How Accurate is Endorectal Ultrasound in the Preoperative Staging of Rectal Cancer?

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In rectal cancer, depth of infiltration and metastatic involvement of lymph nodes are important prognostic factors. The correct choice of operative treatment depends on the extent of the disease. In a prospective study, the value of endorectal ultrasound in staging rectal cancer was evaluated, and factors affecting the method's accuracy are discussed. The overall accuracy in staging depth of infiltration was 89 percent. Overstaging occurred in 10.2 percent, understaging in 0.8 percent. Tumors of the lower rectum are incorrectly staged in 16.7 percent, whereas tumors of the middle and upper rectum had an incorrect staging in 6.3 percent ($P < 0.001$). Compared with computed tomography, endorectal sonography is the more accurate staging method (74.7 *vs.* 90.8 percent). In staging lymph nodes, the overall accuracy was 80.2 percent, sensitivity was 89.4 percent, specificity was 73.4 percent, positive predictive value (PPV) was 71.2 percent, and negative predictive value (NPV) was 90.4 percent. The staging accuracy depends on the size of the node. Endorectal ultrasound is a safe, inexpensive, and accurate staging method, in the assessment of both depth of infiltration and nodal status. The results are strongly related to the experience of the investigator. [Key words: Rectal cancer; Endorectal ultrasound; Preoperative staging; Computed tomography]

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The exact preoperative registration of the depth of infiltration of a rectal cancer and its nodal involvement permit the correct choice of operative procedure. With the clinical staging described by Mason, the extent of infiltration can be predicted in 60 to 80 percent of cases.[2–7] Computed tomography shows the infiltration by the tumor with an accuracy of 53 to 94 percent.[6, 8–12] Nodal involvement cannot be precluded with either method; nor is it possible to distinguish between early tumor stages (T1/T2).[13]

Various studies report a high accuracy of endorectal ultrasound in predicting depth of infiltration and—to a lesser degree—nodal involvement in rectal cancer. Our prospective study reports the results of endorectal ultrasound in staging rectal cancer. Factors affecting the method's accuracy are discussed.

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PATIENTS AND METHODS

Between January 1989 and November 1991, all 125 patients with histologically proven rectal cancer or rectal adenoma were prospectively investigated by endorectal ultrasound. Patients with a stenotic tumor were excluded because a correct ultrasonic evaluation was impossible. All resected specimens of the primary lesion were completely assessed by the same pathologists. One hundred eighteen patients fulfilled the mentioned criteria. There were 58 men and 60 women with a mean age of 68 years (range, 40–93 years). One hundred five patients had a laparotomy (70 anterior resections, 31 abdominoperineal amputations, and 4 Hartmann's procedures), and 13 patients had a local excision (1 Mason proctotomy and 12 transanal disc excisions). Fifty-four tumors were in the lower rectum (0 to 6 cm above the anal verge), 45 were in the middle (7 to 11 cm), and 19 were in the upper third (12 to 15 cm) of the rectum.

Scan Interpretation

The TNM classification adjusted for ultrasound, as described by Hildebrandt and Feifel,[14] served as a standard. The uT1 tumor is confined to the mucosa and submucosa, a uT2 lesion infiltrates the muscularis propria without penetrating the rectal wall, a uT3 lesion invades the perirectal fat, and a uT4 tumor infiltrates surrounding organs. Lymph nodes in the perirectal fat were identified as metastases if they were hypoechoic, as proposed by Beynon *et al.*[15] and recently proved by Glaser and coworkers[16] from Heidelberg, Germany.

The rectal wall is ultrasonically split in five lay-

ers: three echo-poor (hypoechoic) and two echo-rich (hyperechoic). These five layers correspond, as was shown in *in vitro* studies,[6, 17, 18] to the anatomic layers of the rectal wall. Our interpretation of the ultrasound picture corresponds with Beynon and colleagues[19] (Fig. 1). The fourth, hypoechoic layer may be divided in two layers: the inner longitudinal muscle and the outer circular muscle (Fig. 2), separated by a fine hyperechoic layer, probably corresponding to the interface between the two muscular structures.

