Original article

Protective defunctioning stoma in low anterior resection for rectal carcinoma

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Background: Anastomotic leak is a serious complication of resection for low rectal carcinoma.
Methods: Data from a prospective multicentre study conducted between January 2000 and December 2001 were analysed to determine the early outcome after low anterior resection in patients with and without a protective stoma. The morbidity and mortality rates associated with ileostomy and colostomy closure were compared.
Results: Eight hundred and eighty-one (32·3 per cent) of 2729 patients received a protective stoma after low anterior resection. Overall anastomotic leak rates were similar in patients with or without a stoma (14·5 *versus* 14·2 per cent respectively). The incidence of leaks that required surgical intervention was significantly lower in those with a protective stoma (3·6 *versus* 10·1 per cent; $P < 0·001$), as was the mortality rate (0·9 *versus* 2·0 per cent; $P = 0·037$). Logistic regression analysis showed that provision of a protective stoma was the most powerful independent variable for avoiding an anastomotic leak that required surgical correction. Seven hundred and twenty-four of the 881 patients who received a stoma were followed up. The overall postoperative morbidity associated with stoma closure was significantly lower for colostomy than for ileostomy (15·3 *versus* 22·4 per cent; $P = 0·031$).
Conclusion: A protective stoma reduced the rate of anastomotic leakage that required surgical intervention, and mitigated the sequelae of such leakage. Colostomy closure was associated with less morbidity than closure of an ileostomy.

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Introduction

Clinically manifest anastomotic leaks are seen after 3–30 per cent of resections for low rectal carcinoma. The mortality rate associated with symptomatic anastomotic leaks varies between 6 and 22 per cent[1]. Some authors have reported that a leaking anastomosis leads to an increase in local recurrence rate along with a decreased tumour-free survival time[2–4]. The role of a protective enterostomy in avoiding this serious complication has been discussed repeatedly, but prospective randomized studies are rare and the results reported are contradictory. In a prospective multicentre observational study reported in 2002, the Working Group 'Colon/Rectum Carcinoma' (WGCRC) showed that the rate of anastomotic leakage requiring surgical intervention was significantly reduced by the provision of a protective stoma after low anterior resection[5]. On the basis of these results, the authors recommended use of a protective stoma to reduce the impact of any anastomotic insufficiency in situations of intraoperative difficulty, for lower rectal carcinomas and in patients in poor general condition.

This recommendation, however, did not meet with total acceptance[1,6–8]. One objection raised was that closure of a protective stoma represents additional surgery, involving admission to hospital, and a risk of complications and death[9,10]. Furthermore, it not clear whether an ileostomy or a colostomy is best in this setting. The present study provides further information on the value of a protective stoma and on the preferred type of enterostomy.

Patients and methods

Data were drawn from a prospective multicentre observational study on the treatment of rectal carcinoma organized by the An-Institute for Quality Management in Operative Medicine at the Otto-von-Guericke University, Magdeburg, Germany. The data analysed covered the interval from 1 January 2000 to 31 December 2001. The names of the 282 participating clinics and hospitals of the WGCRC, together with information on the design and conduct of the study, have been published elsewhere[11]. Patients who underwent operation and those who had non-surgical treatment were all documented prospectively. A questionnaire containing 68 items relating to the preoperative findings, preoperative investigations, surgery, the postoperative course and tumour histology was completed.

The term rectal carcinoma was applied to all adenocarcinomas located at a distance of 0–16 cm from the anal verge as measured by rigid rectoscopy. Low anterior resection was defined by the height of the resection line, which was a maximum of 8 cm above the anal verge.

The decision to construct a protective stoma was left to the surgeon. Patients who received a protective stoma during the primary intervention were followed up with the aid of a special questionnaire. A differentiation was made between colostomy and ileostomy. The type of colostomy employed (descending or transverse loop) was not recorded.

Postoperative morbidity included both general postoperative complications and specific postoperative complications. General postoperative complications, recorded using the standard questionnaire, comprised fever for more than 2 days, pulmonary complications (effusion, atelectasis), pneumonia, cardiac complications, thrombosis, pulmonary embolism, renal complications, urinary tract infection and multiorgan failure. Specific postoperative complications recorded were haemorrhage requiring reoperation, postoperative ileus requiring reoperation, paralytic ileus lasting more than 3 days that did not require reoperation, wound dehiscence, anastomotic leakage that either did or did not require surgical treatment (clinical and/or radiological), noninfective wound healing difficulties, infection of the laparotomy wound, faecal fistula, diffuse peritonitis, intra-abdominal or retrorectal abscess and stoma complications. An anastomotic leak that required surgery was one that, in the presence or absence of a protective stoma, led to relaparotomy to treat pelvic sepsis during the initial hospital stay.

Mortality rates were calculated based on deaths in hospital, including those that occurred after 30 days. The time elapsed between primary surgery and closure of the stoma was noted. On 1 January 2003 participating hospitals were requested to provide information on the number of stomas that had been closed, and on morbidity or mortality associated with stoma closure. Reasons why the stoma remained unclosed for more than 1 year after the primary operation were noted.

