Chapter 2:

HIGH ONE-YEAR COMPLICATION RATE AFTER LOW ANTERIOR RESECTION FOR RECTAL CANCER.

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Abstract

Introduction: Surgical options after low anterior resection for rectal cancer include a primary anastomosis, anastomosis with a defunctioning stoma and an end-colostomy. This study describes short-term and one-year outcomes of these different surgical strategies.

Methods: Patients undergoing surgical resection for primary mid and high rectal cancer were retrospectively studied in seven Dutch hospitals with one-year follow up. Short term endpoints were postoperative complications, re-interventions, prolonged hospital stay and mortality. One-year end-points were unplanned readmissions and re-interventions, presence of stoma and mortality.

Results: Nineteen per cent of 388 included patients received a primary anastomosis, 55% an anastomosis with defunctioning stoma, and 27% an end-colostomy. Short-term anastomotic leakage was 10% in patients with a primary anastomosis vs. 7% with a defunctioning stoma (P=0.46). An end-colostomy was associated with less severe re-interventions. One-year outcomes showed low morbidity and mortality rates in patients with an anastomosis. Patients with a defunctioning stoma had high (18%) readmissions and re-intervention (12%) rates, mostly due to anastomotic leakage. An end-colostomy was associated with unplanned re-interventions due to stoma/abscess problems. During follow-up, there was a 30% increase in patients with an end-colostomy.

Conclusion: This study showed a high one-year morbidity rate after low anterior resection for rectal cancer. A defunctioning stoma was associated with a high risk for late complications including anastomotic leakage. An end-colostomy is safe alternative to prevent anastomotic leakage, but stomal problems cannot be ignored. Selecting low-risk patients for an anastomosis may lead to favorable short- and one-year outcomes.

Introduction

Colorectal cancer is a significant source of mortality with more than 12.000 cases diagnosed in the Netherlands each year.[1] The cornerstone of treatment is surgical resection.

When discussing surgical treatment options for rectal cancer with patients preoperatively, difficult considerations can be encountered. When tumor size, stage and location allow a sphincter preserving resection, the surgical options consist of an anastomosis, an anastomosis with a defunctioning stoma and an end-colostomy. Both patients and surgeons seem to have a strong preference to avoid a stoma, under the assumption that it will have negative consequences on quality of life.[2, 3] However, an anastomosis bears the risk of anastomotic leakage, which may cause re-operations, prolonged hospital stay, morbidity, mortality and possibly a worse oncological outcome.[4-6] Furthermore, functional outcome after a low anastomosis, especially in combination with radiotherapy or chemoradiation can also lead to an impaired quality of life.[7, 8] Additionally, a defunctioning stoma has been proven to diminish the sequelae of anastomotic leakage.[9] Anastomotic leakage will not occur when an anastomosis is avoided, e.g. when an end-colostomy is constructed. On the other hand, stomas may also have their own significant mid-to long-term morbidity and complications after reversal of the stoma have been reported.[10-14]

In order to inform and involve patients in preoperative clinical decision-making, surgeons need information on outcomes of different treatment options. The aim of this study is to describe the short-term and one-year outcomes of different surgical treatment options for mid and high rectal cancer patients.

Methods

Study population

We explored short term and one-year outcomes of all consecutive patients who underwent surgical resection for primary rectal cancer between the 1st of January 2009 and 31st of June 2011 in 7 different hospitals in the Netherlands. Surgical resection was performed according total mesorectal excision. In patients with high tumors surgical resection was performed five centimeters below the tumor with the mesorectum optionally left in situ. Patients with a tumor less than 5 cm from the anal verge, patients undergoing abdominoperineal resection, and patients with a T4 tumor were excluded, because these patients represent subgroups with other surgical approaches and subsequent different expected outcomes.

Outcomes

We extracted information on the following patient and tumor characteristics: age, gender, ASA-classification, co-morbidity, abdominal surgical history, preoperative tumor complications, tumor stage, additive resections and distance of tumor to the anal verge.

Short term endpoints, defined as endpoints until 30 days after initial surgery, were postoperative complications, re-interventions, prolonged hospital stay and postoperative mortality. Complications were defined as all postoperative complications, both non-surgical and surgical, during hospital admission; anastomotic leakage was defined as clinically relevant anastomotic leak requiring re-intervention, both radiological and surgical; re-interventions were defined as all additional procedures, both radiological and surgical, performed for the treatment of all postoperative complications; surgical re-interventions were laparotomy or laparoscopy; a prolonged hospital stay was defined as hospital stay longer than 14 days; postoperative mortality was defined as in-hospital mortality or within 30 days after primary surgery.

