

CLINICAL INVESTIGATION

Rectum

## PREOPERATIVE THERAPY FOR LOWER RECTAL CANCER AND MODIFICATIONS IN DISTANCE FROM ANAL SPHINCTER

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**Purpose:** To assess the frequency and magnitude of changes in lower rectal cancer resulting from preoperative therapy and its impact on sphincter-saving surgery. Preoperative therapy can increase the rate of preserving surgery by shrinking the tumor and enhancing its distance from the anal sphincter. However, reliable data concerning these modifications are not yet available in published reports.

**Methods and Materials:** A total of 98 cases of locally advanced cancer of the lower rectum (90 Stage uT3-T4N0-N+ and 8 uT2N+M0) that had undergone preoperative therapy were studied by endorectal ultrasonography. The maximal size of the tumor and its distance from the anal sphincter were measured in millimeters before and after preoperative therapy. Surgery was performed 6–8 weeks after therapy, and the histopathologic margins were compared with the endorectal ultrasound data.

**Results:** Of the 90 cases, 82.5% showed tumor downsizing, varying from one-third to two-thirds or more of the original tumor mass. The distance between the tumor and the anal sphincter increased in 60.2% of cases. The median increase was 0.73 cm (range, 0.2–2.5). Downsizing was not always associated with an increase in distance. Preserving surgery was performed in 60.6% of cases. It was possible in nearly 30% of patients in whom the cancer had reached the anal sphincter before the preoperative therapy. The distal margin was tumor free in these cases. **Conclusion:** The results of our study have shown that in very low rectal cancer, preoperative therapy causes tumor downsizing in >80% of cases and in more than one-half enhances the distance between the tumor and anal sphincter. These modifications affect the primary surgical options, facilitating or making sphincter-saving surgery possible. © 2007 Elsevier Inc.

Low rectal cancer, Preoperative radiotherapy, Preoperative chemotherapy, Sphincter-preserving surgery, Endorectal ultrasonography.

### INTRODUCTION

In locally advanced rectal cancer, preoperative treatments have been shown to increase local control and survival (1–6). For tumors of the lower rectum, preoperative treatments can increase the possibility of sphincter-preserving surgery (SPS) (7–12) by tumor regression.

The distance of the tumor from the anal sphincter is the most important element for the surgeon to consider before deciding between SPS and abdominoperineal resection (APR). Despite many published studies concerning the role of preoperative chemoradiotherapy in changing intended APR to SPS (8, 12–18), no clear data are available concerning the effective modifications in the distance between the tumor and

the anal sphincter. Moreover, nothing is known about the frequency of these modifications.

Endorectal ultrasonography (EUS) is an accurate method for the assessment of rectal carcinoma and intramural spread and to study the infiltration of the anal sphincter, especially using a linear array (19–21).

Since 1994, when EUS was introduced at our institution, we have routinely measured the size of the tumor and the distance between the lower border of the lesion and the upper margin of the anal sphincter before and after preoperative therapy for all cancers of the lower one-third of the rectum.

Taking our experience into consideration, the aim of this study was to evaluate the quantitative values, the frequency

of a modification in the tumor–anal sphincter distance after preoperative therapy, and the impact on SPS.

## METHODS AND MATERIALS

Between January 1994 and April 2006, 214 patients admitted to our institution with lower one-third rectal adenocarcinoma ( $\leq 6$  cm from the anal verge) were evaluated by EUS. All patients with operable, locally advanced rectal cancer (Stage uT3-T4N0-N+M0) were eligible for long-course preoperative treatment. In addition, preoperative therapy was proposed to patients with low cancer Stage uT2 with positive lymph nodes at staging. A total of 120 patients underwent preoperative chemoradiotherapy or radiotherapy (RT) only, depending on their age and/or concomitant comorbidities (*e.g.*, cardiovascular, neurologic, or other).