Statistical analysis

Statistical evaluation was carried out using the statistics program SPSS 10.0® (SPSS, Chicago, Illinois, USA). Two-dimensional frequency distributions were compared by applying the χ^2 test; $P < 0{\cdot}050$ was considered statistically significant. Logistic regression was used to determine the impact of the creation of a protective stoma on the rate of anastomotic leakage. The primary outcome was anastomotic leakage that required surgery. Variables studied were distance of the carcinoma from the anal verge, American Society of Anesthesiologists (ASA) grade, body mass index, age, sex, type of anastomosis (stapled or handsewn), provision of a protective stoma, tumour stage, neoadjuvant radiochemotherapy and duration of the operation.

Results

Between 1 January 2000 and 31 December 2001, 19 080 patients with colorectal carcinoma were recruited; 6886 patients had a rectal and 12 194 a colonic carcinoma. Surgery was carried out in 282 hospitals. A total of 2729 low anterior resections were performed and a protective stoma was constructed in 881 patients (32·3 per cent). Eight hundred and seven patients (91·6 per cent) with a protective stoma and 1595 (86·3 per cent) without a stoma underwent curative resection. Significant differences between the two groups are shown in *Table 1*. No differences were observed in risk factors (cardiovascular, pulmonary, renal, hepatic risk factors, obesity (more than 30 per cent according to the Broca index), diabetes mellitus, nicotine abuse, alcohol abuse), ASA grade or body mass index.

Stoma *versus* no stoma

Anastomotic leak was the leading intervention-specific complication after low anterior resection. There was no difference in overall leak rate between groups with and without a stoma. However, provision of a protective stoma significantly reduced the incidence of anastomotic leak that required surgical intervention (*Table 2*). Although the overall postoperative morbidity rate was significantly higher in the group with a

Table 1 Significant differences between groups of patients with and without a protective stoma after low anterior resection

	No protective stoma ($n = 1848$)	Protective stoma ($n = 881$)	P
Age (years)*	66·2(11·0)	64·6(10·4)	< 0·001‡
Men	1009 (54·6)	554 (62·9)	< 0·001§
Tumour height (cm)*†	9·6(2·8)	7·9(2·9)	< 0·001‡
Neoadjuvant radiochemotherapy	80 (4·3)	119 (13·5)	< 0·001§
Total mesorectal excision	1437 (77·8)	803 (91·1)	< 0·001§

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). †Distance from anal verge to tumour. ‡t test; §χ^2 test.

Table 2 Postoperative outcome after low anterior resection in patients with and without a protective stoma

	No protective stoma ($n = 1848$)	Protective stoma ($n = 881$)	P
Anastomotic leak rate			
Overall	262 (14·2)	128 (14·5)	0·806†
Surgery required	186 (10·1)	32 (3·6)	< 0·001†
Morbidity	635 (34·4)	350 (39·7)	0·007†
Deaths	37 (2·0)	8 (0·9)	0·037†
Postoperative hospital stay (days)*	19(11)	21(12)	0·037‡

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). †χ^2 test; ‡t test.

protective stoma, a defunctioning stoma was associated with a significant reduction in postoperative mortality rate (*Table 2*).

Logistic regression analysis showed that provision of a protective stoma was the strongest independent factor for the avoidance of an anastomotic leak that required surgical intervention ($P < 0·001$). Tumour stage according to the International Union Against Cancer had no impact in this regard.

Stoma closure

A protective stoma was fashioned either routinely or selectively after low anterior resection in 163 of the 282 participating hospitals, 142 (87·1 per cent) of which provided follow-up data. Some 818 protective stomas (92·8 per cent of the total) were constructed in these hospitals and 724 patients (88·5 per cent) were available for follow-up. The interval between the primary procedure and the interview was at least 1 year. Six hundred and thirty-six stomas were closed, giving an overall closure rate of 87·8 per cent. The closure rate was similar for ileostomies (407 closed; 89·5 per cent) and colostomies (229; 85·1 per cent) ($P = 0·086$). Reasons for non-closure were patient refusal (15 patients; 17 per cent), general inoperability (20; 23 per cent), tumour progression (34; 39 per cent), death (18; 20 per cent) and anal sphincter insufficiency (one; 1 per cent). The mean interval between primary surgery and stoma closure was 163 (median 115, range 7–360) days. In 41 patients (6·4 per cent) the protective stoma was closed during the first hospital admission.

The 636 protective stomas included 407 ileostomies (64·0 per cent) and 229 colostomies (36·0 per cent). The age and sex distributions, duration of surgery and hospital stay were similar in the two groups.

