Excision of the Levator Muscles With External Sphincter Preservation in the Treatment of Selected Low T4 Rectal Cancers

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PURPOSE: The existence of an anatomic and functional separation between the puborectalis muscle and external anal sphincter permits the performance of an abdominoendoanal excision, instead of an abdominoperineal excision, of the rectum and levator muscles, with preservation of a functioning external sphincter, in selected patients with very low rectal cancer and limited infiltration of the levator muscles. METHODS: Seven patients (4 females; age, 48–69; mean, 60.7 ± 7.8 years) with low posterior or posterolateral localized rectal cancers with infiltration of the puborectalis muscle (T4) were submitted to preoperative chemoradiation and excision of the rectum with the levator muscles, while the external sphincter and its innervation were preserved. A coloanal anastomosis was performed at the dentate line. RESULTS: At a median follow-up of 58 (range, 42–102) months, 6 patients (86 percent) were alive and disease free. No local recurrence was observed. Anorectal function, at three years from surgery was no worse than that of six patients of the same age and gender who had undergone more conventional coloanal anastomoses with preservation of the levator muscles. CONCLUSION: Selected patients with very low rectal cancers infiltrating the levator muscles (T4) and responding to preoperative chemoradiation therapy can still be treated with an advanced sphincter-sparing procedure, instead of an abdominoperineal excision. Oncologic and functional results seem to be satisfactory. [Key words: Anal canal anatomy; Rectal cancer; Preoperative radiochemotherapy; Coloanal anastomoses]

A natomic, embryologic, and *in vivo* studies have demonstrated the existence of an anatomoembryologic separation between the puborectalis muscle (PR) and external anal sphincters (ES).[1–4] This separation is marked by a cleft in adult anatomic specimens[1] and by a depression palpable at mid anal canal in the living subjects.[5] A plane of separation can be identified and developed, endoanally, at this level.[4]

These muscles also have distinct, as well as quite separate, innervations. Direct branches of sacral roots running in their inner surface supply the levator muscles, whereas the pudendal nerve, which runs laterally and externally to them, innervates the external sphincter[3,6]

The possible existence of a functional as well as anatomic separation between the two muscles suggested that one try to remove the rectum (along anatomic boundaries using a combined abdominoendoanal approach) together with a large portion of the levator muscles while preserving the lower anal canal and the external sphincter with its innervation (a major functional structure in the voluntary continence mechanism).[3] The aim was to restore intestinal continuity while maintaining an acceptable sphincter function in selected patients with low posterior-posterolateral T4 (International Union Against Cancer) rectal cancers infiltrating the levator muscles. This article reports the oncologic and functional results obtained with such an atypical procedure in patients otherwise candidates for an abdominoperineal excision.

PATIENTS AND METHODS

In the period between January 1992 and June 1997, among the patients with low rectal cancer infiltrating the structures of the pelvic floor and submitted to preoperative chemoradiation therapy (RTCHT), seven (4 females; age, 48–69; mean, 60.7 ± 7.8 years) were subsequently treated with an atypical surgical approach. Originally, these patients had well-differentiated noncolloid adenocarcinoma (2.5–4 cm diameter)

sited in the posterior or posterolateral rectal wall with an inferior margin at 3 to 4 cm from the anal verge (mean, 3.4 cm). At endorectal ultrasound (ERUS) and nuclear magnetic resonance examination with endorectal coil, the tumors presented an infiltration limited to the central and inner part of the levator muscles (puborectalis muscle). At digital exploration, the neoplastic growth conserved some mobility. The external sphincter and the ischiorectal fossae seemed uninvolved by cancer infiltration. No metastatic diffusion was evidenced by abdominopelvic CT scan, liver sonography, and/or chest x-ray.

A relevant post-RTCHT clinical regression of the tumoral mass and ulceration was observed in all these patients, with improvement of tumor mobility. The neoadjuvant treatment consisted of 45 to 50.4 Gy, at 1.8 Gy/day in 25 to 28 fractions for 5 to 6 weeks, plus 5-fluorouracil, 375 mg/m^2, and leucovorin, 10 mg/m^2, bolus on days 1 to 5 and 29 to 33.

