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The value of endorectal ultrasound in the assessment of adenomas, T1- and T2-carcinomas

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Abstract. In a prospective study we examined the value of endorectal ultrasound (ERUS) in the preoperative staging of potentially locally excisable tumours. During the study period from 1.1.1991 to 1.3.1996 a total of 160 rectal tumours in 152 patients were staged endosonographically (uT/uN) and compared postoperatively with the histologic result (pT/pN) at the University Hospital of Würzburg. Thirty-eight (24%) patients had an adenoma and 15 (9%) a T1-carcinoma. In 29 (18%) cases a T2-cancer was diagnosed, further 67 (42%) and 11 (7%) patients presented with a T3 and T4 tumour, respectively. The sensitivity for adenomas and T1-Ca (uT0/1) was 81%, the specificity 98%. For T2 tumours the sensitivity was only 41% and the specificity 92% as the majority (17 of 29) of pT2 neoplasias were overstaged (uT3). The overall staging accuracy (T1–4) was 77.5%. Two patients with a pT1-Ca and seven with a pT2-Ca had lymph node metastases which were detected preoperatively in five. The accuracy for lymph node staging was 83%. We conclude that adenomas and T1 tumours can be assessed with a high grade of accuracy using ERUS. In these tumours ERUS can be used to assist clinical decision-making (transanal vs. abdominal operation). Owing to the lack of sensitivity, ERUS is of no help in the assessment of T2 carcinomas.

Résumé. Au cours d'une étude prospective, nous avons examiné la valeur de l'échographie endorectale (ERUS) dans la détermination pré-opératoire du stade des tumeurs susceptibles d'être excisées localement. Au cours d'une période allant du 1er janvier 1991 au 1er mars 1995, sur un total de 160 tumeurs rectales, 152 ont fait l'objet d'une détermination endosonographique de leur stade (uT/uN) et ont été comparées avec les résultats postopératoires de l'histologie (pT/pN) à l'Hôpital universitaire de Wurzburg. Trente-huit patients (24%) étaient porteurs d'un adénome et 15 (9%) d'un cancer au stade T1. Chez 29 patients (18%) le diagnostic retenu est d'un cancer au stade T2; de plus, 67 (42%) et 11 patients (7%) patients étaient respectivement porteurs d'une tumeur au stade T3 et T4. La sensibilité pour les adénomes et les cancers au stade T1 (uT0/1) était de 81% avec une spécificité de 98%. Pour les tumeurs au stade T2, la sensibilité n'était que de 41% et la spécificité de 92% étant donné que la majorité des cancers au stade pT2 (17/29) ont été surestimés (uT3). L'exactitude du stade globalement était (T1–4) de 77,5%. Deux patients avec un cancer pT1 et 7 avec un cancer pT2 présentaient des métastases ganglionnaires qui avaient été diagnostiquées en pré-opératoire chez 5 d'entre eux. L'exactitude dans la mise en évidence de ganglions lymphatiques est de 83%. Nous concluons que les adénomes et les tumeurs au stade T1 peuvent être diagnostiqués avec une très grande exactitude au moyen de l'échographie endo-rectale. Dans ces tumeurs, l'échographie peut être utilisée comme aide au diagnostic et au choix thérapeutique (opération par voie transanale versus opératoire par voie abdominale). En raison du manque des sensibilité, l'échographie n'ait d'aucune aide dans la détermination des cancers au stade T2.

Transanal local excision of rectal tumours can be performed for palliative as well as curative reasons. While palliation is usually indicated in the elderly "high risk" patient with poor physical fitness or intercurrent illness, stringent criteria need to be met for curative procedures to minimise the risk of local failure. Tumours suitable for local excision should be mobile, not larger than 3 cm and of a good to moderate histologic differentiation (G1/2) [1]. The most important prognostic factor, however, is the depth of tumour infiltration (T-stage) as the incidence of local lymph node metastases rises sharply with increasing tumour penetration (Table 1) [2]. Regardless of the T-stage and histologic differentation, co-existing local metastases should be sought after so that these patients can be treated primarily according to radical oncological criteria. The aim of our study was to evaluate endorectal ultrasonography (ERUS) in the preoperative staging of potentially lo-