Radiotherapy was delivered using a box or three-field technique. Patients received 50 Gy in 25 daily fractions for 5 weeks. If concomitant chemotherapy was delivered, 5-fluorouracil as an intravenous protracted infusion (225 mg/m<sup>2</sup>/d, 7 d/wk) (22) was administered throughout the RT course using a central venous catheter (Port-a-Cath). Surgery was performed 6–8 weeks after the end of therapy.

A total of 98 patients (59 men and 39 women) had had an EUS examination before and after the preoperative therapy and were evaluated in this study. Of these 98 patients, 61 had undergone preoperative chemoradiotherapy (median age, 62 years; range, 35–78) and 37 RT alone (median age, 71 years; range, 38–84).

The same surgeon (M.G.) performed all the EUS examinations before therapy and 6–8 weeks after the end of therapy, usually a few days before surgery. The pretreatment stage is given shown in Table 1.

The maximal tumor size was measured (length, depth, and circumferential extension, when possible). The distance between the lower pole of the tumor and the upper edge of the internal anal sphincter was routinely recorded in millimeters using the linear 7.5-MHz endoprobe (Aloka biplanar UST 664-5/7.5, Tokyo, Japan). The upper edge of the internal anal sphincter is always easily identifiable on linear EUS and points to the upper border of the anal canal (20, 23). The distal longitudinal spread of the tumor was also investigated by EUS and taken into consideration in the distance evaluation.

For patients undergoing curative surgery, the EUS data were compared with the histopathologic diagnosis. The ypTNM stage and downstaging were evaluated. The presence of disease in the

distal/circumferential margins for patients undergoing SPS was especially investigated. The length of the tumor-free distal margin or, in the case of APR, the distance between the tumor and the anal apparatus was measured on formalin-fixed specimens. Tumor infiltration of the mucosa beyond the anorectal junction and penetration into the sphincter muscles were noted on EUS and compared with the histopathologic findings.

## RESULTS

A total of 98 patients with low rectal cancer underwent pre- and post-treatment EUS studies.

### Quantitative findings

*Tumor size.* After preoperative therapy, 82.5% of the patients had tumor downsizing, with a reduction at EUS of one-third (40.8%) to one-half (23.4%) to two-thirds or more (18.3%) of the original tumor mass. In 17.3% of cases, the original tumor size did not change or increase (Table 2). Good correspondence was noted between the EUS post-treatment tumor size and the pathologic macroscopic size of the fresh specimens of the operated patients.

*Tumor distance to anal sphincter.* After preoperative therapy, the distance between the lower part of the tumor and the upper margin of the anal sphincter increased in 59 (60.2%) of the 98 patients (Fig. 1), did not change in 35 (35.7%), and decreased in 4 (4%). The distance measured in millimeters on EUS is reported in centimeters in Fig. 2. With enhancement, the median increase was 0.73 cm (range, 0.2–2.5) and was 0.66 cm in the patients who underwent RT only and 0.77 cm in those who underwent chemoradiotherapy.

Taking into consideration the shrinkage resulting from the formalin, the pathologically measured distance from the tumor to the anal sphincter corresponded well with the EUS-measured distance in the SPS specimens and APR specimens. Likewise, if anal apparatus infiltration had been noted at EUS, it was always confirmed at the histologic examination.

*Tumor size and distance to anal sphincter.* Concerning the relationship between downsizing and modifications in

Table 1. Comparison between EUS pretreatment stage and ypTN pathologic stage

N stage	T stage					Total
	T0	T1	T2	T3	T4	
<b>Pretreatment EUS stage</b>						
Nx	—	—	—	3	3	6 (6.1)
N0	—	—	—	29	3	32 (32.6)
N+	—	—	8	40	12	60 (61.2)
Total (%)	—	—	8 (8.1)	72 (73.4)	18 (18.3)	98 (100)
<b>Pathologic stage</b>						
Nx	—	—	—	—	—	—
N0	12	8	19	13	2	54 (60.6)
N+	1	1	5	25	3	35 (39.4)
Total (%)	13 (14.6)	9 (10.1)	24 (26.9)	38 (42.6)	5 (5.6)	89 (100)

Abbreviation: EUS = endorectal ultrasonography.

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