The shrinkage effect of the neoadjuvant treatment was confirmed by preoperative endorectal ultrasound. Nonetheless, the levator muscles—which seemed infiltrated before RTCHT—were believed to be at high risk of harboring residual cancer, and therefore, their excision was considered to be oncologically indicated.

Surgery was performed after six to nine weeks from the end date of RTCHT treatment. A combined abdominoendoanal excision of the rectum, upper anal canal, and pelvic musculature (puborectalis and pubococcygeus muscles), with preservation of the lower anal canal and the external sphincter with its innervation, the pudendal nerve, was planned and performed.

Operative Procedure

The sigmoid colon and the rectum with mesorectum were mobilized from the hollow of the sacrum, pelvic side walls, prostate, or posterior vaginal wall as in a standard total mesorectal excision for low rectal cancer. The relationship between the postchemoradiation residual tumor mass or induration and the pelvic floor musculature was evaluated. The operator proceeded to expose the levator muscles except in the area suspected of being, or having been, infiltrated by cancer. The rectosigmoid was then sectioned at the sigmoid/descending junction with a stapler.

Perineal Phase

The patient was placed in the lithotomy position. A palpable depression, in the wall of the anal canal, at the level of the dentate line (1–1.5 cm above the intersphincteric groove), detected preoperatively in all the patients, was considered the site of the anatomic separation of PR from ES (Fig. 1).

The anal mucosa, submucosa, internal sphincter, and the longitudinal muscle was incised circumferentially, using electrocautery, at the dentate line,. The distance below the tumor was never less than 1.5 cm (Fig. 2). The intersphincteric plane between the internal and external sphincter was entered and enlarged with scissors. In five patients a demarcation between the circular fibers of the body of the external sphincter and the overlying levator muscular structures was easily identified and entered with scissors. A plane separating PR from ES was developed circularly in the posterior and posterolateral walls of the anal canal. It was possible to exclude the presence of overt infiltration of the external sphincter and/or the ischiorectal fossa. The introduction of a finger, at this site, enabled a better clinical definition of the neoplastic infiltration or induration in the levator muscles.

In two patients a demarcation between PR and ES could not be clearly identified. In these cases the amount of distal sphincteric musculature to be preserved was decided on clinical grounds so as to maintain a consistent distal muscular ring.

The operation continued to separate PR completely from ES, after step-by-step incision of overlaying anal mucosa, submucosa, internal sphincter, and longitudinal muscle, also in the anterior quadrant. Once the external sphincter had been identified and separated from the pelvic floor, the latter was opened and the abdominal cavity entered. Scissors were advanced along the plane of separation to open the Waldayer fascia (Fig. 3) under the guidance of the abdominal operator.

The levator muscles were never entered too laterally so as to not damage the pudendal nerves at their entrance into the ischiorectal fossa (Fig. 3). Eventually, the excised specimen included only the puborectalis muscle, in four cases, and this muscle and part of the pubococcygeus muscle in three cases.