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Table 1. Percentage of lymph node metastases in rectal cancer with regard to depth of infiltration (T) and histologic grading in 1.237 patients of the Dpt. of Surgery, University of Erlangen/Germany [2]

Depth of infiltration	T	Grade 1	Grade 2	Grade 3
Submucosa	T1	3	3	–
Muscularis propria int.	T2a	6	20	17
Muscularis propria ext.	T2b	18	24	56
Perirectal	T3	37	54	86

cally excisable rectal tumours, i. e. adenomas and Dukes A (T1 and T2) cancers.

Patients and methods

In a prospective study at the Department of Surgery, University Hospital of Würzburg 152 patients with a total of 160 rectal tumours were examined by ERUS preoperatively in the period from January 1991 to March 1996. One patient exhibited three synchronous tumours, five others had two neoplasias each. All tumours were staged using the uT/uN classification by Hildebrandt and Feifel [3]. In accordance with other investigators [3–6] we do not distinguish between adenomas and T1 carcinomas as both tumours lead to a broadening of the first hypoechoic layer which corresponds with the lamina mucosa et submucosa. Therefore, all benign polyps (T0) and T1 malignancies were classified together (uT0/1). All patients underwent surgery. If tumours were removed transanally, only adenomas were entered in the study due to the lack of information regarding the lymph node status in patients with a T1 tumour ($n = 4$ in the study period). No patient with a T2 carcinoma was treated by local excision. The postoperative histologic result (pT/pN) was then compared with the preoperative staging. For each T-stage the sensitivity, specificity, positive as well as negative predictive value was calculated. The calculations were also carried out on the combined stages T1+T2 (= local Dukes A) and T3+T4 (= local Dukes B). All sonographically detectable lymph nodes were documented as uN+ and also compared with the postoperative results. Statistical significance was assayed by using the chi-square test, and a *p*-value below 0.001 was considered highly significant.

Endorectal ultrasound is performed using a Kretz Co. rotating scanner (Combison 310+, Zipf, Austria). The rectal probe measures 16 cm in length with a head diameter of 21 mm. During the examination the frequency can be switched from 7.5 MHz to 5.0 MHz with a maximum tissue penetration of about 7 cm for the latter. The resolution for both frequencies is less than 1 mm. The transducer rotates at a speed of 12 cycles per second generating at 360° real-time-image. The beams can be emitted in longitudinal or transverse plane in relation to the longitudinal axis of the rectum. The probe is covered with a rubber sheath which for the purpose of better acoustic contact can be filled with degassed water. Following a thorough rectal digital examination the probe is carefully introduced and slowly advanced under sonographic control. Usually the tumour is first examined using the 7.5 MHz frequency. Subsequently the pararectal tissue is scanned for suspicious lymph nodes with 5.0 MHz. If very small or soft polyps are encountered we prefer to use the ultrasonic probe devised by Heintz and Bueß [4], which is introduced through a rigid rectoscope into the water filled rectum (Fig. 1). Polyps are not pressed against the rectal wall but are rather floating in the water so that the different sonographic layers can still be differentiated and interpreted. This technique was used in nine patients, all of which had adenomas. We use two enemas for patient preparation and prefer to examine in the lithotomy position, although the left lateral position is acceptable for the very elderly or bedridden patients. The examinations were carried out by four different surgeons.

