Sphincter-Saving Resection for All Rectal Carcinomas

The End of the 2-cm Distal Rule

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Objective: To assess oncologic outcome of patients treated by conservative radical surgery for tumors below 5 cm from the anal verge.

Summary Background Data: Standard surgical treatment of low rectal cancer below 5 cm from the anal verge is abdominoperineal resection.

Methods: From 1990 to 2003, patients with a nonfixed rectal carcinoma at 4.5 cm or less from the anal verge and without external sphincter infiltration underwent conservative surgery. Surgery included total mesorectal excision with intersphincteric resection, that is, removal of the internal sphincter, to achieve adequate distal margin. Patients with T3 disease or internal sphincter infiltration received preoperative radiotherapy.

Results: Ninety-two patients with a tumor at 3 (range 1.5–4.5) cm from the anal verge underwent conservative surgery. There was no mortality and morbidity was 27%. The rate of complete microscopic resection (R0) was 89%, with 98% negative distal margin and 89% negative circumferential margin. In 58 patients with a follow-up of more than 24 months, the rate of local recurrence was 2% and the 5-year overall and disease-free survival were 81% and 70%, respectively.

Conclusions: The technique of intersphincteric resection permits us to achieve conservative surgery in patients with a tumor close to or in the anal canal without compromising local control and survival. Tumor distance from the anal verge is no longer a limit for sphincter-saving resection.

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In patients with rectal cancer, the development of surgical technique led to the improvement of local control of the disease and patient survival.[1] Standardized surgery consists of removing the rectum with its mesentery through a midline laparotomy. Sphincter-saving resection, that is, restoration of bowel continuity, is one of the main objectives of surgical treatment of rectal cancer. It was introduced in the 1950s for the rectosigmoid tumors,[2] then for the midrectal tumors,[3] and more recently for some low rectal cancers.[4]

Historically and traditionally, decision-making for sphincter-saving resection is related to the distance between the tumor and the anal sphincters. This is because of the potential risk of microscopic involvement of the rectal wall below the tumor.[2] Therefore, at least 5 cm of distal margin was required until the 1980s, after which 2 cm was considered adequate.[5,6] Because of the 3–4-cm median length of the anal canal,[7,8] all the rectal tumors located below 5 cm from the anal verge are not generally considered for sphincter-saving procedures. Indeed, it is not technically possible to obtain a 2-cm distal margin with a conventional laparotomy. In addition, to obtain adequate circumferential margin with sphincter preservation in low rectal cancer is not certain, and incomplete microscopic resection is associated with a risk of local recurrence.[9] Finally, for both technical and oncological reasons, the standard surgical treatment in very low rectal cancer is abdominoperineal resection (APR), ie, removal of the rectum with the whole of the anal sphincters followed by an abdominal colostomy.[10]

The surgical technique of intersphincteric resection (ISR) has been proposed to offer sphincter preservation in patients with very low rectal carcinoma.[11] The goal of ISR is to divide the rectum transanally and to remove part or the whole of the internal anal sphincter, to obtain adequate distal margin and restore bowel continuity. However, few data are available and include mainly early rectal cancer (ie, T1 and T2 tumors) and lesions without internal sphincter involvement.[11–13] Moreover, long-term results have never been reported.

Since 1990, we used the technique of ISR in low rectal tumors, including for advanced disease, ie, T3 tumors, and for lesions involving the internal anal sphincter.[14,15] The aim of this prospective study was to demonstrate that oncological

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outcome was not altered in patients treated by conservative surgery for very low rectal cancer.

METHODS

Patient Selection

The technique of ISR was proposed in patients with rectal carcinoma located at or below 4.5 cm from the anal verge. In all cases, the lower edge of the tumor was less than 2 cm from the anorectal ring. The anorectal ring, or top of the surgical anal canal (top of the anal sphincters), was defined by the sling of muscle forming the anal hiatus of the pelvic diaphragm (Fig. 1).