One-year outcomes were unplanned readmissions and re-interventions after initial admission, presence of a stoma and mortality within one-year. From patients with a defunctioning stoma or end-colostomy, we extracted data on whether a second surgery was performed to restore bowel continuity; post-operative complications and hospital stay of this procedure were also analyzed.

Analyses

The study population was divided in three groups according to their received surgical treatment: anastomosis, anastomosis with defunctioning stoma, or end-colostomy. Whether or not patients with an end-colostomy had a resection of the rectal stump was not taken into account. During the study period, patients switched between these groups, because of re-interventions for complications, or because of elective secondarily stoma reversal. Patient and tumor characteristics and short-term postoperative outcomes were described in relation to the initial received surgical treatment. For analysis of the one-year outcomes, analyses groups were defined according their anastomosis/stoma status after first hospital admission. A Chi-squared analysis was performed to investigate differences in short-term outcomes.

For one-year outcomes the differences in readmission rate, re-intervention rate and 1-year mortality were statically tested. Statistical significance was defined as $p<0.05$. All statistical analyses were performed in PASW Statistics, Rel. 18.0.2009.

Results

During the period of January 2009 to June 2011, 843 consecutive patients underwent surgical resection for primary rectal cancer in the 7 participating hospitals. A total of 455 patients were excluded (14 urgent resections, 386 patients with low rectum tumors (<5 cm) and/

or undergoing an abdominoperineal resection,), and 45 patients with a T4 tumor). Patients with unknown anastomosis/stoma status were excluded as well (n=10). After selection according the eligibility criteria, 388 patients undergoing low anterior resection for rectal cancer were included in this study.

Short-term outcomes

Table 1 shows patient and treatment characteristics according to initial surgical treatment; seventy-two patients (19%) received a primary anastomosis 214 patients (55%) had an anastomosis with defunctioning stoma, and 102 patients (27%) an end-colostomy. Patients with an end-colostomy were significantly older; and a higher ASA-classification when compared to both other groups; patients with an anastomosis had significantly higher tumors; patients with a defunctioning stoma less often had distant metastases and more often received neoadjuvant chemo-radiation therapy. Fifty-nine per cent of the defunctioning stomas concerned loop ileostomies; 41% were loop transversostomies

Postoperative complications

Table 2 shows the short-term outcomes after initial surgery. One third of all patients developed a postoperative complication; regardless of the type of surgery. Anastomotic leakage rates were 10% (n=7) in patients with an anastomosis; and 7% (n=14) in patients with defunctioning stoma (not statistically significant; p=0.46).

Re-interventions and hospital stay

There were no statistically significant differences between the three treatment groups in overall percentage of re-interventions. In patients with an anastomosis with or without a defunctioning stoma, re-interventions were mainly surgical, while patients with an end-colostomy mainly underwent re-interventions for stoma or wound management. Eighty-six per cent of patients, in which anastomotic

leakage occurred, needed a surgical re-intervention. This percentage was similar for patients with and without a defunctioning stoma (respectively 6 out of 7 and 12 out of 14). Patients with a defunctioning stoma and patients with an end-colostomy had a trend towards a longer hospital stay, although this difference was not statistically significant.

Postoperative Mortality

Postoperative 30-day or in-hospital mortality rates were low: 0% in patients with an anastomosis, 1% in patients with an anastomosis with a defunctioning stoma and 2% in patients with an end-colostomy.

One-year outcomes

Unplanned readmissions

Table 3 shows the follow up outcome of the three groups as situated after first hospital admission: 62 patients (16%) with an anastomosis; 209 patients (54%) with an anastomosis with a defunctioning stoma, and 117 patients (30%) with an end-colostomy. Patients with a defunctioning stoma had a readmission rate of 18%, mostly due to (late) anastomotic leakage. Patients with an end-colostomy had a readmission rate of 17%, mostly due to stoma-related problems. Patients with a primary anastomosis had a significantly lower readmission rate than both other groups. Only one patient of the primary anastomosis group was readmitted because of anastomotic leakage, and two patients for other reasons.