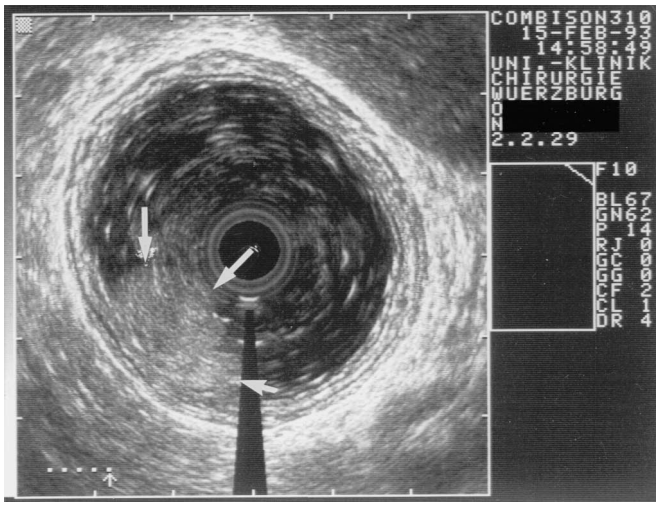


Fig. 1. Large villous adenoma (arrows) in the water filled rectum using an ultrasound probe which is introduced through a rectoscope. All five layers are still intact

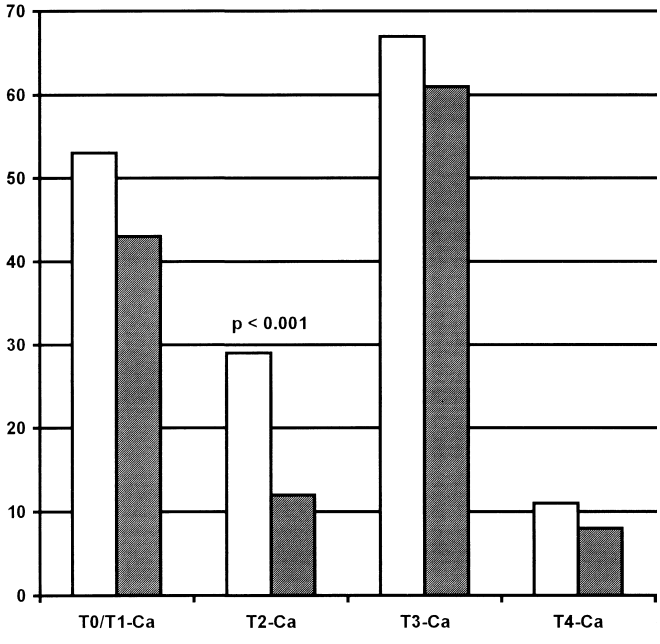
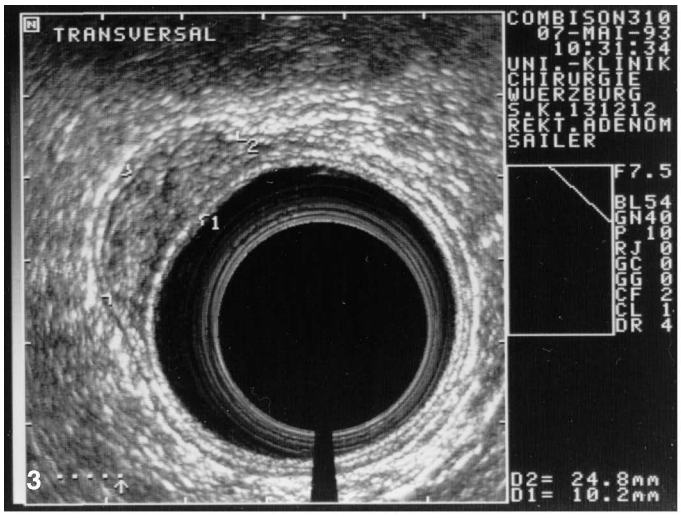
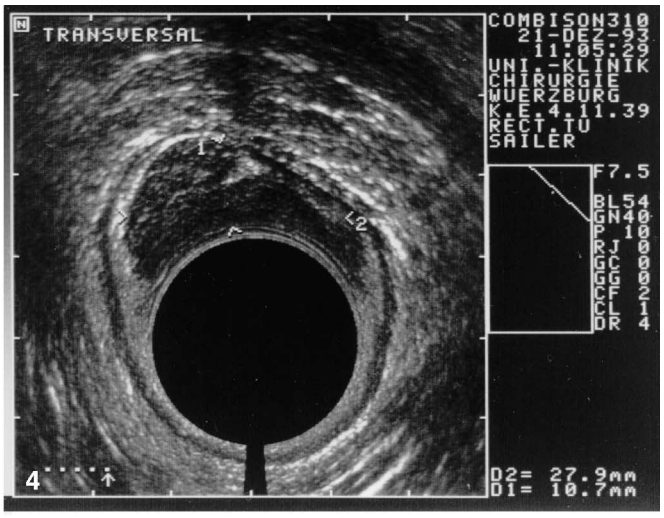


