DISEASES OF THE COLON & RECTUM

ORIGINAL CONTRIBUTION

Impact of Pelvic Radiotherapy on Morbidity and Durability of Sphincter Preservation After Coloanal Anastomosis for Rectal Cancers

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PURPOSE: This study was designed to assess the impact of pelvic radiotherapy on the incidence of complications and colostomy-free survival of patients after a coloanal anastomosis for rectal cancer.

METHODS: A total of 192 patients underwent a coloanal anastomosis between 1982 and 2001: 87 patients did not receive pelvic radiotherapy; 105 patients received pelvic radiotherapy (39 preoperative and 66 postoperative). Early and late complications requiring surgical intervention and the colostomy-free survival rate were assessed by retrospective review of patient records.

RESULTS: After a median follow-up of 62 months, 151 patients were alive. The most frequent complication was development of an anastomotic stricture (5-year rate of a stricture, 16 percent; 95 percent confidence interval, 10–21). Patients receiving pelvic radiotherapy had a higher rate of complications other than anastomotic strictures, including fecal incontinence, fistulas, abscesses, and bowel obstructions compared with patients not receiving pelvic radiotherapy (5-year rate: 20 percent (95 percent confidence interval, 10–29) *vs.* 5 percent (95 percent confidence interval, 0–10); $P=0.001$). Patients receiving pelvic radiotherapy had a lower colostomy-free survival than did patients not receiving pelvic radiotherapy (5-year colostomy-free rate: 72 percent (95 percent confidence interval, 62–84) *vs.* 92 percent (95 percent confidence interval, 86–98); $P<0.001$). There was no significant difference in the colostomy-free survival of patients receiving preoperative and postoperative pelvic radiotherapy.

CONCLUSIONS: After coloanal anastomosis, a significant number of patients will have complications requiring surgical intervention, and some will require a permanent colostomy. Pelvic radiotherapy, whether it is administered preoperatively or postoperatively, significantly increases the need for a permanent colostomy.

KEY WORDS: Rectal cancer; Coloanal anastomosis; Pelvic radiotherapy; Complications; Colostomy-free survival.

Better understanding of tumor biology and advances in surgical techniques have made coloanal anastomosis an acceptable treatment option for distal rectal cancer in appropriate patients.[1–4] The role and rationale of pelvic radiotherapy (radiation *vs.* no radiation) and its timing (preoperative *vs.* postoperative) in the management of patients with rectal cancer continues to evolve. The primary intent of this approach is to achieve and *maintain* long-term sphincter preservation while accomplishing oncologic efficacy and acceptable functional results. Current evidence suggests that in addition to appropriate surgery, pelvic radiotherapy decreases local recurrence rates and might improve survival for rectal cancer.[5,6] Consequently, a significant number of patients with rectal cancers receive pelvic radiotherapy as a part of their treatment regimen.[7–17] The impact of pelvic radiotherapy on the functional results after a coloanal anastomosis have been documented.[10,12,15–21] However, the effect of pelvic radiotherapy on morbidity and subsequent long-term durability of sphincter preservation in a large patient cohort has not been reported. Our purpose was to assess the impact of pelvic radiotherapy on the long-term surgical morbidity and sphincter preservation of patients after a coloanal anastomosis.

PATIENTS AND METHODS

Between 1982 and 2001, 192 patients underwent a coloanal anastomosis for a histologically proven rectal adenocarcinoma at the Mayo Clinic Rochester, Minnesota and Jacksonville, Florida. A total of 151 patients were alive

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DOI: 10.1007/s10350-007-9099-x • VOLUME 51: 32–37 (2008) • ©THE ASCRS. 2007

after a median follow-up of 62 months. Data regarding complications, colostomy-free survival, and overall survival were abstracted from patient histories and clinical records.