Technique of Endorectal Ultrasound

All investigations are done in the lithotomy position. After a cleansing enema, a digital rectal examination and a rectosigmoidoscopy with a rigid instrument are performed. The height of the lesion is measured. Endorectal ultrasound is performed with an 1846 Brüel & Kjaer (Naerum, Denmark) scanner with an 1860 rotating probe. The instrument with a 7.0-MHz transducer at the top is introduced through the rectoscope (360° view, 90° scanning plane, focal length 2 to 5 cm, 4 to 6 cycles per second). The transducer is covered with a rubber sheath filled with 50 to 60 ml of degassed water, providing an optimal acoustic pathway. By slowly retracting the rotating probe, any alterations of the rectal wall and perirectal structures may be visualized.

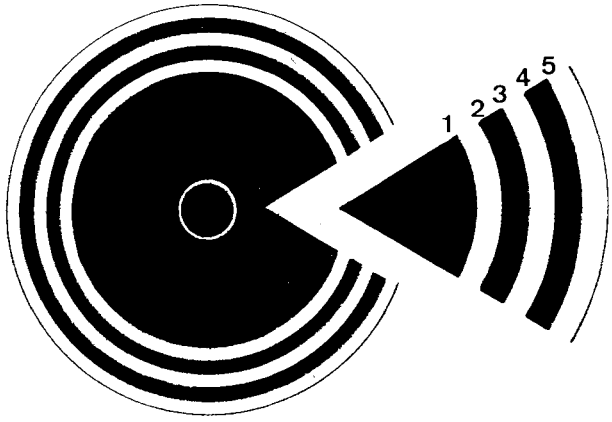

Figure 1. Interpretation of endorectal ultrasound scan. 1-Interface between water-filled balloon and mucosal surface. 2-Mucosa and muscularis mucosae. 3-Submucosa. 4-Muscularis propria. 5-Interface between muscularis propria and perirectal fat or serosa.

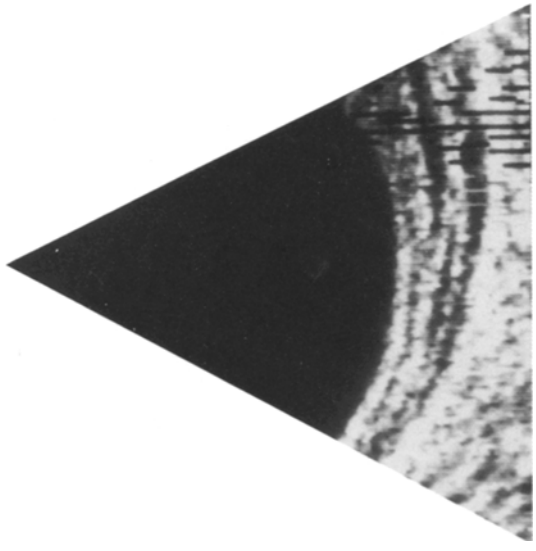

Figure 2. The seven-layer picture of the normal rectal wall.

Computed Tomography (CT)

CT scans were performed with a Philips (The Netherlands) CX-scanner. Contrast medium was introduced into the rectum without any prior bowel preparation. Pictures were taken at 1-cm intervals, and three degrees of infiltration were defined: tumor limited to the rectal wall, infiltration of the perirectal fat, and infiltration of neighboring organs.

RESULTS

Depths of Infiltration

Applying the uT classification in the manner of Hildebrandt and Feifel,[14] we found 20 adenomas or uT1 carcinomas (Fig. 3), 20 uT2 carcinomas (Fig. 4), 75 uT3 carcinomas (Fig. 5), and three uT4 lesions (Fig. 6). According to the TNM staging system,[13] the pathologists found 22 adenomas or

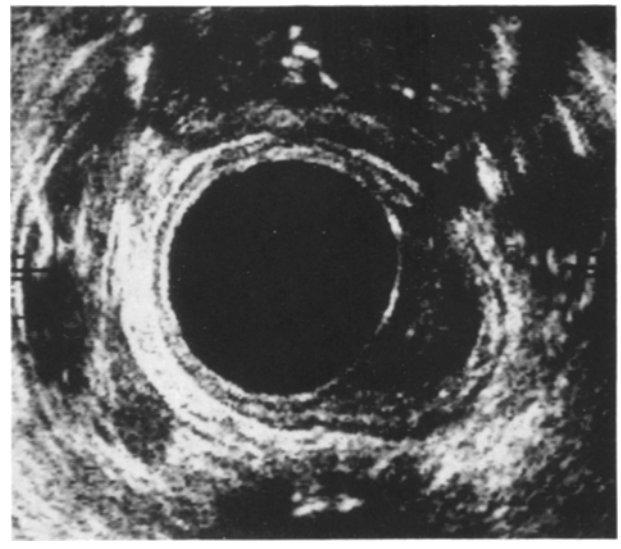

Figure 3. uT1 carcinoma. Homogenous tumor without infiltration of the submucosal layer.