Fig. 2. Comparison of ERUS staging (uT, ■) with histology (pT, □) ($n = 160$)

Results

Of the 152 patients with a total of 160 rectal neoplasms 38 (24%) had an adenoma (T0) and 15 (9%) a cancer invading the submucosa (pT1). We found a tumour infiltrating the muscularis propria (pT2) in 29 (18%), the perirectal tissue (pT3) and neighbouring structures (pT4) in 67 (42%) and 11 (7%) cases, respectively (Fig. 2). The results for sensitivity, specificity, positive and negative predictive value are subdivided according to tumour stage and listed in Table 2.





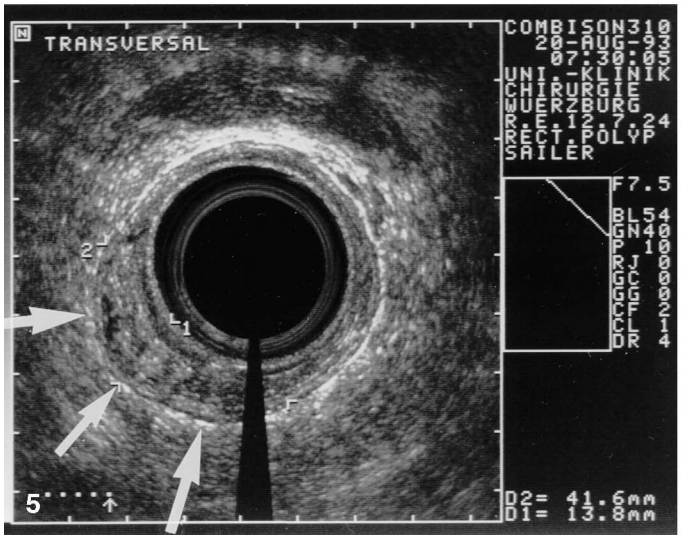


Fig. 3. Adenomatous polyp extending from 9 to 11 o'clock leading to a broadening of the first hypoechoic layer which corresponds with the mucosa and submucosa

Fig. 4. A pT1 cancer in the anterior position. Only the first, inner hypoechoic layer is broadened while the outer one, representing the muscularis propria, is still intact. Note the rather echo-poor structure which can be an indication for malignant transformation

Fig. 5. A pT2 tumour infiltrating the muscularis propria. The outer hyperechoic layer (arrow), which marks the interface between the muscle layer and the perirectal fat tissue, is not breached

Table 2. Endosonographic staging (uT) of 160 rectal tumours compared with histology (pT)

uT \ pT	T0/1 [c]	T2	T3	T4	*n*
T0/1	43	1			44
T2	10	12	1	1	24
T3		16	61	2	79
T4			5	8	13
n	53	29	67	11	160
Sensitivity	81	41	91	73	77,5
Specificity	99	92	81	97	
PPV [a]	98	52	77	62	
NPV [b]	91	88	93	98	
Sensitivity	80		97		
Specificity	97		80		
PPV [a]	97		83		
NPV [b]	83		97		

[a] PPV = Positive predictive value
[b] NPV = Negative predictive value
[c] T0 = adenoma (*n* = 38); T1-Ca (*n* = 15)

Adenomas and T1-Carcinomas

Fifty-three cases of either adenomatous polyps (*n* = 38) (Fig. 3) or T1-carcinomas (*n* = 15) (Fig. 4) were seen. Ten cases were overstaged, i. e. a villous polyp (*n* = 6) or a pT1-Ca (*n* = 4) was classified as a uT2 lesion endosonographically (false positive). Altogether the sensitivity was 81%, the specificity 99%, the positive predictive value (PPV) 91% and the negative predictive value (NPV) 81%.

