapted to the irregularity of the tumor surface. In addition, it may compress the tumor and deform the layers in cases of overdistention. Second, use of a frontal probe allows a larger degree of liberty to rotate the transducer in the rectal cavity, facilitating selection of the best plane for examination of the tumor. Use of a frontal probe also makes it easier to freely reexamine the tumor under various angles and eliminate artifacts. The radial transducer is much more limited in receiving an optimal orientation while inserted in the rectum. In addition, the accuracy of ultrasound imaging is a function of the resolu-

tion and penetration of the acoustic beam. The penetration of a higher frequency beam is lower, but the resolution is better. The lateral resolution is inversely related to the aperture of the transducer. These differences between the probes may explain the better results obtained with use of a curved array transducer of 8 MHz for F-TRUS than with the radial 10-MHz rotating probe used for R-TRUS, although the F-TRUS will require the operator to adjust to a different type of image.

Errors in staging involve a risk of missing the possibility of adapting treatment that can have medical or financial implications. Overstaging may result in overtreatment, and understaging may alter the prognosis by not providing the best treatment. Overstaging is not an unusual finding.<sup>16–18</sup> It occurs most frequently with T2 tumors. Overstaging by MRI has been reported range from 30% to 38%.<sup>19,20</sup> It occurs because of the lack of reliability in distinguishing between an inflammation or desmoplastic reaction and tumor extension. No patients were overstaged by F-TRUS, and only 5% were overstaged by R-TRUS. Because we had only a small number of patients who were overstaged with use of the R-TRUS method, the difference between both methods was not significant. In our series understaging occurred more frequently. Understaging occurred in 26% of cases evaluated with R-TRUS and in 11% of those evaluated with F-TRUS. Similar results (13% rate of understaging) were recently reported by Garcia-Aguilar *et al.*<sup>13</sup> The understaged cases consisted mainly of patients with missed focal penetration into the muscularis propria. Understaging may be related to the strong posterior attenuation of the ultrasound beam caused by luminal secretions or hyperechoic or ulcerated tumors. F-TRUS resulted in fewer cases of downstaging. This lower rate may be related to the lesser distention of the rectal wall caused by the water injected and the absence of air at the interface between the tumor and the probe.

The accuracy of a diagnostic method is essential to determine its clinical use. But accurate staging implies that the entire tumor is examined; otherwise the feasibility of the method is undermined. R-TRUS has been traditionally limited to mid rectal tumors. Bipat *et al.*<sup>6</sup> proposed that TRUS should be limited to tumor located up to 8 to 10 cm from the anal verge. Doornebosch *et al.*<sup>21</sup> observed that the median distance from the dentate line was 11 cm in non-assessable tumors and 7 cm in assessable tumors. A proximal location of the tumor was associated with a relatively high rate (18%) of misstaging in a series of 118 patients undergoing R-TRUS.<sup>22</sup> In our series 16 of 74 (22%) of the rectal tumors could not be evaluated because nine were too proximal to be reached by the radial transducer and seven were obstructive. Nevertheless, seven of seven stenotic tumors and seven of nine proximal tumors were accurately staged by the F-TRUS technique. Overcoming the limitations of R-TRUS was achieved by use of an end-fire transducer, which was chosen because ultrasound waves are

transmitted frontally, along the axis of the rectum. This enabled us to examine up to approximately 20 cm from the anal verge. Other modalities, such as endoscopic ultrasound and transvaginal ultrasound, have been described for the examination of inaccessible tumors.<sup>23,24</sup> Although the use of an endoscopic ultrasound may be helpful for the cannulation of stenotic tumors, the overall accuracy of this examination was found to be as low as 49%,<sup>23</sup> so further studies are needed.

The diagnosis of nodal infiltration is still challenging because there are no universally accepted criteria. Some authors consider any lymph node in the perirectal tissue as a positive finding, whereas others use a cutoff ranging from 3 to 10 mm.<sup>25–27</sup> We selected a cutoff value of 5 mm in peritumoral hypoechoic round-shaped nodes for the diagnosis of potential positive metastasis. With use of this cutoff, the accuracy of both methods was similarly high (88% with R-TRUS and 90% with F-TRUS). Nevertheless, Brown<sup>28</sup> noted that 15% of patients who underwent a total mesorectal excision were reported to have nodal involvement when at preoperative TRUS a 5 mm cutoff value was used to determine the presence of potential metastatic lymph nodes. Higher sensitivity rates for the detection of metastatic lymph nodes may be obtained by use of different echogenic patterns. Mixed echogenicity, as opposed to a pure hypoechoic pattern, is considered by others as a potential predictor of positive metastatic lymph nodes.<sup>29</sup> Therefore, the combination of the various sizes and different echogenic patterns should be studied to optimize the determination of lymph node involvement.

Our study has two primary limitations. First, a single operator (MBG) performed both techniques in a large majority of the patients. One might speculate that there was a subjective interest in favor of the new method. That is, that F-TRUS, as a new method for the staging of rectal cancer, might have been credited with enthusiastic results in this first publication. It has been stated before that selective reporting of studies featuring positive results might result in overestimation of the capability of TRUS. However, the same operator had no information about the findings of any other imaging modality previously performed, and the result of histopathologic staging of the resected specimen was unavailable before both techniques were performed. In addition, two different machines with different files were used, making each examination a different experience. However, the details of both examinations were reviewed at the end of each session to overcome any potential subjective involvement. Second, the study had a retrospective design. Nevertheless, the procedures evaluated were performed before surgical intervention, and all consecutive patients were included.

In conclusion, in this first report of the use of an end-fire probe, F-TRUS was demonstrated to overcome the traditional limitation of R-TRUS in the T staging of rectal

cancer. It is recommended for the staging of proximal or stenotic rectal tumors. The better accuracy of F-TRUS as compared with R-TRUS makes this method useful as a first-line diagnostic modality in any case of rectal cancer.

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