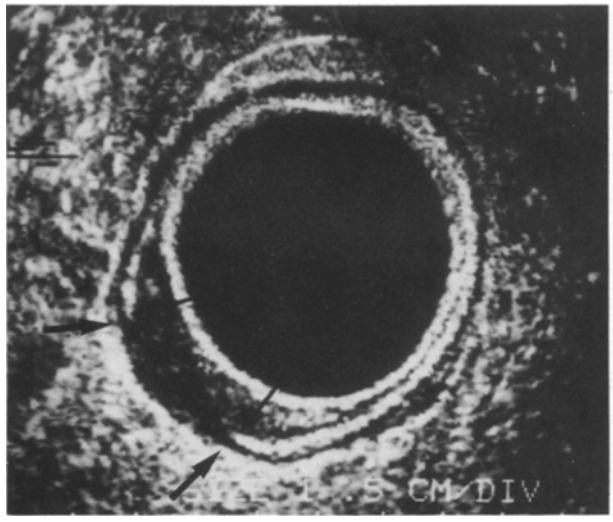

Figure 4. uT2 carcinoma. The third hyperechoic submucosal layer is infiltrated by tumor. Arrows show disruption of the submucosal layer.

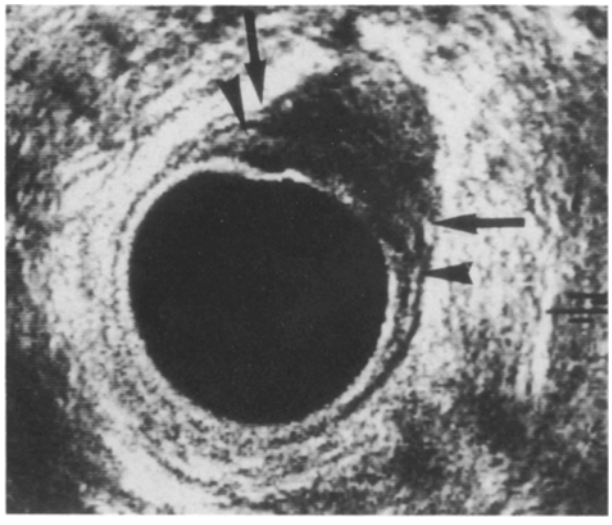

Figure 5. uT3 carcinoma. Both the hyperechoic submucosal and the hypoechoic muscularis layers are destroyed by the rectal carcinoma. Arrowheads show disruption of the submucosal layer. Arrows show disruption of muscularis propria.

pT1, 26 pT2, 68 pT3, and two pT4 carcinomas (Table 1).

The overall staging accuracy for all 118 patients was 89 percent. Twelve tumors (10.2 percent) were overstaged: five times there was a remarkable, histologically proven peritumoral inflammation, three times a peritumoral abscess was found, once the patient had preoperative radiotherapy, and three times the tumor stage was misinterpreted by the investigator. In one case, the tumor was overstaged (0.8 percent); it was a giant adenoma with localized infiltration of the submucosa (pT2).

Figure 6. uT4 carcinoma. All rectal wall structures are destroyed by the tumor infiltrating neighboring organs.

Table 1.
Correlation of Endosonographic and Histopathologic Staging of Rectal Cancer

pT \ uT	uAd/uT1	uT2	uT3	uT4
Ad/pT1	19	3		△
pT2	1	17	8	
pT3			67	1
pT4				2
	□			○

□: understaging; ○: correct staging; △: overstaging.

Which tumors were incorrectly staged? Three times a pT1 lesion was staged as uT2; all tumors had marked signs of peritumoral inflammation or even an abscess. Eight times a histologically proven pT2 tumor was staged as uT3: three with peritumoral inflammation, one abscess formation, one after radiotherapy, and three misinterpretations. One uT4 tumor with an abscess was finally a pT3 lesion.

Tumors in the lower third of the rectum (n = 54) were incorrectly staged in 16.7 percent (9/54), in the middle third (n = 45) 6.7 percent (3/45), and in the upper third of the rectum (n = 19) only 5.3 percent (1/19). The difference in staging accuracy between tumors of the upper/middle rectum and of the lower rectum is strongly significant ($P < 0.001$). Both preoperative staging methods—CT and endorectal ultrasound—were applied in 87 patients (Table 2). The overall accuracy with CT was only 74.7 percent, whereas with endorectal ultrasound in 90.8 percent the depth of infiltration was correctly predicted.