T2-Carcinomas

Of the 29 histologically proven T2 cancers only 12 were staged correctly by ERUS (Fig. 5). One T2 tumour was understaged whereas 16 neoplasias were overstaged as uT3. Furthermore, one T3 and one T4 cancer had been understaged as uT2. This resulted in a sensitivity of 41%, a specificity of 92%, a PPV of 88% and a NPV of 41%. The difference in staging accuracy of T2 tumours com-

Table 3. Lymph node staging in T1 carcinoma ($n = 15$)

uT \ pT	+	–	*n*
+	2	1	3
–	0	12	12
n	2	13	15

Table 4. Lymph node staging in T2 carcinoma ($n = 29$)

uT \ pT	+	–	*n*
+	3	2	5
–	4	20	24
n	7	22	29

pared with both, T0/1 ($\chi^2 = 13.41$; $p<0.001$) and T3 ($\chi^3 = 27.40$; $p<0.001$) carcinomas was highly significant.

Dukes A

If adenomas and all cancers that are confined to the rectal wall i. e. local Dukes A cancers are combined, all ten false positive uT2 tumours as well as the single false negative uT1 carcinoma (pT2) fall into one group and can therefore regarded as being correctly staged. Sensitivity would then be 80%, specificity 97%, PPV and NPV 97% and 83%, respectively.

Lymph node metastases (T1 and T2 cancers)

In two patients with a pT1 tumour lymph node metastases were found on histologic examination which were detected preoperatively by intraluminal ultrasound in both cases. However, one endosonographically suspicious lymph node was reported inflammatory (false positive) (Table 3). Of the 29 pT2 cancers seven patients (24%) had positive lymph nodes which went undetected in four (false negative) by ERUS (Table 4). For both T-stages together this resulted in overall accuracy (true positive and true negative) of 83%. The sensitivity for the sonographic detection of lymph node metastases (for T1 and T2) was 62% with a specificity of 91%.

Discussion

Transanal local excision is one of several therapeutic options in the treatment of rectal tumours. In principle one has to distinguish between indications for palliative and curative transanal procedures. An individually tailored approach is warranted for patients in whom a palliative operation is considered. Various factors, i. e. the patient's age and request, the presence of metastatic disease and/or serious co-morbidity need to be taken into account and appraised. If, however, transanal excision is offered as a curative procedure, stringent criteria have to be met in order to avoid local failure such as recurrence or loco-regional metastases. Benign rectal tumours, usually adenomatous polyps, are particularly suited for this mode of treatment. For malignant disease the indication for local excision has to be viewed much more critically. According to Hermanek [1] "low risk" and "high risk" tumours have to be differentiated. Microscopically demonstrable tumour infiltration of blood or lymphatic vessels or invasion of perineural sheaths is deemed unfavourable ("high risk") so as, even in the case of a T1 cancer, a local excision should be avoided. Indications for transanal removal of T2 lesions are not generally accepted. Depending on the depth of penetration into the muscularis propria these carcinomas can be further subdivided into T2a (infiltration of the inner, circular muscle layer) and T2b (infiltration of the outer, longitudinal muscle layer). Whereas some authors advocate transanal excision of T2a-stage tumours with a good or moderate histologic differentiation (G1/2) [7, 8], others would consider the presence of a T2 cancer as a clear contraindication [5, 9]. Considering a frequency of local metastases of up to 20% for T2/G2 cancers [2], we would also argue against curative local treatment of these tumours.

Apart from accepted macroscopic (tumour size <3 cm, preferably pedunculated, and non-ulcerated) and histologic criteria [1], the preoperative assessment of the depth of tumour infiltration is paramount in the decision-making as to which therapeutic option should be recommended. In recent years ERUS has gained much interest in treatment planning [5, 9, 10], as comparative studies were able to demonstrate its superiority in the preoperative staging of rectal growths compared with CT, MRT or clinical judgement [11–14].