Major postoperative complications were defined as complications requiring surgical intervention within 30 days of the initial surgery. Early complications were defined as complications requiring surgical intervention more than 30 days after the initial operation but before ileostomy closure. Late complications were defined as complications requiring surgical intervention more than 30 days after the initial operation (if the patient did not have a temporary ileostomy) or more than 30 days after closure of the ileostomy. Colostomy-free survival was calculated based on the time from the initial operation (if an ileostomy was not performed) or from closure of the ileostomy to the time surgery for permanent fecal diversion was performed for any reason.

All operations were performed by board-certified colorectal surgeons. The rectal dissection was performed in anatomic planes following the oncologic principles of mesorectal excision as described previously.[22] The type of the anastomosis to the anal canal (stapled *vs.* handsewn or colonic J-pouch *vs.* straight) and need for temporary fecal diversion was performed according to the surgeon's preference. Pelvic radiotherapy, preoperative or postoperative, was delivered as a long-course regimen; external beam megavoltage radiation therapy to a total dose of 45 to 53.5 Gy in 1.7 to 2.1 Gy fractions during five weeks. Two-, three-, or four-field techniques were allowed, and treatment of the whole pelvis was required. The irradiation volume encompassed the primary tumor and/or the tumor bed with 2-cm margins as well as the internal iliac and presacral nodes. The superior border of the field was between the inferior aspect of the sacroiliac joints and the top of the fifth lumbar vertebral body, and the inferior limit of the field was located at the obturator foramina. A boost dose to a smaller field was allowed. Surgery was usually performed six to eight weeks after completion of radiation in cases of preoperative radiotherapy and six to eight weeks after surgery in the case of postoperative radiotherapy.

Statistical Analysis

Complication rates, colostomy free-survival, and overall survival were compared among three main groups: 1) patients not receiving pelvic radiotherapy, 2) patients receiving preoperative pelvic radiotherapy, and 3) patients receiving postoperative pelvic radiotherapy. Groups were compared on baseline demographics and outcomes, such as complications and colostomy-free survival. Outcomes comprised of continuous variables were compared by using Wilcoxon's rank-sum tests or Kruskal-Wallis tests. Discrete nominal variables were analyzed by using chi-squared tests and discrete ordinal variables were compared by using Wilcoxon's rank-sum tests and Kruskal-Wallis tests.[23,24] Colostomy-free survival and late complications were analyzed as time-to-event outcomes, and the cumulative probability of these events was estimated by using the method of Kaplan and Meier.[25] Differences in rates of occurrences of these events among the groups were evaluated by using log-rank tests.[26] All statistical tests were two-sided, and $P<0.05$ was considered significant.

RESULTS

Of the 192 patients who underwent a coloanal anastomosis, 87 did not receive pelvic radiotherapy, whereas 105 patients did receive pelvic radiotherapy (39 preoperative and 66 postoperative). Characteristics of the patients, the tumor, and operative treatments are shown in Tables 1, 2, and 3.

Postoperative and Early Complications Requiring Surgical Intervention

Six major postoperative complications that required surgical intervention occurred within 30 days of the initial operation. These complications included three anastomotic leaks, two pelvic abscesses, and one small-bowel obstruction.

Twelve early complications that required surgical intervention occurred in 11 patients more than 30 days after the initial operation but before closure of the ileostomy. Among the patients who did not receive pelvic radiotherapy, three patients developed an anastomotic stricture that was managed by anal dilatations (2 patients) and an anoplasty (1 patient). Among the patients who received preoperative pelvic radiotherapy, there were complications in four patients that included a pouch-

Table 1. Characteristics of patients (N=192) undergoing a coloanal anastomosis

	No XRT (n=87)	*Preoperative XRT (n=39)*	*Postoperative XRT (n=66)*	*P value*
Median age at surgery (yr)	60 (28–85)	61 (28–75)	56.5 (22–77)	0.1
Median follow-up (mo)	65 (0–236)	33 (1–154)	64 (7–248)	<0.01*
Male (%)	67	77	79	0.2
Median BMI (kg/m^2)	27.4	28.3	26.6	0.15
BMI>30 (kg/m^2) (%)	23	39	23	0.11

XRT = pelvic radiotherapy; BMI = body mass index. • Data are medians with ranges in parentheses unless otherwise indicated. • * Preoperative XRT significantly different from no XRT and postoperative XRT groups.

