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and Other Interventional Techniques

# The value of endosonographic rectal carcinoma staging in routine diagnostics

# A 10-year analysis

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## Abstract

*Background:* Endosonography is currently the gold standard for the local staging of rectal carcinoma, but its accuracy varies from 62% to 91%. This study aimed to determine the accuracy of endosonography, to evaluate the interobserver variability, and to compare the performance of the 7.5-MHz and the 10-MHz ultrasound scanners.

*Methods:* Between 1990 and 2000, 458 patients with rectal cancer were included in the study. All the patients had undergone rectal endosonography with a 7.5-MHz scan (period 1: 1990–1996) or a 10-MHz scan (period 2: 1997–2000). Endosonographic staging was compared with pathologic staging.

*Results:* The overall rate for correctly classified patients was 69% with respect to the T category and 68% with respect to the N category. There was no difference between the two scanners. In terms of accuracy, the T3 category tumors were the most (86%) and the T4 tumors the least (36%) accurately classified. Overstaging of tumors (19%) was much more frequent than understaging (12%). A high interobserver variability of 61% to 77% was noted. For pT1 tumors, the 10-MHz scan was almost two times more accurate than the 7.5-MHz scan (71% vs 36%).

*Conclusions:* The accuracy of endosonographic staging of rectal carcinoma very much depends on the T category. A high-resolution scanner and an experienced examiner can help to ensure that endosonography remains an important tool in the staging process of patients with rectal carcinoma, especially early carcinoma.

**Key words:** Endosonography — Rectal carcinoma — Preoperative staging

In the stage-oriented therapy of rectal carcinoma, the exact pretherapeutic determination of the T and N categories is essential. After distant metastases have been excluded, the T category determines the therapeutic strategy that will be used. For example, well-differentiated (G1-G2) early invasive carcinomas can be excised locally [6], whereas locally advanced carcinomas currently are considered to be most appropriately treated with a neoadjuvant radio/chemotherapy strategy. In addition, ongoing clinical studies currently are evaluating the role of neoadjuvant radio/chemotherapy for the improved long-term survival of patients with T3 category tumors [3, 4, 16]. Endosonography currently, is the gold standard for the pretherapeutic local staging of rectal carcinoma. Its accuracy in determining the tumor invasion depth (uT) for all stages varies from 62% to 91% (mean, 84%), according to the literature [2, 10].

The current retrospective study aimed to determine the accuracy of endosonographic staging in routine diagnosis over 10 years in an university teaching hospital, to evaluate the interobserver variability, and to compare the performance of the 7.5-MHz ultrasound scanner with that of the 10-MHz scanner using the same ultrasound equipment.

#### Patients and methods

We reviewed the charts of 693 patients with the diagnosis of rectal carcinoma. As a result, 458 patients who fulfilled the inclusion criteria (Table I) were included in the study. None of these patients had undergone previous treatment including short-course radiotherapy. We excluded 235 of the 693 patients. In 96 patients (14%), the tumor could not be completely evaluated due to tumor stenosis, and 129 patients (19%) had undergone neoadjuvant treatment. For 10 patients (1%), technical problems had occurred. The study consisted of two investigation periods, as outlined in Table 2.

All the patients were examined in the lithotomy position. After digital examination to assess mobility and morphology, the tumor was inspected through a rigid endoscope. A 7.5-MHz (1990–1996) or a 10-

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#### Table 1. Inclusion criteria

#### Adenocarcinoma Between 0 and 15 cm from the linea anocutanea Tumor stenosis completely accessible by endosonography Tumor not previously treated Tumor primarily resectable

#### Table 2. Investigation periods

	1990–1996	1997–2000	
No. of Examiners	7	4	
Transducer (MHz)	7.5	10	
n	382	311	
Primary resection $n$ (%)	266 (77)	192 (61)	

MHz (1997–2000) endosonographic probe (Type 1850; B & K Medical, Naerum, Denmark) was introduced through the endoscope and very carefully passed from the anal verge to the upper rectum. The probe was covered with a rubber balloon, which then was filled with water to achieve optimal contact with the rectal wall. The probe next was retracted slowly to the level of the tumor. In both periods, the examination was performed either by a board-certified and experienced surgeon or by different members of the training program.