Table 2.
Preoperative Staging with CT and Endorectal Ultrasound: Results in 87 Patients

	CT (%)	EUS (%)
Accuracy	74.7	90.8
Sensitivity	68.9	98.3
Specificity	86.2	75
PPV	90.9	89.2
NPV	58.1	95.4

EUS = endorectal ultrasound; PPV = positive predictive value; NPV = negative predictive value.

Lymph Node Metastases

It has been mentioned that, under containing metastases, nodes are seen as hypoechoic structures in the perirectal fat (Fig. 7). Of 125 patients with rectal cancer, 111 underwent a surgical procedure that allowed a conscientious evaluation of the perirectal nodes. The endosonographic diagnostic evaluation of nodal disease resulted in an overall accuracy of 80.2 percent, a sensitivity of 89.4 percent, and a specificity of 73.4 percent. The PPV was 71.2 percent, and the NPV was 90.4 percent. Overall, 17 times a false-positive and five times a false-negative result was obtained. In three of the five cases with unrecognized metastatic disease, the nodes were smaller than 5 mm; the other two false-negative lymph nodes measured between 6 and 10 mm. This observation shows that the staging accuracy depends on the size of the node.

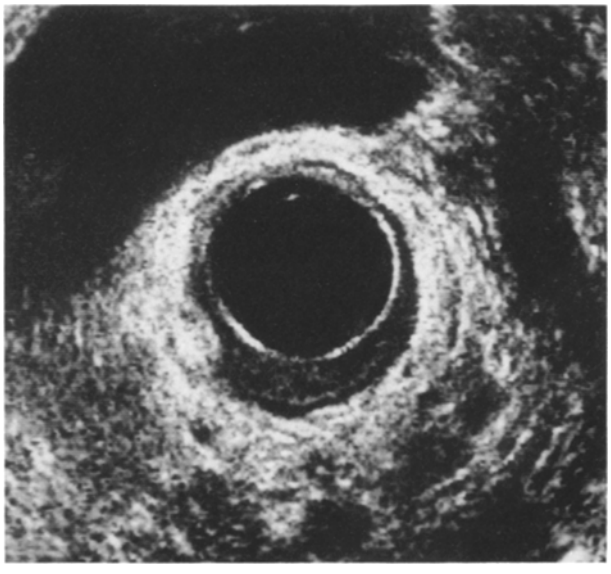

Figure 7. Lymph node metastases. A tumor is infiltrating the rectal wall and several hypoechoic structures in the perirectal fat.

Eleven of 14 (79 percent) nodes smaller than 5 mm, 22 of 24 (92 percent) nodes with a size between 6 and 10 mm, and all nine (100 percent) nodes greater than 11 mm were correctly staged. Correct staging of nodes smaller than 5 mm was significantly worse ($P < 0.05$) than staging of nodes greater than 6 mm.

DISCUSSION

The therapeutic approach for cancer of the lower rectum—local excision *vs.* low anterior resection or amputation—may be evaluated with the help of exact preoperative staging. The goal of any staging method is to predict the main prognostic factors of rectal cancer, *i.e.*, the depth of infiltration and nodal involvement. Since clinical staging[20] is strongly dependent on the investigator's experience, the result cannot be reproduced, and tumors in the upper third of the rectum are, in addition, not within reach of digital examination. Therefore, the method has lost its appeal as a staging method, especially since CT and endoluminal ultrasound (EUS) were found to be more accurate staging methods.

To interpret published results of CT in staging rectal cancer is difficult because the authors fail to mention which of the staging systems they applied.[21–23] It is well known that with CT it is impossible to distinguish between T1 and T2 tumors, but infiltration into the perirectal fat or into neighboring organs is more easily demonstrated. Under these circumstances it is hard to see how some authors are able to rely in their staging systems on the TNM system.[21, 24, 25] In demonstrating infiltration of perirectal fat, CT is more reliable than in showing depth of invasion within the bowel wall. The overall accuracy is reported to be between 76 and 94 percent.[2, 6, 8, 10, 12, 21, 26] In our series, we reached an accuracy of 74 percent. The low NPV is indicative of the inability of CT to demonstrate small areas of infiltration. Comparing both methods—CT and EUS—EUS was always superior.[11, 23, 25, 27, 28] In our series of 87 patients, the accuracy with CT was 74.7 percent, and with EUS we were able to correctly identify the depth of invasion of the rectal wall in 90.8 percent.