Table 2. Tumor characteristics (N=192)

	No XRT (n=87)	*Preoperative XRT (n=39)*	*Postoperative XRT (n=66)*	*P value*
Tumor distance from the anal verge (cm)	6 (2–18)	6 (1–12)	6.5 (2–15)	0.08
Tumor stage				
0	3 (3.4)	0 (0)	0 (0)	<0.01*
I	60 (69)	0 (0)	0 (0)	
II	10 (11.5)	10 (25.6)	19 (28.8)	
III	11 (12.6)	27 (69.2)	45 (68.2)	
IV	3 (3.4)	2 (5.1)	2 (3)	

XRT = pelvic radiotherapy. • Data are medians with ranges in parentheses or numbers with percentages in parentheses unless otherwise indicated. • * No XRT significantly different from preoperative XRT and postoperative XRT.

vaginal fistula and anastomotic stricture (n=1), pouch-vaginal fistula (n=1), anastomotic stricture (n=1), and chronic pelvic abscess (n=1). All four of these patients eventually underwent a permanent colostomy as a result of these complications. Among the patients who received postoperative pelvic radiotherapy, there were four complications, including small-bowel obstruction (n=3) and an anastomotic stricture (n=1); the patient with the stricture required a permanent colostomy at the time of ileostomy reversal (he received postoperative pelvic radiotherapy before ileostomy closure; Table 4).

Late Complications Requiring Surgical Intervention

Late complications requiring surgery occurred in 47 patients (5-year rate of late complications: 27 percent; 95 percent confidence interval (CI), 19–34). The most frequent late complication was development of an anastomotic stricture at the coloanal anastomosis (5-year rate of a stricture, 16 percent; 95 percent CI, 10–21). There was no significant difference in the stricture rate among patients not receiving pelvic radiotherapy (5-year rate: 16 percent; 95 percent CI, 7–23), receiving preoperative pelvic radiotherapy (5-year rate: 14 percent; 95 percent CI, 2–25), or receiving postoperative pelvic radiotherapy (5-year rate: 17 percent; 95 percent CI, 7–26; $P=0.82$.

Table 3. Operative characteristics of patients (N=192) undergoing a coloanal anastomosis

	No XRT (n=87)	*Preoperative XRT (n=39)*	*Postoperative XRT (n=66)*	*P value*
Type of anastomosis				
Straight	63 (55)	49 (19)	59 (39)	0.31
J-pouch	37 (32)	51 (20)	41 (27)	
Mucosectomy	61	41	50	0.1
Temporary diversion	74	95	77	0.02*

XRT = pelvic radiotherapy. • Data are percentages with numbers in parentheses unless otherwise indicated. • * Preoperative XRT significantly different from no XRT and postoperative XRT.

Table 4. Early and late complications of patients (N=192) undergoing a coloanal anastomosis

	No XRT (n=87)	*Preoperative XRT (n=39)*	*Postoperative XRT (n=66)*
Stricture	15*	6	12*
Abscess	0	3	1
Fistula	0	2†	1†
Bowel obstruction	1	0	6
Incontinence	1	1	7‡

XRT = pelvic radiotherapy. • * One patient also had a bowel obstruction. • † One patient also had a stricture. • ‡ Two patients also had a bowel obstruction.

Because of the small number of complications in the other categories (Table 4), individual statistical comparisons of these complications between the three groups were not performed and were instead combined together for analysis. Patients receiving pelvic radiotherapy (5-year rate: 20 percent; 95 percent CI, 10–29) had a higher rate of complications other than anastomotic strictures, which included fecal incontinence, fistulas, abscesses, and bowel obstruction compared with patients not receiving pelvic radiotherapy (5-year rate: 5 percent; 95 percent CI, 0–10; $P=0.001$). Patients receiving pelvic radiotherapy also had a higher rate of complications that required fecal diversion compared with patients who did not receive pelvic radiotherapy (5-year rate: 24 percent (95 percent CI, 12–34) *vs.* 6 percent (95 percent CI, 0–11); $P<0.001$).