The sigmoid stump was delivered outside the abdomen through the preserved anal canal. The specimen remained attached with its lower anterior part to the puborectalis/pubococcygeus muscles and to the
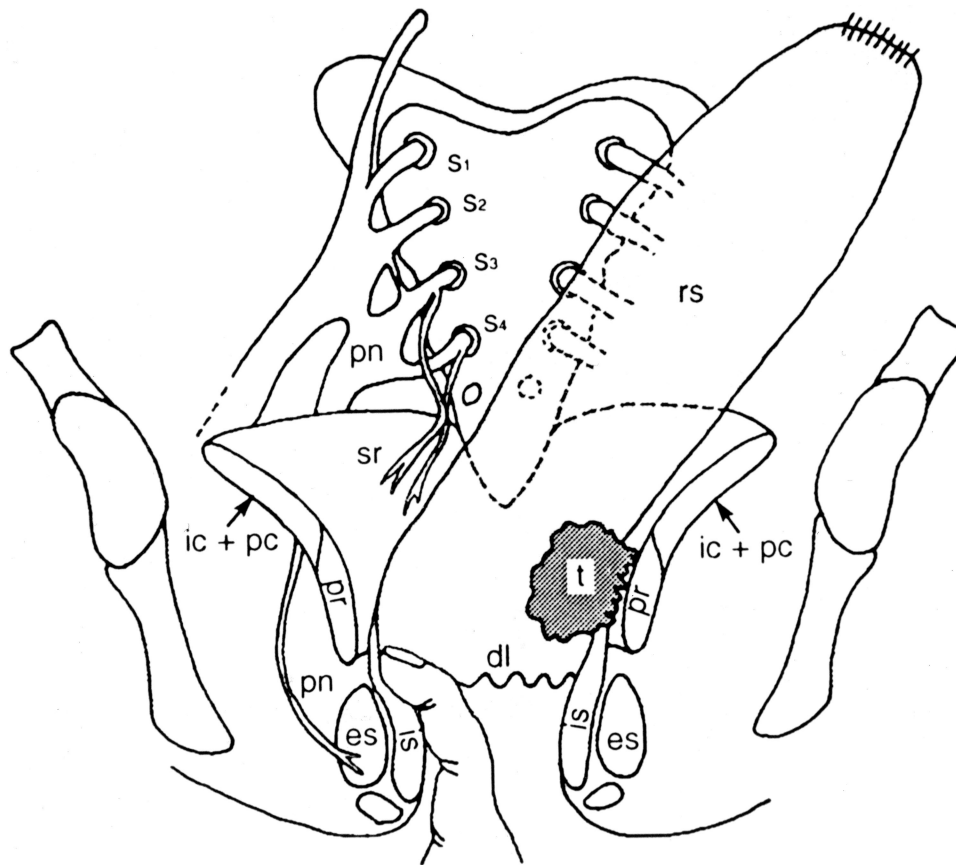
Figure 1. A palpable depression in the posterior and posterolateral walls of the mid anal canal at the level of the dentate line was regarded as the site of separation between the puborectalis muscle and external anal sphincter. sr = sacral roots; pn = pudendal nerve; ic = ileococcygeus muscle; pr = puborectalis muscle; pc = pubococcygeus muscle; es = external sphincter; t = tumor; dl = dentate line; is = internal sphincter; rs = rectal stump.

inferior Denonvilliers fascia or rectovaginal septum (Fig. 4).

The perineal operator sectioned the pubic insertions of the levator muscles. The other structures were then progressively separated with sharp dissection from the anterior rectal wall (Figs. 4 and 5). The specimen was then removed.

Lateral margins of the removed levator muscles and the distal rectal margin were examined with frozen sections. All were negative for cancer.

In three cases it was not possible to deliver the proximal end of the sigmoid stump through the anus because of the presence of a bulky mesorectum. Hence, anterior rectal wall detachment from lower vagina, prostate was achieved endoanally (*i.e.*, start: upper edge of the isolated external sphincter proceeding cephalad). The levators' detachment was achieved collaboratively with the abdominal operator and the specimen was delivered from the abdomen. A manual, *per anum*, coloanal

anastomosis (five J-pouch, two straight anastomoses) with the descending colon (Fig. 6) reestablished intestinal continuity. After 8 to 12 weeks, the patients' protective loop ileostomy was closed. After the operations all patients were followed-up according to an established schedule with carcinoembryonic antigen monitoring and clinical examination associated with ERUS.[7]