Re-interventions

Both patients with a defunctioning stoma and patients with an end-colostomy had a 12% re-intervention rate. In patients with a defunctioning stoma, 5% underwent a surgical re-intervention in which the anastomosis was disconnected and an end-colostomy was created. Five percent of patients underwent a radiological drainage. Revision of the stoma was the most frequent re-intervention in patients with

an end-colostomy (7%). Also, in this group, 5% of patients underwent radiological drainage of an abscess. Only one patient with a primary anastomosis underwent a re-intervention because of anastomotic leakage. In this patient, the anastomosis was disconnected and an end-colostomy was created.

Stoma reversal

In the majority of patients with a defunctioning stoma, bowel continuity was restored with a second surgery. In 22% of patients, the stoma was not reversed after one-year. The overall complication rate after stoma closure was 24%; and the anastomotic leakage rate was 4% (*Table 3*). In patients with an end-colostomy, 5% underwent a second surgery to restore bowel continuity. In half of the patients, this secondary surgery was performed within 6 months after the initial surgery. The mean hospital stay after stoma reversal was 6 days for both defunctioning stomas and end-colostomies. There were no deaths after stoma closure.

Mortality

One-year mortality rate was the highest in patients with an end-colostomy; twenty-two patients (19%) in this group died. None of these deaths were surgery-related; all deaths were due to progression of the underlying disease or due to other diseases.

Switching between treatment groups

Due to changes in anastomosis/stoma status, patients switched between the three different treatment groups during the entire study period (*Figure* 1). After initial surgery, 19% of patients had a primary anastomosis, 55% had an anastomosis with defunctioning stoma, and 27% of patients had an end-colostomy. The percentage of patients with an end-colostomy increased with 30% (n=31). This increase consisted mainly of patients with initially a defunctioning stoma, in which anastomotic leakage occurred. Due to unplanned re-interventions and elective stoma

reversal, eventually 60% of all patients had an anastomosis, 6% had an anastomosis with defunctioning stoma, and 34% had an end-colostomy.

Discussion

Overview of findings

The present study described short-term and one-year outcomes of different treatment strategies in rectal cancer surgery. Although patients with a defunctioning stoma had a somewhat lower risk for short-term anastomotic leakage, they had a high risk for unplanned readmissions and re-interventions, mostly due to late anastomotic leakage. Furthermore, these patients had an additional high risk for postoperative complications after restoration of bowel continuity, including anastomotic leakage. In contrast, the one-year outcomes of patients with an anastomosis were surprisingly good. Although both groups were not completely comparable, the large difference in one-year outcomes could hardly all be due to lower tumors and a higher use of chemoradiotherapy in patients with a defunctioning stoma.

One expects that patients with an end-colostomy would have worse post-operative outcomes, since these patients were significantly older, and had a higher ASA-classification. Interestingly, these patients had a similar risk for postoperative complications, and even a lower risk for invasive re-interventions. This is probably an over-estimation of the actual risk associated with an end-colostomy. On the long-term however, end-colostomies were associated with stoma problems or pelvic abscesses causing unplanned readmissions.

Comparison with other studies

The value of a defunctioning stoma to diminish the consequences of

anastomotic leakage has been the subject of debate for a long time. Earlier randomized studies showed fewer anastomotic leaks and reoperations after low anterior resection with a defunctioning stoma.[9,15,16] A considerable amount of retrospective studies also describes the beneficial effect of a defunctioning stoma on direct postoperative anastomotic leakage rates.[6,17-19] On the other hand, there studies that support the notion that the routine use of a defunctioning stoma in low anterior resection is not advisable. Fielding et al. observed that there was a higher leakage rate in patients with a defunctioning stoma (18% versus 7%); Enker et al and Matthiessen et al showed that a defunctioning stoma did not reduce the incidence of anastomotic leakage in patients undergoing low or ultralow anterior resection.[20,21] Furthermore, a study from our own group showed that while during the last decade there was an increase in the use of defunctioning stomas, anastomotic leakage rates remained similar.[22]