Colostomy-Free Survival

Of the 192 patients who underwent a coloanal anastomosis for rectal cancer, 46 patients eventually required permanent fecal diversion at last follow-up. Twenty-eight patients (61 percent) required diversion because of anorectal dysfunction (incontinence, stricture or fistula/abscess): four patients (9 percent) because of bowel obstruction, ten patients (22 percent) because of recurrent pelvic disease or metastasis, and four patients (9 percent) because of patient-related reasons (3 patients were not fit for surgery and 1 patient preferred not to be reversed; Table 5).

Patients receiving pelvic radiotherapy had a lower colostomy-free survival compared with patients not receiving pelvic radiotherapy (5-year colostomy-free rate: 72 percent (95 percent CI, 62–84) *vs.* 92 percent (95 percent CI, 86–98); $P<0.001$). When patients who received preoperative or postoperative pelvic radiotherapy were analyzed separately, patients who received preoperative (5-year colostomy-free survival: 60 percent (95 percent CI, 33–100) or postoperative (5-year colostomy-

Table 5. Indications for permanent fecal diversion (N=46) among patients undergoing a coloanal anastomosis

	No XRT (n=12)	*Preoperative XRT (n=10)*	*Postoperative XRT (n=24)*
Recurrence (local or distant)	4 (33)	2 (20)	4 (17)
Patient preference/ health	2 (17)	0	2 (8)
Bowel obstruction	1 (8)	0	3 (13)
Incontinence	1 (8)	1 (10)	7 (29)
Fistula	0	2 (20)	1 (4)
Stricture	3 (25)	2 (20)	6 (25)
Abscess/leak	1 (8)	3 (30)	1 (4)

XRT = pelvic radiotherapy. • Data are numbers with percentages in parentheses unless otherwise indicated.

free survival: 74 percent (95 percent CI, 63–87) pelvic radiotherapy had a lower colostomy-free survival than patients who did not receive pelvic radiotherapy ($P=0.008$ and $P<0.001$, respectively; Fig. 1). There was no significant difference between the colostomy-free survival of the patients who received preoperative and postoperative pelvic radiotherapy ($P=0.61$; Fig. 1).

DISCUSSION

Clinical measures assessing the results of a coloanal anastomosis for rectal cancers include not only oncologic adequacy, functional, and quality of life outcomes but also its durability in terms of sphincter preservation. We found that pelvic radiotherapy delivered preoperatively or postoperatively had a negative impact on complications and colostomy-free survival.

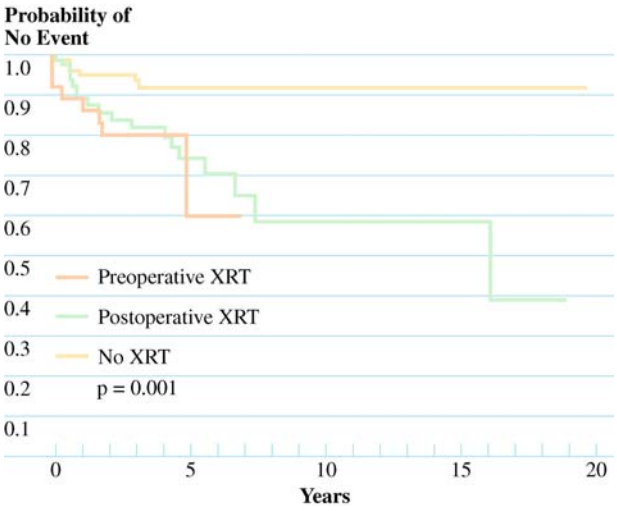

FIGURE 1. Colostomy free survival of patients who did not receive pelvic radiotherapy and who received preoperative and postoperative pelvic radiotherapy.