After three years, anorectal function was examined in six survivors (4 J-pouches and 2 straight anastomoses) by means of anal manometry and questionnaire. Continence was assessed using the Browning and Park's criteria–derived scale: Grade A, normal continence; Grade B, incontinence to flatus; Grade C, incontinence to flatus and liquids; Grade D, complete incontinence.[8] The results were compared with those of 6 patients of a group of 42, who in the same period had undergone preoperative RTCHT and more conventional peranal handsewn coloanal anastomoses for higher (5–7 cm)
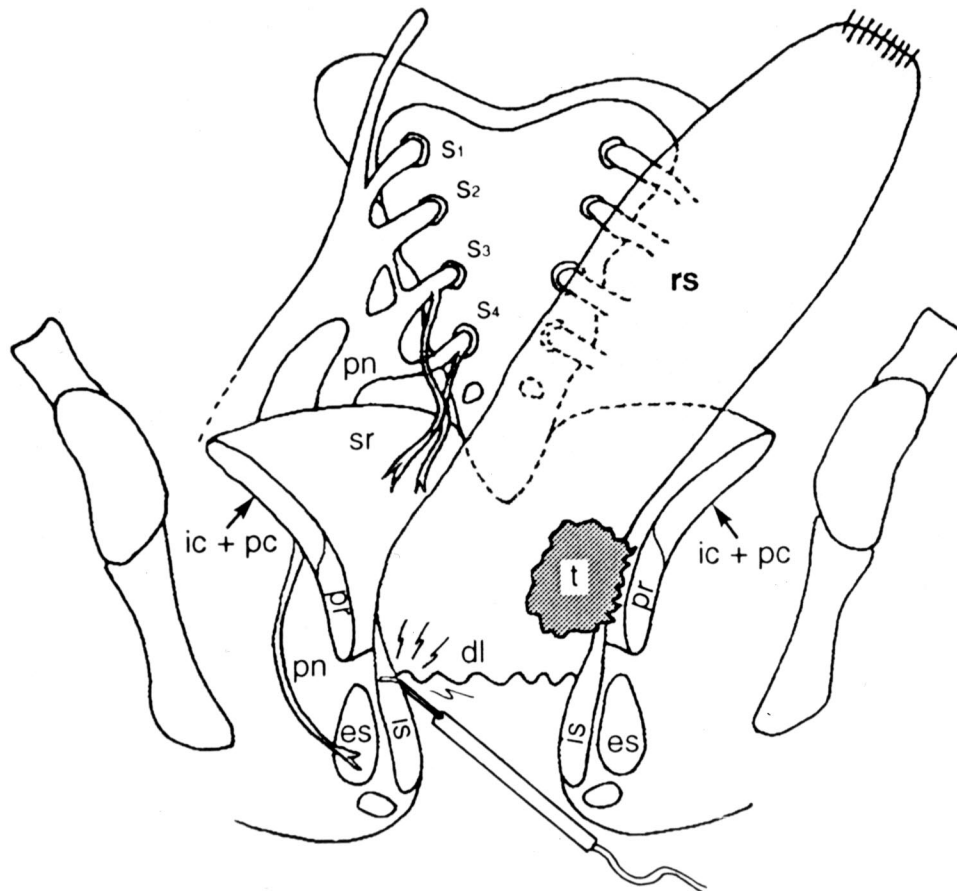
Figure 2. Incision with electrocautery of mucosa, submucosa, internal sphincter, and longitudinal muscle of the posterior and posterolateral walls of the anal canal at the level of the dentate line. sr = sacral roots; pn = pudendal nerve; ic = ileococcygeus muscle; pr = puborectalis muscle; pc = pubococcygeus muscle; es = external sphincter; t = tumor; dl = dentate line; is = internal sphincter; rs = rectal stump.

advanced, operable (T3) rectal cancers. These six patients were the same age and gender and presented the same type of coloanal anastomosis (4 J-pouches and 2 straight anastomoses) as those in the study. Three of them had undergone an excision of the upper part of internal sphincter, from the abdomen. None of the examined patients had received postoperative chemotherapy.

RESULTS

Final pathologic staging of these originally suspected T4 lesions was as follows: one T0, two T2, two T3, two T4; two patients had lymph node involvement (N1). Liver metastases appeared at the end of RTCHT in one patient.

Minor postoperative complications represented by a limited disruption of the coloanal anastomosis running subclinically were observed in three patients (43 percent). One patient presented a persistent perianal radiodermitis. Major complications occurred in two patients (one presented gastric bleeding, and one, pulmonary embolism; 28 percent).

At a median follow-up of 58 (range, 42–102) months, six patients were alive (86 percent). One patient died of metastatic liver disease 36 months after the date of operation. Another patient underwent a right hepatectomy for an isolated metastasis that appeared five years after the date of operation. She was alive without evidence of disease after 20 months. No local recurrence has been observed to date in any patient.