The general postoperative complication rate associated with closure of a protective stoma was 4·7 per cent (30 patients); rates after ileostomy and colostomy closure were 5·7 per cent (23 patients) and 3·1 per cent (seven patients) respectively ($P = 0·137$). The specific postoperative complication rate was higher after ileostomy closure (76 patients; 18·7 per cent) than after colostomy closure (30 patients; 13·1 per cent), but the difference was not significant ($P = 0·068$). However, there was a statistically significant difference in the rate of two specific complications. Leakage of a closed stoma was seen in nine patients (2·2 per cent) after ileostomy closure, but in none after colostomy closure ($P = 0·030$). None of the patients with this complication had undergone preoperative or postoperative radiotherapy. Postoperative paralytic ileus occurred in 17 (4·2 per cent) and two (0·9 per cent) patients respectively ($P = 0·026$).

The overall postoperative morbidity rate for closure surgery was 19·8 per cent, 22·4 per cent for ileostomy and 15·3 per cent for colostomy ($P = 0·031$). There were two postoperative deaths, both after closure of an ileostomy (0·5 per cent).

Discussion

Development of an anastomotic leak is dependent on numerous factors[12], including male sex[4,13], advancing age, obesity, general health status, concomitant treatment such as bowel preparation[14], radiotherapy[15], site of the anastomosis[16–18], surgical procedure and experience of the surgeon. The hypothesis that mechanical bowel preparation before elective rectal surgery lowers the risk of an anastomotic leak and other complications is not supported by the results of three randomized studies and

a Cochrane review[19]. On the other hand, proof to the contrary is lacking[20].

With regard to the type of anastomosis, a systematic review of randomized controlled trials[21] and a meta-analysis[22] both failed to establish the superiority of either handsewn or stapled anastomoses independently of the level of the anastomosis. However, in the case of low anterior rectal resection a handsewn anastomosis is often technically difficult or impossible to perform.

The effect of adjuvant therapy on anastomotic healing has not been established firmly because prospective randomized studies are lacking. Experimental studies in animals have provided contradictory results, although some appeared to show a negative effect for fluorouracil[23–25]. Milsom *et al.*[26] showed that preoperative radiation results in an early and persistent decrease in colorectal mural blood flow regardless of the anastomotic technique. Adjuvant radiochemotherapy is associated with a risk of radiation enteritis, small bowel obstruction and rectal stricture[27].

This study of 2729 patients who underwent low anterior resection of the rectum showed that the overall rate of anastomotic leakage was not influenced by the presence of a protective stoma, although patients with a stoma developed significantly fewer leaks that required surgical correction. Construction of a protective stoma was associated with a higher overall morbidity rate, but had the clear advantage of reducing the postoperative mortality rate.

The present data suggest that a protective stoma should be considered in the setting of a difficult operation (low tumour, narrow male pelvis, complications during construction of the anastomosis), poor initial condition of the patient, after neoadjuvant radiochemotherapy and after total mesorectal excision. A similar approach has been recommended by Poon *et al.*[7].

The present study also included an analysis of the further course of 724 patients with a defunctioning stoma; 636 stomas (87·8 per cent) were eventually closed, but 10·5 per cent of patients with an ileostomy and 14·9 per cent of those with a colostomy did not have intestinal continuity restored. Ileostomy and colostomy are equal in their ability to provide complete faecal diversion. Morbidity and mortality rates associated with stoma closure are therefore of decisive importance when choosing the appropriate type of defunctioning stoma. However, there is no consensus in the literature on the preferred type of protective stoma[28–35]. In keeping with the results of Law *et al.*[36] and Gooszen *et al.*[30], this study showed an advantage for colostomy over ileostomy in terms of a significantly lower overall morbidity rate after stoma closure. In particular, ileostomy closure was associated with a significantly higher rate of anastomotic leakage, and a mortality rate of 0·5 per cent. This suggests that closure of an ileostomy is more technically demanding. However, Edwards *et al.*[35] have advanced two arguments against defunctioning colostomy: the more common occurrence of parastomal hernia and the higher rate of incisional hernia after colostomy closure. There is also a greater likelihood of stoma prolapse when a transverse loop colostomy is used.

The higher complication rate seen after closure of an ileostomy might be related to the fact that a segmental resection is usually required, whereas, provided that the posterior wall is intact, colostomy closure can be achieved simply by suturing the defect in the anterior wall. Leakage after closure of an ileostomy is often detected clinically only after a delay. Peritoneal irritation by small bowel contents is less severe than that caused by large bowel contents.

Quality of life in patients with a stoma is not primarily dependent on the type of stoma[35,37,38]. When deciding on whether to use a protective colostomy or ileostomy, individual patient-related factors should be taken into account. For example, Rosen and Schiessel[39] recommended use of an ileostomy in obese patients in whom the transverse colon cannot be mobilized adequately. On the other hand, it may be easier to construct a colostomy in obese patients with a thick lower abdominal wall. Colostomy is preferred in patients with obstruction and dilatation of the colon. Preoperative or postoperative radiotherapy, which may give rise to radiation enteritis, is an additional argument in favour of colostomy.

Taking the present results together with other published data, it may be concluded that colostomy has a significant advantage in terms of postoperative morbidity associated with stoma closure. However, procedure-specific complications must also be taken into consideration, and a general recommendation favouring colostomy for the protection of an anastomosis after low anterior resection would appear premature at the present time.

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