Previous studies described the long-term stoma problems of both defunctioning stomas and end-colostomies.[13,14] A study of 163 patients undergoing an extended Hartmann resection, showed pelvic abscesses in 30% of patients, diagnosed on a median of 35 days postoperative (range 7-434).[23] Two studies reported on high readmission rates of patients with defunctioning stomas.[24,25] In contrast with our findings, patients were mostly readmitted because of dehydration. This might be related to the fact that in our study, 41% of the defunctioning stomas were transversostomies, which are known to have less dehydration problems than ileostomies.[26] Den Dulk et al described the policy of stoma formation in patients entered in the Dutch TME-trial for rectal cancer, and found that 20% of the stomas were never reversed, which is similar to our findings. We found a high overall morbidity and anastomotic leakage rate after stoma reversal, which is confirmed by previous publications; overall morbidity rates of 20-30% and anastomotic leakage rate of 2-9% after closure of defunctioning stomas have been reported.[12,27,28]

Strengths and limitations

An important strength of this study is that both the short-term and one-year outcomes were thoroughly evaluated. As far as we are aware, this is the first study to take into account one-year outcomes of all three surgical options. In most studies and audits, only short-term results are reported. As shown in this study, ongoing changes in outcome occur during the first year after surgery for rectal cancer due to complications and stoma reversal. Therefore, it is critical to take these long term outcomes into account when different surgical strategies are considered.

However, some limitations deserve mentioning. There was a possibility of a selection bias, as we randomly selected seven different hospitals. However, comparison of our cohort to the national data of the Dutch Surgical Colorectal Audit, including all patients undergoing surgical resection for colorectal cancer in the Netherlands, showed no significant differences in patient, tumor and treatment characteristics (data not shown).[29] Moreover, due to our small sample size, the outcomes could not be corrected for differences in case-mix since this requires a large amount of cases to prevent over-fitting. A larger study is needed in order to provide a case-mix adjusted comparison in both short- and long-term outcomes between the different groups.

Clinical implications and future research

In this study, we found favorable outcomes in patients with an anastomosis. These are probably caused by adequate identification of high-risk patients. In these patients, an end-colostomy to prevent short-term anastomotic leakage may be the best decision. Although an end-colostomy has the risk for stoma problems or pelvic abscesses on the long term, these are less consequential than immediate postoperative anastomotic leakage. Avoiding or limiting the risk for anastomotic leakage by routine creation of defunctioning stomas is not desirable, especially considering its poor one-year outcomes found in this study.

Scoring systems that could predict a patients' risk for anastomotic leakage pre-operatively should be the focus of future studies to facilitate decision-making.[30] Also, focusing on improvements in intraoperative conditions and surgical techniques rather than routine creation of defunctioning stomas may be the way to go. Previous studies with intraluminal devices showed good results in preventing anastomotic leakage and a multicenter randomized study is currently being performed.[31]

While the decision whether or not to make an anastomosis remains difficult, patients' preferences concerning the risk of morbidity and mortality of anastomotic leakage versus the consequences of stomas should be taken into account. This consideration requires thorough preoperative counselling.

Conclusion

Although a large proportion of patients received defunctioning stomas, these were associated with significant long-term morbidity including late anastomotic leakage. An end-colostomy may be a safe alternative to prevent anastomotic leakage, but long-term problems may also occur. Favorable outcomes in patients with an anastomosis are probably caused by adequate selection of low-risk patients, which should be the focus of future investigation.

Table 1: Characteristics according to type of surgery after initial surgery in 388 rectal cancer patients diagnosed between 01 January 2009 and 31 June 2011.

		Anastomosis		***Anastomosis with defunctioning stoma***		***End-colostomy***	
		Nr	**%**	**Nr**	**%**	**Nr**	**%**
Total (after initial surgery)		**72**		**214**		**102**	
Age	Mean	64		63		72*	
Gender	Female	38	53	87	41	47	46
ASA classification	ASA 3+	9	13	23	11	17	17*
Charlson	1	13	18	37	17	29	28
	2+	13	18	35	16	17	17
Preoperative complications**		1	1	9	4	1	1
Tumor (T-) stage	pT0	4	6	22	10	8	8
	pT1	5	7	13	6	10	10
	pT2	12	17	64	30	21	21
	pT3	47	65	107	50	62	61
Distant metastases	M1	15	21	7	3*	21	20
Abdominal surgical history		18	25	64	30	22	22
Extensive resection		3	4	25	12	10	10
Distance of tumor to anal verge	Mean	13		10*		10*	
Neoadjuvant therapy	5x5 Gy	27	37	92	43	31	43
	Chemoradiation	13	18	107	50*	17	24

Numbers with an * were statistically significant ($p<0.05$) when compared to patients with an anastomosis.
ASA classification=American Society of Anaesthesiologists classification. ** obstruction, perforation, abscess and bleeding.