Regarding anal continence, none of the examined subjects had incontinence to solid stools. Two patients with excision of the levators had normal continence (33 percent; Grade A), two had incontinence to flatus only (33 percent; Grade B), and two had occasional leakage of liquid stools (Grade B-C). The latter had been using a pad since the operation. Regarding patients with levators pre-
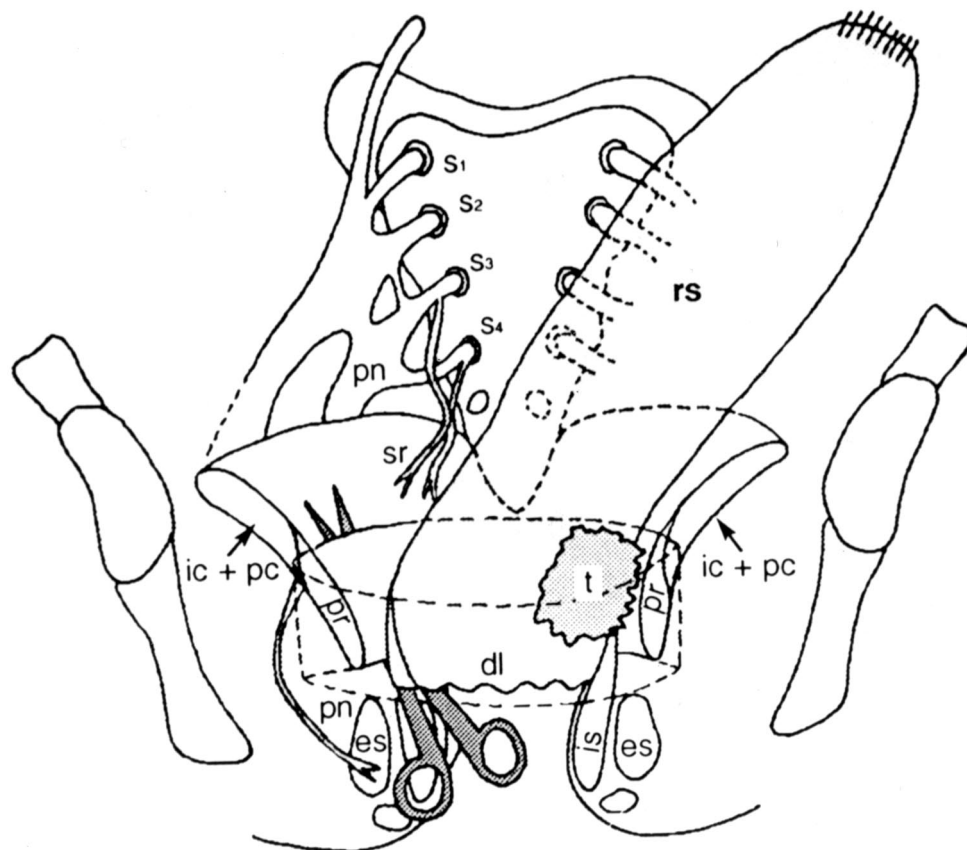
Figure 3. Opening of the pelvic floor with scissors at a distance from tumor after separation of the puborectalis muscle from the external anal sphincter. The dotted lines represent the sites of the excision of the pelvic musculature and upper anal canal. sr = sacral roots; pn = pudendal nerve; ic = ileococcygeus muscle; pr = puborectalis muscle; pc = pubococcygeus muscle; es = external sphincter; t = tumor; dl = dentate line; is = internal sphincter; rs = rectal stump.

served, four (66 percent) referred a normal continence (Grade A), whereas two had only minor impairment (33 percent). None used a pad. Other clinical or laboratory parameters examined are reported in Table 1.

Curiously, patients who had levators removed did not report symptoms of obstructed defecation as reported by three of those with standard coloanal anastomosis. The same percentages of patients in the two groups declared that they were fully satisfied or satisfied (50 and 33 percent, respectively) with the operation. No perineal hernia has been observed to date in the patients with levators removed. No patient complained of limitation to his or her social life.