The overall staging accuracy for endoluminal sonography is in the range of 75 to 94 percent[6, 29–35] (Table 3). As others,[34, 36, 37] we observed a greater percentage of overstaging than understaging. In our series we found, in 8 of 12 cases (67

Table 3.
Overall Accuracy of Endorectal Ultrasound in the Preoperative Staging of Rectal Cancer (Depth of Infiltration)

Literature	No. of Patients	No. with Correct Diagnosis	Accuracy (%)
Rifkin *et al.*[35]	101	61	60
Saitoh *et al.*[29]	88	79	90
Orrom *et al.*[31]	77	58	75
Glaser *et al.*[30]	86	76	88
Accarpio *et al.*[32]	54	51	94
Beynon *et al.*[6]	89	82	92
Hildebrandt *et al.*[33]	98	87	89
Jochem *et al.*[34]	50	40	80
Present study	118	105	89

percent), inflammatory changes as the reason for a false-positive interpretation. The inflammatory peritumoral changes mimicked direct extension of the tumor. As shown by Napoleon *et al.*,[37] who confirm former observations of Mascagni and colleagues[38] and Dershaw *et al.*,[36] radiation therapy causes serious changes in the perirectal fat. It then becomes impossible to identify the known tissue planes and to distinguish between tumor and radiation-induced inflammation or fibrosis. In our series there was one tumor after preoperative radiation therapy staged as uT2 rather than uT1.

Initially, in the learning period, three tumors were overstaged. As nicely shown by Orrom and colleagues,[31] results are strongly dependent on the investigator's experience. In their study, they reached a significant improvement in the staging accuracy between the learning period and the experienced period (84 *vs.* 95 percent).

The treatment of choice for rectal cancer in the middle and upper thirds of the rectum is anterior resection. The surgical approach, which is clearly defined by Heald *et al.*,[39, 40] who recommend in every case the resection of the mesorectum, is hardly influenced by a positive or negative nodal status. The treatment of cancer in the lower third of the rectum is defined by the depth of infiltration and nodal involvement. T1 tumors may be resected by local excision, whereas the treatment of T2 or higher-staged tumors is abdominoperineal amputation. Relying on endorectal ultrasound only, the decision may result in an inadequate treatment. In our series, 9 of 54 tumors (16.7 percent) in the lower rectum and only 4 of 64 tumors (6.25 percent) in the middle and upper rectum were incorrectly staged. The difference is great but does not reach significance ($P < 0.25$) (Table 4). The reason for this poor staging accuracy in the lower rectum is a technical one. With a rigid instrument it is difficult to reach all sites of the ampulla recti, an observation recently reported by Jochem *et al.*[34] of the Mayo Clinic. To get correct ultrasound imaging with consecutively correct staging, the ultrasound waves should penetrate the tumor perpendicularly. If the tumor lies posteriorly, it is nearly impossible to fulfill the above-mentioned criteria of correct positioning of the transducer.

Controversy exists about the assessment of nodal disease. Tio and Tytgat[41] first described the hypoechoic pattern of metastatic lymph nodes. Later on, Beynon *et al.*[15] and Hildebrandt and colleagues[42] applied Tio and Tytgat's observation to the rectum. At present an accuracy of 72 to 83 percent (Table 5) with ultrasonic diagnosis of nodal improvement is reported. Other radiologic methods—*i.e.*, lymphoscintigraphy,[44–46] immunoscintigraphy,[47, 48] CT,[10, 27, 49] or MRI[50, 51]—were investigated with different success. The experience with most of these techniques is small, and further results are needed to evaluate their real values.

With CT it is difficult to predict nodal imvolvement because nodes smaller than 1 cm are seen

Table 4.
Staging Accuracy in Relation to Tumor Localization

Distance from Anal Verge	No. of Patients	No. of Understaging	No. of Overstaging	False Staging (%)
0–6 cm	54	1	8	16.7
7–11 cm	45	—	3	6.7
12–15 cm	19	—	1	5.3

a: $P < 0.25$; b: $P < 0.05$; c: $P < 0.001$.