For interpretation of the endorectal ultrasound image, we relied on the five-layer model described by Hildebrandt et al. [10] and Beynon et al. [2]. Suspected tumor involvement of lymph nodes was determined according to the following criteria: size, shape, margins, and echogenicity [8]. Sharply defined, hypoechogenic, round lymph nodes more than 5 mm in diameter were assumed to be involved by tumor (uN1).

For all the patients, the endosonographic depth of infiltration by the tumor (uT) was compared with the histopathologic category (pT) of the resection specimen. For the patients who had undergone radical surgery, lymph nodes classified as positive for metastatic spread (pN1) were compared with endosonographic lymph node involvement (uN1). Comparisons between groups were performed using Fisher's exact test. A probability value less than 0.05 was considered significant.

#### Results

#### T category

Overall accuracy for the T category was 69%, with 19% of the tumors overstaged and 12% understaged. Accuracy was significantly higher for the pT3 category than for the other T categories. The overall accuracy for the differentiation between a tumor located on the rectal wall or penetrating beyond the rectal wall was 94%. The sensitivity was 82%, and the specifity 81%, with a positive predictive value of 70% and a negative predictive value of 90% (Table 3).

## N category

Overall accuracy for the N category was 68%. The sensitivity for nodal involvement was 52% and the specifity 82%, with a positive predictive value of 71% and a negative predictive value of 66% (Table 4).

## Interobserver variability

The board-certified surgeon had a significantly higher overall accuracy with regard to the T and N categories

 Table 3. Accuracy of endosonography for the preoperative determination of the T category

Histopathologic	п	Accuracy	Overstaging	Understaging
T category		(%)	(%)	(%)
pT1 pT2 pT3 pT4 Total	64 122 225 47 458	52 59 86 <sup>a</sup> 36 69	uT2: 36 uT3: 12 uT3: 39 uT4: 4  19	uT1: 2 uT2: 11 uT2: 9 uT3: 55 12

<sup>a</sup> p < 0.05 vs pT1, pT2, and pT4

 Table 4. Accuracy of endosonography for the preoperative determination of the N category

Histopathologic N category	n	Accuracy (%)	Overstaging (%)	Understaging (%)
pN0	186	82	18	
pN1	163	52	_	48 <sup>a</sup>
Total	349	68	10	14

<sup>a</sup> p < 0.05 vs. pN0 (overstaging)

**Table 5.** Accuracy of endosonography according to the experience of the examiner

	T category (%)	N category (%)
Board-certified surgeon Members of the training program	77 <sup>a</sup> 61	78 <sup>a</sup> 58

<sup>a</sup> p < 0.05 vs members of the training program

than the members of the training program (Table 5), especially for patients with T1/2 tumors.

## 7.5 MHz vs 10 MHz scanner

There was no difference between the 7.5-MHz and 10-MHz scanners with regard to the overall accuracy of the T and N categories. However, for patients with a pT1-tumor, the 10-MHz scanner was almost two times more accurate than the 7.5-MHz scanner (71% vs 36%) which, was statistically significant (p = 0.005).

## Discussion

Transrectal ultrasounds currently is the most precise method for the pretherapeutic staging of rectal carcinoma [14]. The total accuracy obtained in this study was 69% for the T category. This is consistent with the findings of other authors [1, 7, 10, 17], considering the high number of pT1 and pT2 tumors in our patient population and the fact that a high number of patients with advanced tumors (19%) were excluded from the study because of preoperative radiochemotherapy.

In previous studies concerning the accuracy of transrectal ultrasound, most of the tumors had invaded beyond the bowel wall. The accuracy of the method was lowest for pT1 and pT4 carcinomas, whereas pT3 car-

cinomas of the rectum were the most accurately staged. The differentiation between pT1 and pT2 rectal carcinomas is especially difficult, which is reflected by the fact that the uT2 category had the highest overstaging rate (39%). The best explanation for this problem is the presence of an inflammatory or fibrotic reaction in the tissue surrounding the tumor, which makes the tumor appear to infiltrate deeper than it actually does.

Additional sources of difficulty include (a) the fact that carcinomas usually are hypoechogenic, and because the muscularis propria also is hypoechogenic, infiltration into this layer is difficult to identify; (b) the fact that endosonographic layers are produced by interface reactions from the intestinal wall and do not exactly correspond to anatomic layers; and (c) the fact that microscopic tumor infiltration cannot be recognized by endosonography, which results in understaging of the tumor [7, 13].