Table 2: Short-term outcomes of patients with an anastomosis, an anastomosis with a defunctioning stoma, and an end colostomy.

	Anastomosis		***Anastomosis with defunctioning stoma***		***End-colostomy***	
	Nr	**%**	**Nr**	**%**	**Nr**	**%**
Total (after initial surgery)	**72**		**214**		**102**	
Postoperative complications	21	30	65	31	32	29
Anastomotic leakage	7	10	14	7	n.a.	n.a.
Re-interventions	11	16	27	13	13	12
Radiological drainage	1	1	3	1		
Surgical (laparoscopy/laparotomy)	8	11	20	9	5	5
Stoma/wound management	2	3	4	2	8	8
Prolonged hospital stay	12	18	47	23	23	22
Postoperative mortality	0	0	1	1	2	2

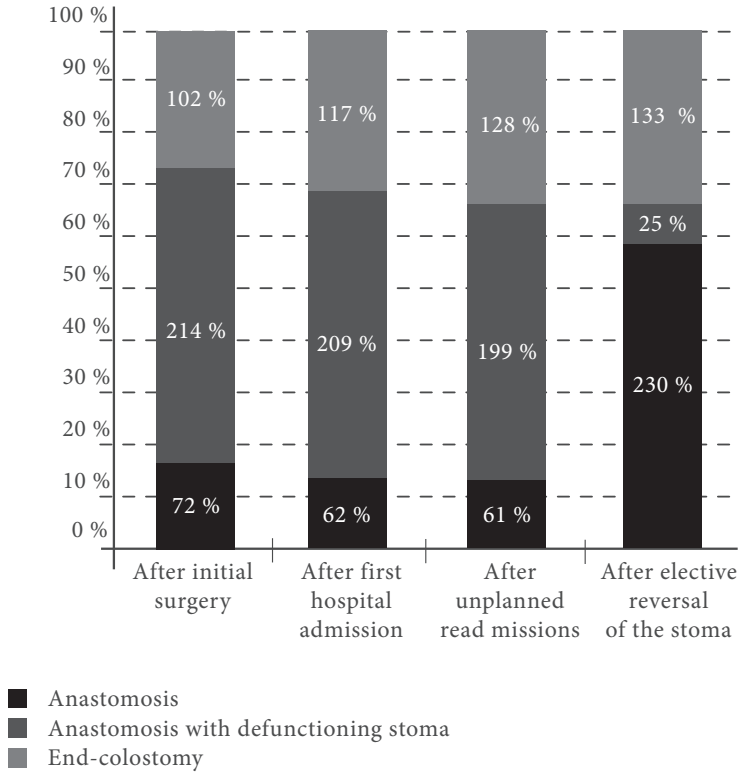
None of the differences were statistically significant

Table 3: One-year outcomes according to type of surgery after first hospital admission.

		Anastomosis		*Anastomosis with defunctioning stoma*		*End-colostomy*	
		Nr	**%**	**Nr**	**%**	**Nr**	**%**
Total (after first hospital admission)		**62**		**209**		**117**	
Readmissions		3	5	38*	18*	20*	17*
Reason for readmission	Anastomotic leakage	1	2	24	11	n.a.	n.a.
	Ileus	0	0	3	1	3	3
	Stoma problems	n.a.	n.a.	5	2	12	10
	Other**	2	3	6	3	5	4
Re-interventions		1	2	26*	12*	14*	12*
Type of re-intervention	Revision stoma			5	2	8	7
	Disconnect anastomosis + construction stoma	1	2	11	5		
	Drainage			10	5	6	5
Stoma reversal				163	78	6	5
Complications	All			39	24	2	33
	Anastomotic leakage			6	4	0	0
	Other			33	20	2	33
	Hospital stay (mean days)			6		6	
Time to reversal	<3 month			41	25	1	17
	3-6 months			64	39	2	33
	6-9 months			31	19	2	33
	>9 months			26	16	1	17
1-year mortality		2	3	7	3	22*	19*

Differences in readmission rate, reintervention rate and 1-year mortality were analyzed with a Chi-Squared test. Numbers with an * were statistically significant ($p<0.05$) when compared to patients with an anastomosis. ** includes dehydration and infection.

Figure 1. Changes in distribution of patients undergoing resection for mid and high rectal cancer according to stoma or anastomosis construction during the first year.



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