DISCUSSION

In recent years the interest in sphincter-saving procedures for the treatment of low rectal cancers has greatly increased. Nowadays, coloanal anastomoses are usually performed for tumors sited at 6 to 7 cm from the anal margin.[9] Very low tumors, sited at 3 to 5 cm from the anal verge are still, mostly, treated with an abdominoperineal excision. This is because of the fact that it is impossible to obtain adequate margins from the tumor without damaging the sphincteric structures. Several recent experiences[10–17] suggest that, in selected tumors not infiltrating the levators or the external sphincter, it is possible to achieve a distal margin of 2 cm or more from the tumor, by extending the rectal excision to part of the whole of the internal sphincter and perform a coloanal anastomosis at, or below, the dentate line without major impairment of the anorectal function. The results of this operation—known as an "intersphincteric resection"—which is usually performed using an abdominoendoanal approach, seem to be satisfactory both oncologically and functionally.[14,16,17]

Infiltration of the levator muscles and/or the external sphincter (T4 tumors), however, remains an absolute contraindication also for this advanced procedure[11,15]; preservation of these muscles has been
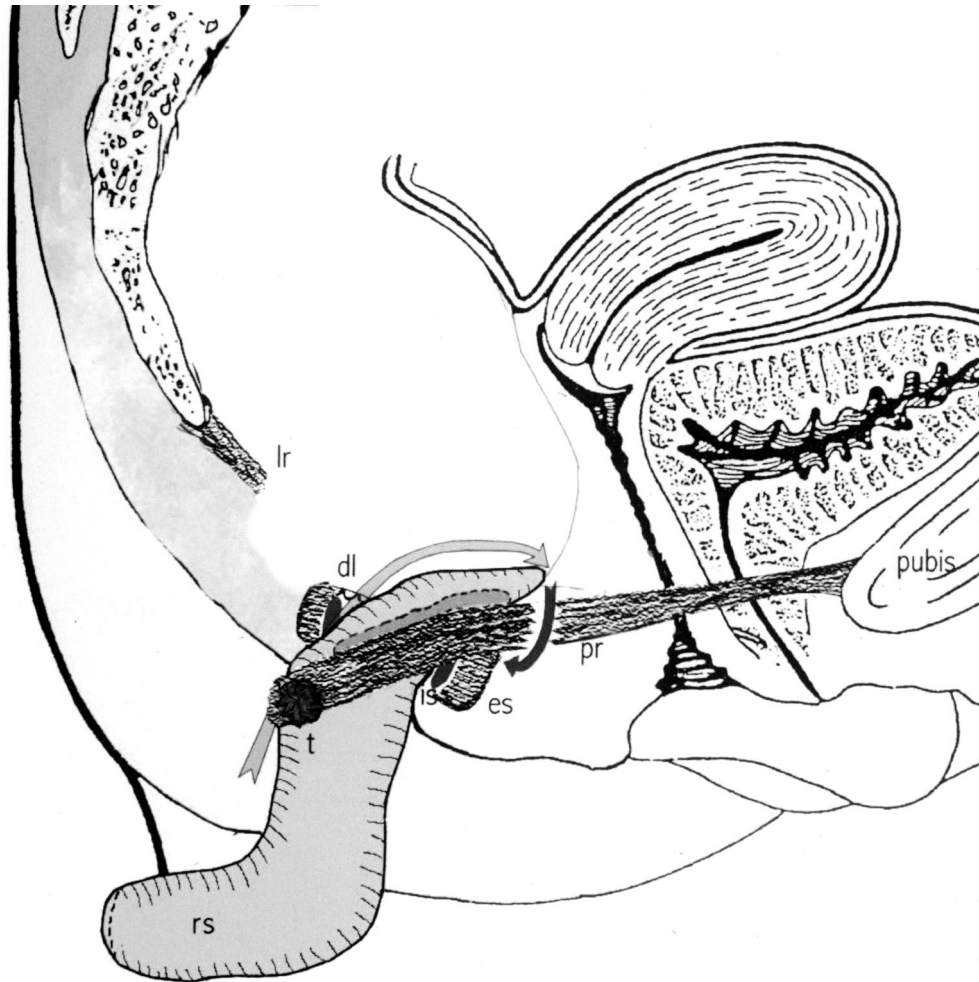
Figure 4. Diagrammatic lateral view of the operation after posterior and posterolateral excision of levator muscles and delivering of the rectal stump through the anus. The detachment of the anterior rectal wall from the vagina is obtained following the routes indicated by arrows. lr = levator residue; pr = puborectalis muscle; es = external sphincter; t = tumor; dl = dentate line; is = internal sphincter; rs = rectal stump.