The aim of our study was to evaluate the usefulness and practicability of transrectal sonography in the preoperative staging of lesions, potentially suitable for transanal excision, i. e. adenomatous polyps, T1 and T2 cancers. The differentiation of adenomas and T1 carcinomas by ERUS is very limited since both lesions lead to a broadening of the first hypoechoic layer (Fig. 3 and 4) which corresponds anatomically with the mucosa and submucosa. In accordance with other authors [3–6] we agree that neither the submucosa nor the muscularis mucosae are sonographically definable structures, so that benign polyps and T1 tumours should be classified together (uT0/1). On the other hand, Kuntz and co-workers [15] reported excellent results in discriminating adenomatous lesions from T1 carcinomas. Of 93 patients who were thought to have an adenoma and were subsequently operated upon, 28 turned out to have malignant disease. ERUS was able to preoperatively detect 27 of these cancers, thus reaching a sensitivity of 96%. The distinction was based on the difference in the echogenicity as, according to the authors, malignant transformation is far more likely in echo-poor lesions. Applying however, the same criterion, Adams and Wong [16] were only able to reach a 50% sensitivity in their group of 59 T0/1 patients.

The problem of differentiating adenomas from carcinomas using the echogenicity as a criterion is highlighted in

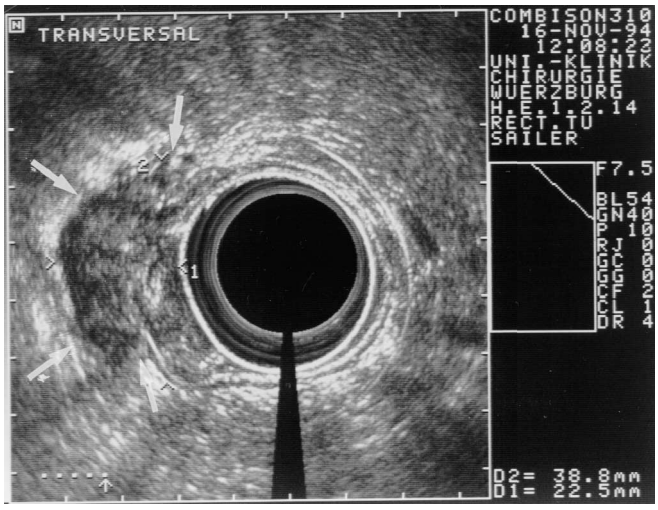


Fig. 6. A large rectal tumour on the right lateral position seemingly penetrating the perirectal tissue (arrows) by sonographically extending beyond the interface muscularis/perirectal tissue (uT3). Two days prior to the examination biopsies were taken leading to an inflammatory response with "pseudo-infiltration". Histology revealed a pT2 cancer

the study by Strunk et al. [17]. They found that 96% of all tumours with an homogeneous echo pattern were adenomas, and 92% of all lesions with an inhomogenous echo-poor displayed malignant transformation. Nevertheless, only 65% of all adenomatous lesions had an homogenous and 73% of all cancers an inhomogenous echo pattern. They conclude that differentiation based on the echogenicity is rather subjective and no proof for the presence or absence of malignancy. Using a so called acoustic window system (AWS) Rafaelsen et al. [18] were able to detect 23 of 24 carcinomas with a false positive result in three of 26 benign polyps. The introduction of new techniques and the development of more sophisticated high-frequency ultrasound probes [19] could lead to an improved preoperative assessment of tumour infiltration.