The anal verge was defined as the lower part of the surgical anal canal. The exact levels of the lower edge of the tumor from the anal verge and the anorectal ring were assessed by the surgeon, by digital examination with and without voluntary contraction. Infiltration of the internal sphincter by the tumor was identified by clinical examination and endoanal ultrasonography.

Patients who were excluded from ISR were those with infiltration of the striated muscles of the pelvic floor, ie, external sphincter or levator ani; fixed tumors (except partial vaginal fixity and patients with synchronous metastases); and those who had impaired anal sphincter with fecal incontinence more than 6 months before diagnosis. These patients were treated by a conventional APR.

Patients were classified according to the UICC classification after abdominal and pelvic computed tomography, endorectal ultrasonography, chest radiography, colonoscopy, and biopsy. Patients with T3 disease, and those with T2 disease and infiltration of the internal sphincter, received preoperative radiochemotherapy to obtain downstaging and facilitate surgery.[15]

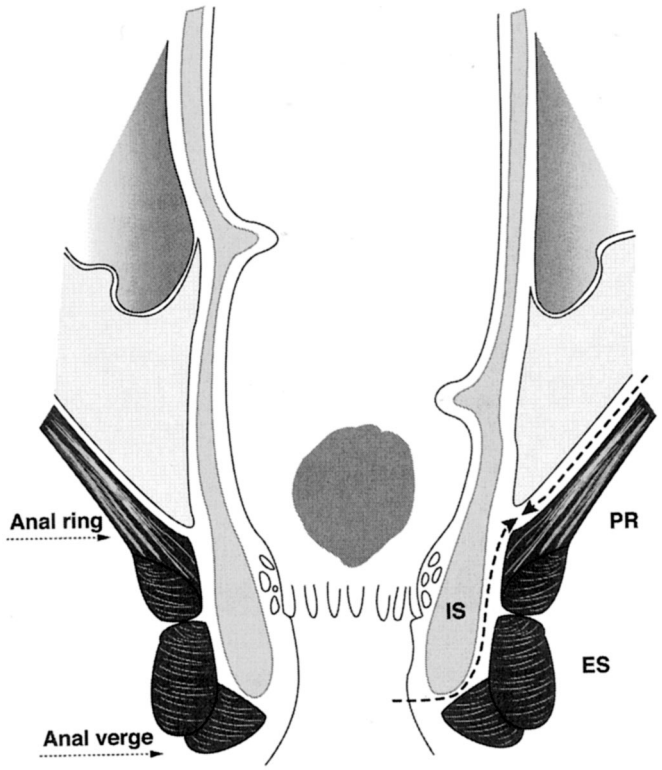

FIGURE 1. Technique of intersphincteric resection. The tumor reaches the anal ring and is lying close to the dentate line. Transanal division of the internal anal sphincter connects with pelvic dissection, allowing adequate distal margin. IS, internal sphincter; ES, external sphincter; PR, puborectalis.

Surgical Technique

The principle of the technique is based on the facts that rectal tumors expand into the visceral structures, ie, the rectum and distally the internal anal canal, and that there is an embryonic plane of fusion between the visceral structures and the surrounding somatic skeletal muscles of the pelvic floor.[16] The aim was to remove the viscus without damaging the skeletal muscles (Fig. 1).

Surgery was performed 6 weeks after radiotherapy. The surgical technique includes both abdominal and perineal approaches. The abdominal dissection was carried out first through a midline laparotomy or a laparoscopic procedure.[15,17] A total mesorectal excision with a high ligation of the inferior mesenteric artery and preservation of the pelvic plexuses was performed. The rectum was mobilized to the pelvic floor as low as possible to facilitate the perineal dissection. The dissection had to reach the puborectalis muscle posteriorly and the upper part of the external sphincter anteriorly, ie, the apex of the prostate gland in men.