The incidence of early and late complications in our patients after coloanal anastomosis compares favorably with that reported elsewhere.[7,9,14,15,20,21,27–31] Significant early complications were few but had serious consequences in patients who received pelvic radiotherapy. Early complications led to permanent fecal diversion in all four patients who had received preoperative pelvic radiotherapy and in one patient who received postoperative pelvic radiotherapy. None of the patients who did not receive pelvic radiotherapy lost intestinal continuity as a result of early complications.

The most common long-term complication of a coloanal anastomosis in our cohort was anastomotic stricture. Importantly, we found no difference in the incidence of anastomotic strictures between patients who did or did not receive pelvic radiotherapy. We further found that anastomotic strictures behaved in a benign fashion, were managed well with anal dilatations, and had no impact on long-term sphincter preservation.

In contrast, patient's receiving pelvic radiotherapy had a higher rate of fecal incontinence, fistulas, abscesses, and bowel obstruction compared with patients who did not receive pelvic radiotherapy. These data are consistent with two large meta-analyses of patients undergoing surgery for rectal cancer, which found that the most frequent postoperative complications were sepsis, anastomotic leak, and intestinal obstruction.[5,6] In these reports, pelvic radiotherapy was an associated risk factor for all of these complications. Furthermore, patients in our series who received pelvic radiotherapy and suffered a postoperative complication had a lower colostomy-free survival compared with patients who did not have a postoperative complication.

As in nearly all other similar studies, we found that a proportion of patients subsequently failed to regain or maintain intestinal continuity over time. There were two main reasons: 1) biology of the disease resulted in local recurrence or distant metastasis, which subsequently precluded reestablishing intestinal continuity; and 2) the morbidity of the procedure itself, as patients required permanent fecal diversion because of postoperative strictures, abscesses/fistulas, incontinence, or bowel obstruction. Evidence regarding the detrimental impact of radiotherapy on pelvic tissue and anal sphincter function has emerged recently.[20] Our findings that the colostomy-free survival was significantly lower among patients who received pelvic radiotherapy compared with patients who did not confirm these observations. Furthermore, in our study this adverse impact on colostomy-free survival occurred irrespective of whether pelvic radiotherapy was given preoperatively or postoperatively.

The goal of a coloanal anastomosis is to preserve fecal continence and avoid a permanent stoma, because a stoma is considered to have an adverse impact on patient quality of life, a fact that is currently being disputed.

Peeters *et al.*[32] in their analysis of the late side-effects of surgery and radiotherapy among patients from the Dutch colorectal cancer group study reported that 74 percent of patients with a stoma and 55 percent of patients without a stoma were satisfied with their bowel function. They contended that sphincter preservation because of its associated dysfunction should not necessarily be the fundamental objective in the surgical management of rectal cancer. Although this is a reasonable contention, we believe it should be put into an appropriate context. More than 90 percent of the patients in our cohort who underwent a coloanal anastomosis and did not receive pelvic radiotherapy maintained intestinal continuity at ten years with minimal morbidity. Sphincter preservation in this group is thus realistic and an achievable goal, which we recommend pursuing.

On the other hand, approximately two of five patients who received pelvic radiotherapy did not maintain intestinal continuity because of complications; results, although not dismal enough to justify abandoning attempts at sphincter preservation, do warrant significant caution and deliberation, as well as upfront discussions with the patient. It is imperative to acknowledge that although pelvic radiotherapy has its role in the management of advanced rectal cancer, in its present form this comes at the price of significant morbidity and risk to long-term sphincter preservation in patients undergoing a coloanal anastomosis. These are important considerations that need to be taken into account when deciding the surgical approach and counseling patients. It also mandates the judicious use of pelvic radiotherapy under circumstances when it is warranted and its avoidance whenever possible.

CONCLUSIONS

Coloanal anastomosis for rectal cancer is a durable and reliable operation when sphincter preservation is a priority. A significant number of patients will develop complications and a proportion of patients will eventually be unable to maintain long-term intestinal continuity. Pelvic radiotherapy, whether it is preoperative or postoperative, has a significant adverse affect on colostomy-free survival. The oncologic benefit of radiation therapy in this group of patients must, therefore, be weighed against its impact on postoperative complications and colostomy-free survival.

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