always considered to be essential for the maintenance of continence.[18]

Abdominoperineal excision of the anorectum (often preceded by preoperative radiation or chemoradiation), together with fashioning of a terminal abdominal stoma, is therefore the standard adopted procedure for these T4 lesions.[19] Nevertheless, local and distant recurrence rate is high.[20] Infiltration of the levator muscles is often accompanied by cancer diffusion to other structures such as the pelvic sidewalls or presacral fascia, which are usually not removed during standard lymph node (AP) resections: this might possibly account for the high rate of local failure. However, in a few low-lying cancers (specifically those which arise in the posterior-posterolateral rectal walls near the anorectal ring) the infiltration of the levator muscles could initially occur without compro-

mise of either other pelvic structures or the external sphincter. Whether these cancers (also classified as T4 and treated with AP resection) harbor the same risk of local recurrence as other more advanced T4 lesions has not yet been investigated, let alone established.

Our experience seems to demonstrate the existence of a subset of advanced low rectal cancers (preoperatively classified as T4 only, because of limited infiltration of the puborectalis muscle) with a less adverse prognosis. These tumors could be treated with an abdominoendoanal resection (instead of an AP resection), which preserves the external sphincter and the lower anal canal. This procedure enables the reestablishment of intestinal continuity with satisfactory oncologic results and permits an anorectal function which is no worse than that of patients undergoing more conventional coloanal anastomosis.
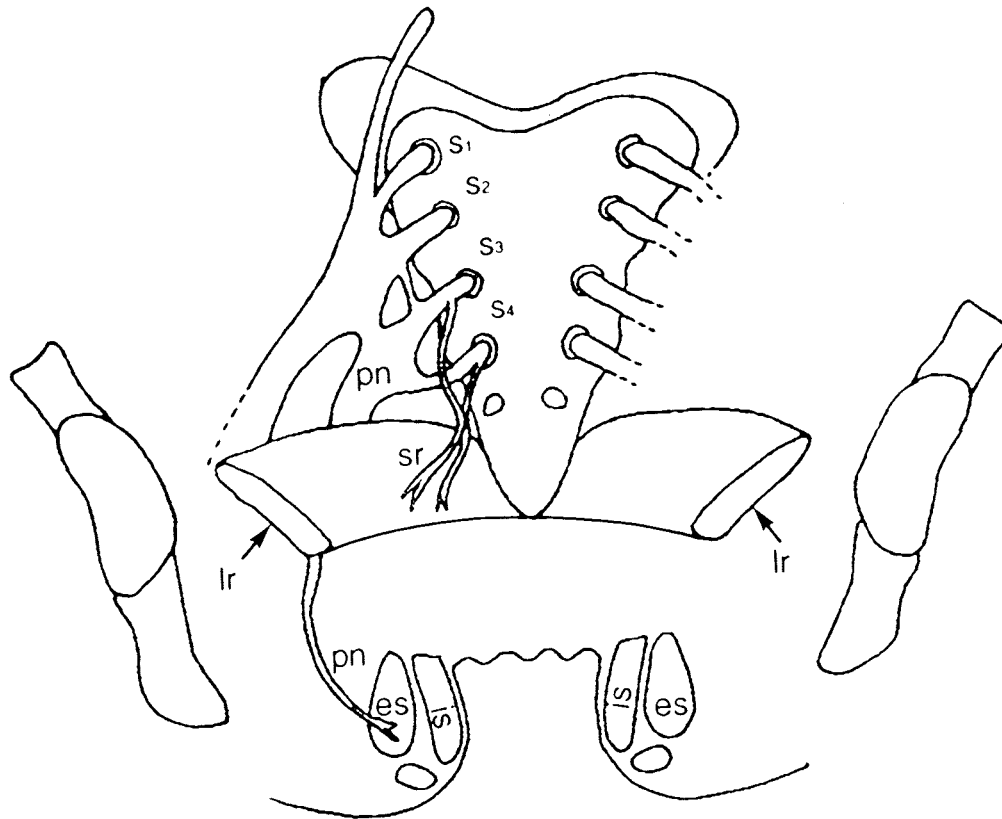
Figure 5. Diagrammatic view of residual pelvic floor and anal canal after removal of the specimen. sr = sacral roots; pn = pudendal nerve; es = external sphincter; is = internal sphincter; lr = levator residue.
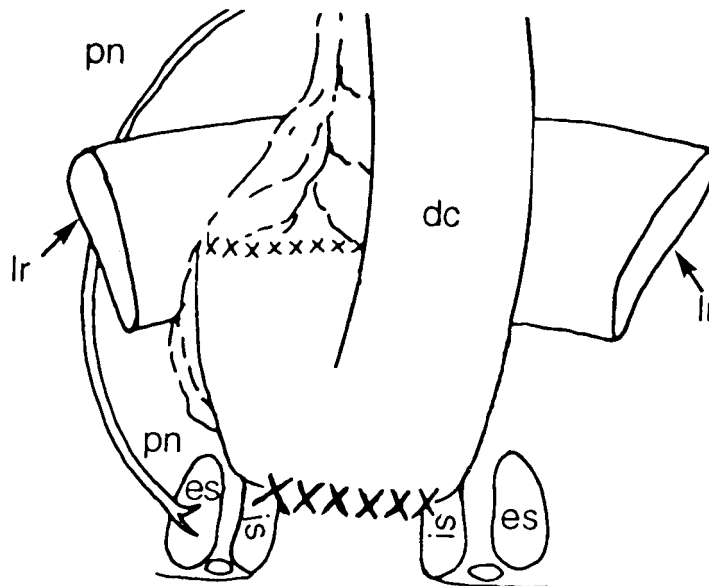
Figure 6. Final diagrammatic aspect of the coloanal anastomosis. dc = descending colon; pn = pudendal nerve; es = external sphincter; is = internal sphincter; lr = levator residue.