The perineal dissection was carried out transanally after exposure of the anal canal. The first step included a circumferential incision of the mucosa and the internal sphincter, 1–2 cm distal to the tumor, followed by a careful dissection of the internal sphincter free of the external sphincter in a bloodless plane. The dissection began posteriorly and then laterally where the external sphincter was easier to identify and finished anteriorly where the plane was more adherent. The rectum was then closed transanally by suture to avoid tumor seeding. The second step was a longitudinal dissection between the upper part of the internal sphincter and the puborectalis muscle. Finally, transanal division of the superior sheath of the pelvic floor and then of the presacral Waldeyer's fascia allowed us to reach the abdominal dissection. The rectum was then removed en bloc with the internal sphincter usually through the abdomen.

For patients with neoadjuvant treatment, the exact level of transection of the internal sphincter was decided before radiation and according to the distance from the anal verge, to avoid underestimation of the irradiated tumors and potential risk of tumor transection. ISR started at the dentate line to

remove the upper half of the internal sphincter for tumors 3 to 4.5 cm from the anal verge (partial or high ISR); it started below the dentate line, removing the whole of the internal sphincter for tumors below 3 cm from the anal verge (total or low ISR). A colonic pouch was associated with the coloanal anastomoses, and all patients had a diverting stoma.

Follow-up

After surgery, a standardized follow-up was carried out every 6 months and included clinical, laboratory (carcinoembryonic antigen), and radiologic (abdominal and pelvic computed tomography, chest radiography) investigations. Colonoscopy was also performed 1 year after surgery, then every 3 years. Patients with suspected (ultrasound N1) or confirmed lymph node metastases (pN1) received postoperative chemotherapy with 5-fluorouracil and folinic acid for 6 months. In patients with positive margins after ISR, it was proposed that they undergo either APR with definitive colostomy or an intensive follow-up including endorectal ultrasonography every 3 months during the first 2 years.

Endpoints Assessment

The endpoints of the study were the rate of complete microscopic resection, local recurrence, and survival. The rates of distal metastases and morbidity were also recorded.

Complete microscopic resection was defined as R0 resection and included both distal and circumferential negative margins.[18] Circumferential margin was assessed microscopically on fixed and ink-stained specimens. Distal and circumferential margins were considered as positive if microscopically involved by the tumor or ≤1 mm, respectively.[9] Local recurrence was defined as any recurrence diagnosed or suspected in the pelvis (tumor bed, pelvic nodes, anastomosis, drain site, or perineum) occurring alone or with other sites of recurrence.[19] Distal metastases were defined as any recurrence occurring outside the pelvis. The overall and disease-free survivals were calculated by using the Kaplan-Meier method. Time to last follow-up evaluation, treatment failure, or death were measured from the date of rectal excision. Assessment of recurrence and survival was carried out in patients with a follow-up more than 24 months and who had curative surgery (patients with synchronous metastases not removed were excluded).

RESULTS

Population Study

From 1990 to 2003, of 584 patients with invasive rectal carcinoma, 92 underwent ISR for a tumor less than 5 cm from the anal verge. Demographic data and tumor characteristics are given in Table 1. The median lower edge of the tumor was 3 cm (range 1.5–4.5) from the anal verge and 0.5 cm (−1.5 to 1.5) from the anal ring. Infiltration of the internal sphincter by the tumor was present in 20% of the cases ($n = 18$). Most patients had T3 disease. Eighty-one patients (88%) received preoperative radiotherapy (median dose pelvis 44 Gy, tumor bed 54 Gy), 54 with concomitant chemotherapy (continuous 5-fluorouracil). Six patients had synchronous liver metastases and were staged as M1.

TABLE 1. Patients Treated by Intersphincteric Resection for a Low Rectal Cancer ($n = 92$)

Age* (yrs)	65 (25–86)
Sex (M:F)	57:35
Tumor distance from anal verge* (cm)	3.0 (1.5–4.5)
Tumor distance from anal ring* (cm)	0.5 (−1.5–1.5)
Tumor stage	
T1	2
T2	12
T3	72
T4	6
Preoperative radiotherapy	81

*Values are median (range).