The accuracy rectal endosonography also is limited by the nonuniformity of tumor wall invasion. It is therefore imperative to examine the entire lesion.

Whereas overstaging is of less importance, understaging (2 of 122 patients with pT2 category) could lead to undertreatment. If histologic examination of the locally excised specimen shows a higher T category than preoperatively determined, immediate abdominal resection, according to oncologic criteria, should follow. The low accuracy of the endosonographic classification for T2 tumors confirms the argument against transanal resection of these tumors. This leads to the concept that only benign adenomas and "low-risk" T1 tumors are suited for local excision. Although three-dimensional endosonography and magnet resonance imaging with endorectal coil are promising techniques for overcoming this drawback, to date there are no data to prove the superiority of either method over conventional endosonography [11, 20].

Relevant tumor stenosis was present in 14% of our patient population. Because the depth of tumor infiltration could not be accurately evaluated, these patients were excluded from our study. The use of colonoscopic miniprobe ultrasonography can overcome this problem and may have a considerable impact for patients with stenotic rectal cancer [12]. Another important factor in the use of endosonography for rectal carcinomas is the differentiation between tumors located on the rectal wall or penetrating beyond the rectal wall. This study showed an overall accuracy of 94%, a positive predictive value of 70%, and a negative predictive value of 90%, indicating that endosonography remains an important tool for the preoperative assessment of patients with rectal carcinoma considering the possible use of neoadjuvant treatment options. Despite the exclusion of the most advanced tumors, the accuracy of rectal endosonography in diagnosing transmural invasion was high, and compared with conventionell computed tomography or magnetic resonance imaging, rectal endosonography not only was less expensive and commonly available, but also showed a higher accuracy for assessing the depth of rectal wall invasion [15].

Our data confirm that the accuracy of endosonography for determination of the N category is unsatisfactory. One major problem in this regard is that there are no clearly defined criteria for distinguishing reactive from metastatic lymph nodes by endosonography. Additional problems are that 30% of positive lymph nodes actually are smaller than the 5-mm size criterion, that lymph nodes outside the focus area are poorly visualized, and that the main lymphatic drainage areas along the large vessels are not reached by transrectal ultrasound [5, 8]. The lymph node stage can be important for the therapeutic approach for pT1 carcinomas. If it cannot be clearly determined that a tumor (G1 or G2) is confined to the mucosa, and if the involvement of lymph nodes cannot be ruled out, the tumor would not be locally excised.

The high interobserver variability in this study underscores the dependency of endosonographic accuracy on the experience of the examiner. Similar to other studies [5, 18], we found accuracy to be lower when endosonography was performed by a rather inexperienced member of the training program, as compared with an experienced board-certified surgeon. In addition to the aforementioned problems, technical problems (image artifacts, malpositioning of the scanner, inadequate filling of the balloon) are particularly liable to misinterpretation by inexperienced examiners.

The higher resolution obtained by the 10-MHz ultrasound scanner resulted in a higher staging accuracy than that achieved by the 7.5-MHz ultrasound scanner for only pT1 tumors (71% vs 36%). However, even with the 10-MHz scanner, differentiation between an adenoma and a pT1 carcinoma is difficult, as well as the distinction between mucosal and submucosal infiltration [19]. It can be improved by the use of a high-frequency ultrasound scanner and special examination techniques (e.g., filling the rectum with fluid to preserve compression artifacts). Harada et al. [9] evaluated the degree of submucosal invasion in colorectal cancer by using a 15-MHz ultrasound miniprobe. Although the accuracy of the miniprobe in categorizing submucosal invasion into three subclasses (invasion limited to the upper third, invasion limited to the middle third, invasion limited to the lower third) was low, the accuracy for identifying invasion limited to the mucosa or upper third of the submucosa was 85.7%.

The accuracy of endosonographic staging of rectal carcinoma very much depends on the T category. A high-resolution scanner and an experienced examiner can help to ensure that endosonography remains an important tool in the staging process of patients with rectal carcinoma especially early carcinoma. New techniques such as magnetic resonance imaging with an endorectal coil and ultrasound miniprobes still need further evaluation.

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