CONCLUSIONS

Selected patients with no history of anorectal impairment, with an anal canal measuring at least 2.5 cm in length, with T4 low posterior-posterolateral, well-differentiated noncolloid rectal cancers situated at least at 3 cm from the anal verge, and demonstrating (at ERUS) an infiltration of the levator muscles limited

Table 1.
Clinical and Laboratory Anorectal Function After Three Years in Patients With Preserved Levator Muscle (n = 6) *vs.* Excised Levator Muscle (n = 6)

	With Levator Muscle	Without Levator Muscle	P
Urgency	1	4	0.08*
Fractionated defecation	3	4	NS*
Bowel content typification	6	4	NS*
RAIR	2	0	NS*
No. daily defecations	1.4 ± 0.5	1.5 ± 0.8	NS†
ARP (mmHg)	21.1 ± 2.5	15.3 ± 2.5	NS†
MARP (mmHg)	47.1 ± 14.5	40.2 ± 7	NS†
MVC (mmHg)	100.3 ± 50.6	70.8 ± 33	NS†
MVC (sec)	16.9 ± 10.7	17.2 ± 11	NS†
MTV (ml)	136 ± 52.8	140 ± 31	NS†

MARP = maximum anal resting pressure; MVC = maximal voluntary contraction; MTV = maximal tolerated volume; RAIR = rectoanal inhibitory reflex; NS = not significant.

Figures are number of patients and mean ± standard deviation.

* Fisher's exact probability test.

† Student's *t*-test.

to the puborectalis muscles, can be treated with the above-reported advanced sphincter-sparing procedure with satisfactory oncologic and functional results. The aforesaid holds true provided that 1) the tumors respond to preoperative RTCHT; 2) the ES is preserved (separation from PR should preferably be performed along their anatomic plane of separation); and 3) the levator or levators that seem infiltrated before RTCHT is or are excised. A major part of the anorectal function can be maintained by the external sphincter alone and the residual anal canal.

A final aspect which is worth mentioning in the approach to this operation concerns ERUS. In our opinion, this examination should be performed concomitantly with digital exploration by the same surgeon who is to perform the operation. Obviously, he must be familiar with endorectal ultrasound and with the anatomy of the anorectal region. Only a personal, combined evaluation of the two examinations can offer the correct information as to the extent of tumoral infiltration and hence permit the surgeon to decide on such an approach.

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