The surgical procedure was performed through a laparotomy in 45 cases and laparoscopically in 47 cases. The coloanal anastomosis was located at a median of 1.5 cm (range 0.5–3.5) from the anal verge. It was associated with a colonic J pouch in 52 cases, a coloplasty in 26 cases, and was straight in 14 cases.

Complications

There was no procedure-related death. Postoperative morbidity was 27% (Table 2).

Four patients underwent APR: 1 for pelvic hemorrhage, 1 for pelvic sepsis, 1 for colonic ischemia, and 1 for positive margins.

Pathologic Data

The median distal resection margin, assessed in fresh specimen without traction, was 2 cm (range 0.5–3) and was positive in 2 cases (2%). The median circumferential margin was 5 mm (range 0–15) and was positive (≤1 mm) in 10 cases (11%). The 2 patients with positive distal margin had both distal and circumferential positive margins. Overall, the

TABLE 2. Surgical Morbidity ($n = 92$)

Anastomotic leakage	10
Anovaginal fistula	2
Isolated abscess	3
Pelvic hematoma	6
Occlusion	2
Colonic ischemia	1
Pancreatitis	1

rate of complete microscopic resection, ie, of R0 resection, was 89% (82 of 92). One patient with positive circumferential margin underwent APR without evidence of residual tumor in the specimen.

Local Recurrence

Of 58 patients with a follow-up of more than 24 months (median 40 months), the rate of local recurrence was 2% (1 of 58). An obese male patient with a T3N1 tumor at 4.5 cm from the anal verge and 2 cm of distal resection margin on the specimen presented extramural pelvic recurrence without involvement of the coloanal anastomosis 22 months after surgery. Recurrence was treated by curative pelvic exenteration.

Distant Metastases

The rate of distant metastases was 19% (11 of 58). Liver metastases occurred in 9 patients and multiple distant metastases in 2. Six patients underwent curative hepatectomy, whereas the other patients were treated by palliative chemotherapy.

Survival

Ten patients died, 5 from distant metastases and 5 from intercurrent disease (cardiovascular disease; $n = 5$). The overall survival was 81% at 5 years and the disease-free survival was 70% at 5 years (Fig. 2).

DISCUSSION

Traditionally, all the rectal carcinomas lying less than 5 cm from the anal verge or less than 2 cm from the anal ring are treated by APR. Indeed, the conventional sphincter-saving procedures, ie, low anterior resection, do not permit us to achieve rectal excision with complete microscopic resection, and incomplete microscopic resection exposes us to a high risk of local recurrence.[20–22] This is more frequently the case when the tumor reaches or involves the anal canal.

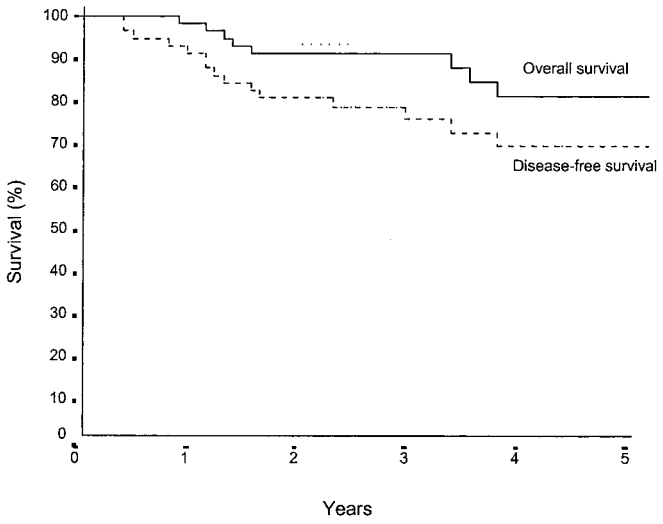

FIGURE 2. Kaplan-Meier survival after intersphincteric resection for low rectal cancer