In our cohort of 53 T0/1 tumours (38 T0; 15 T1) the sensitivity was 81%, the specificity 99% with a PPV of 98%. Ten cases were overstaged, i. e. a pT0/1 tumour was diagnosed uT2. This is in keeping with the literature, stating sensitivities between 80% [20] and 96% [21] for T0/1. Peritumoural inflammatory reactions as well as preceding biopsies are probably the two main factors for overstaging rectal tumours by ERUS [20]. Both lead to changes of the rectal wall architecture which in turn obscures the typical five-layer structure or mimics the invasion of deeper structures. Being a tertiary referral centre, most of our examined tumours (approx. 70%) had already undergone biopsy prior to employment of ERUS at our hospital. The precise staging of cancers confined to the rectal wall is notoriously fraught with difficulty, resulting in an excess of overestimated T2 malignancies in most studies [4, 20, 22]. In our study more than half of the 29 patients with a pT2 carcinoma were overstaged, so that merely a 41% sensitivity could be attained for this tumour stage (Fig. 6). In a report by Hulsmans et al. [23] only four patients of a total of 22 with a pT2 tumour were staged correctly by intraluminal ultrasound thus reaching a sensitivity of 18%. A detailed analysis of the problem revealed that also by altering the staging criteria retrospectively, when re-interpreting hard copies, the overall sensitivity in differentiating T2 from T3 could not be increased significantly. It has, therefore, to be accepted that current imaging techniques, including ERUS, are of limited value in the correct preoperative assessment of T2 tumours.

While, from an oncological point of view, overstaging is of no importance, understaging which happened in only three of our 152 patients could potentially lead to an undertreatment. Should the histologic examination of a transanaly excised specimen reveal a deeper infiltration than preoperatively thought, immediate abdominal resection, adhering to oncological criteria, should follow [7]. In our view the insufficient endosonographic characterisation of T2 cancers adds to the arguments against transanal treatment of these tumours, especially as it is impossible to differentiate between stage T2a and T2b. Combining T1 and T2, in terms of Dukes A cancer, would lead to an acceptable staging accuracy (Table 2). However, it is of no clinical relevance if one accepts the notion that only benign polyps and "low risk" T1 cancers are suited for local excision.

Regardless of the T-stage, we are of the opinion that all patients undergoing local tumour excision should be entered in a follow up programme to allow local recurrence to be detected at an early stage. With the employment of ERUS in the follow up of patients with rectal cancer, extramural recurrence might be discovered at an earlier point in time [24]. In our practice all patients with rectal cancer are examined using endoluminal ultrasound at three-monthly intervals. Further studies are needed to establish a survival benefit for these patients.

Detection of perirectal lymph node metastases is possible using ERUS. Sensitivities between 70% and 83% are reported in literature (Table 5). Lymph node size is only an indirect indication for malignancy, all the more so as two thirds of all metastatic lymph nodes are smaller than 5 mm [1]. Although there are no distinct sonographic features that enable us to differentiate between metastatic and inflammatory changes, hypoechoic lymph nodes are more likely to harbour malignant cells [25, 26]. However, since the presence of a single positive lymph node is a definite contra-indication for a transanal excision with curative intention, we support the view that all sonographically detectable lymph nodes should be considered malignant. Milsom et al. [27] have suggested ERUS guided fine nee-

Table 5. Sensitivity of ERUS in predicting lymph node involvement

Author	Year	*n*	Sensitivity (%)
Beynon [22]	1989	95	83
Rifkin [12]	1989	102	82
Hildebrandt [21]	1990	113	79
Glaser [16]	1990	97	78
Herzog [18]	1994	142	80
Present study	1996	160	83

dle biopsies of suspicious pararectal lymph nodes. Apart from technical difficulties particularly with small lesions, a negative result does not exclude malignancy so that we do not see any advantge in this approach.

We conclude that ERUS is of excellent value in the preoperative evaluation of adenomatous lesions and T1 cancers with a sensitivity of 81% and a specificity of 99%, thus assisting the decision making process in the choice of the appropriate operative procedure (transanal vs. abdominal). The endosonographic assessment of T2 carcinomas, however, is too inaccurate with the majority of T2 tumours being overstaged as uT3, resulting in a sensitivity of only 41% in the present study. Taking into consideration the relatively high risk of local metastases and the unsatisfactory endosonographic characterisation of T2 cancers, we do not advocate transanal excision of these lesions. All patients undergoing local tumour excision should be followed up closely, preferably including ERUS, so that local failure can be detected as early as possible.

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