Table 5.
Accuracy of Endorectal Ultrasound in the Detection of Nodal Involvement

Literature	No. of Patients	No. with Correct Diagnosis	Accuracy (%)
Saitoh *et al.*[29]	71	52	73
Beynon *et al.*[15]	95	79	83
Orrom *et al.*[31]	77	63	82
Rifkin *et al.*[35]	102	83	81
Hinder *et al.*[43]	20	16	80
Hildebrandt *et al.*[42]	113	89	79
Glaser *et al.*[30]	34	26	76
Jochem *et al.*[34]	39	28	72
Present study	111	89	80

only with difficulty, and visible lymph nodes may finally show reactive inflammatory changes.[11, 15, 27, 35] Node size is a bad indicator of metastatic disease, as shown by Herrera-Ornelas *et al.*[52] In their series of 52 patients with colorectal cancer, 40 percent had positive lymph nodes. Two-thirds of these metastatic nodes were smaller than 5 mm, and 88 percent were smaller than 10 mm.

If not the size of a node, what else makes the correct diagnosis of a lymph node metastasis possible?

Glaser *et al.*[16] validated the now-accepted fact that hyperechoic lymph nodes correspond to inflammatory nodes and hypoechoic lymph nodes are metastases, by computerized B-scan texture analysis. They found that metastatic lymph nodes are hypoechoic with poor contrast within the node, whereas inflammatory nodes are more hyperechoic with more contrast. This observation is independent of the size of the nodes and the surrounding fat tissue and is based on a significant difference between inflammatory and tumorous nodes concerning gray level and mean gradient.

In another study, recently published by Hildebrandt *et al.*,[42] the physical basis of differentiation of lymph nodes was assessed *in vitro* by determination of ultrasound parameters. They found no difference in the speed of sound between involved and uninvolved lymph nodes, a tendency toward a lower acoustic impedance in involved nodes, a clear lower backscattered amplitude in metastatic lymph nodes, and a significant lower attenuation coefficient in tumorous nodes. These differences may be explained by the different architectures of inflammatory and metastatic nodes. Applying these criteria, Hildebrandt and colleagues[42] report a sensitivity of 72 percent and a specificity of 83 percent in their collective of 113 controlled specimens.

Our results, with an accuracy of 80.2 percent, compare well with the published reports (Table 5). The sensitivity predicting metastatic involvement was 89.4 percent. Of 47 histologically proven metastases, 42 were correctly diagnosed with endosonography, whereas five times lymph node involvement was missed. Three of these five nodes were smaller than 5 mm, and two were between 6 and 10 mm. Considering the whole collective of nodes smaller than 5 mm (n = 14), we missed the correct diagnosis in 21.4 percent, for nodes between 6 and 10 mm (n = 24) we failed in 8.4 percent, and in the group of nodes greater than 11 mm we did not miss any lymph node metastases. Specificity was 73.4 percent; of 64 tumor-free nodes, 47 were correctly diagnosed by endosonography, but in 17 cases a false-positive diagnosis was made. Transitional forms with changing degrees of inflammation and cross-sectioned vessels in the perirectal fat, misinterpreted as lymph nodes, explain this high rate of false-positive nodes.

Already, Saitoh *et al.*[29] mentioned that nodes as small as 5 mm could be detected by ultrasound. Rifkin and Wechsler[27] defined lymph nodes as abnormal if, regardless of their size, they were detected by ultrasound. With this technique they reached an overall sensitivity of 67 percent and a specificity of 91 percent. Similar results are reported by Beynon *et al.*[15] and Glaser and colleagues.[30] Beynon *et al.*[15] stressed the ultrasonic guided fine needle aspiration of suspicious structures to determine the true status of a node, and Glaser *et al.*[30] hope that, with a 10-MHz transducer, predicting lymph node involvement may be improved. Hinder *et al.*[43] propose a re-evaluation of the perirectal fat for nodal structures on videotape because they believe that the investigator is primarily attracted by the tumor and its depth of penetration and misses the correct interpretation of the mesorectum.

CONCLUSION

Endorectal ultrasound is a promising method in staging rectal cancer. The method is safe, inexpensive, and accurate, in the assessment of both depth of infiltration and nodal status. The results are strongly related to the experience of the investigator.

With a flexible instrument instead of a rigid probe, the distal part of the rectum—the ampulla recti—could be assessed more accurately. A 10-MHz transducer, which offers better resolution with a shorter focal length, could possibly improve prediction of lymph node involvement.

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