In the present series, the tumors were located at less than 1 cm from the anal ring with 20% of internal sphincter involvement. All of these patients would have required APR if treated traditionally. We demonstrated that it was possible to obtain both complete microscopic resection and a low local recurrence rate after conservative surgery for these very low rectal tumors. These results are due to the technique of ISR, which allowed us to obtain adequate margins. The selection for conservative surgery was not related to the conventional distance between the tumor and the anal verge or the anorectal ring, but to infiltration or not of the external anal sphincter. Patients without infiltration of the external sphincter had conservative surgery, whereas those with infiltration of the external sphincter had APR. This new concept clearly demonstrates that almost all rectal carcinomas can benefit from sphincter preservation and that the decision-making for conservative surgery does not depend on the 2-cm distal rule between the tumor and the anal ring.

The technique of ISR used for conservative treatment depends on the level of the tumor. A high ISR that disconnects anatomically the upper part of the internal sphincter from the puborectalis muscle is performed to obtain adequate distal margin in tumors close to the anal ring, whereas a low ISR disconnecting the whole internal sphincter from the puborectalis and the external sphincter is necessary for tumors involving the internal sphincter. The former can be carried out through an abdominal approach[13] and the latter only transanally.[11,12] The transanal approach appears, however, to be the optimal way for both high and low ISR, because the dissection is more anatomic and visual and permits a more accurate evaluation of the lower edge of the tumor. In addition, this enables us to obtain optimal distal margin in all cases, including in a difficult narrow pelvis and in obese patients. In the present study with 92 rectal carcinomas at 3 cm from the anal verge, the distal resection margin was 2 cm and was negative in 98% of the cases. Finally, transanal division of the internal sphincter permits us to treat conservatively all rectal carcinomas, including those involving the internal anal sphincter.

For 10 years, circumferential resection margin has been shown to be a more important oncologic concept than distal margin in rectal cancer surgery.[9,23] In the Dutch study including 1861 patients, of whom 17% had a positive circumferential margin, the 2-year local recurrence rate was 13% after positive margin, compared with 4% after negative margin.[24] In our study, concentrating on low rectal tumors, although the mesorectum was thin or lacking at this level, we observed a low rate of positive circumferential margin and consequently of local recurrence: 11% and 2%, respectively. This is due to the use of long-course preoperative radiother-

apy, which increases circumferential resection margin.[15] In addition, long-term preoperative radiotherapy reduces the tumor volume and transforms vegetative lesions into ulcerative scar that facilitates surgery and decreases tumor spillage. In contrast to others,[25,26] we believe that the role of preoperative radiotherapy is not to transform an APR procedure into a conservative procedure by shortened distal margin, but to increase the circumferential margin and to facilitate surgery.

In our series including mainly T3 rectal tumors, the 81% 5-year survival we observed showed that survival was not compromised by pushing the oncologic limits lower for sphincter-saving resection. According to the present series and to others,[11,13,15,21,25] the limit for sphincter-saving resection in low rectal cancer appears to be functional rather than oncologic. The loss of the rectum induces stool frequency and urgency. Furthermore, internal sphincter excision may induce fecal incontinence.[27,28] However, in our opinion, the technique of ISR is justified because recent improvement in surgical management of fecal incontinence permits us to treat patients after surgical injury.[29]

The technique of ISR modifies the concept of sphincter-saving resection in the treatment of rectal cancer. The decision between a conservative procedure and APR is not related to the distance between the tumor and the anal verge or the anal ring; it becomes solely related to the infiltration of the external sphincter. Achievement of complete microscopic resection with a low local recurrence rate and without compromising survival after ISR for carcinomas at or below 4.5 cm from the anal verge supports this new concept.

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