Relatively high incidence of complications after loop ileostomy reversal

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ABSTRACT

INTRODUCTION: A de-functioning loop ileostomy (LI) reduces the consequences of anastomotic leak following low anterior resection, but its construction as well as its closure can be associated with complications. The aim of the present study was to identify risk factors for postoperative complications and particularly to determine if operation performed by trainees carry a higher risk of complications than operation performed by experienced surgeons.

MATERIAL AND METHODS: This was a retrospective single-centre analysis of the medical records of 159 consecutive patients who underwent LI closure following low anterior resection for rectal cancer in the period from January 2002 to December 2008.

RESULTS: Postoperative complications developed in 32 patients (20.1%). Surgical complications occurred in 27 patients (17%) including small bowel obstruction in five (3%), anastomotic leak in four (2.5%), wound infection in eight (5%) and incisional hernia in eight (5%). There was no postoperative mortality. Univariate analysis showed that an increased rate of complications was associated with female gender ($p = 0.02$), small bowel resection at closure ($p = 0.009$) and a long interval between construction and closure of the loop ileostomy ($p = 0.049$).

CONCLUSION: Closure of an LI is associated with a low mortality, but a relatively high rate of complications. Operation performed by trainees was not associated with an increased complication rate. More complications were seen in patients who underwent small bowel resection and those who had delayed ileostomy closure.

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Low anterior resection (LAR) has gained wide acceptance as a sphincter-saving treatment for rectal cancer [1]. However, low pelvic anastomoses are associated with a substantial risk of anastomotic leak and pelvic sepsis.

Faecal diversion through a temporary stoma can reduce the effects of anastomotic leak [1, 2] and also the rate of leak-related re-interventions [3-6]. It remains controversial whether a loop colostomy (LC) or a loop ileostomy (LI) is better for faecal diversion even though numerous studies have addressed the matter [7]. LI has proved superior to LC, especially in elective surgery [1, 8-10]. The risk of serious complications is lower after closure of LI than closure of a LC [1]. At our centre, LI is the standard de-functioning stoma for LAR.

LI construction has long been considered a simple procedure, but a review by Shabbir & Britton has shown that it may be associated with a 21-70% complication rate [11]. LI reduces the quality of life [2] and it should be therefore closed as early as possible. LI closure may give rise to complications of which some are serious. Prospective and retrospective studies have shown a varying frequency and pattern of complications after stoma closure. The discordant results of these studies may be due to the heterogeneity of the indications for stoma construction among the patients enrolled in these studies [12]. A recent Danish study emphasized the role of the surgeon's grade in reducing the risk of postoperative complications [13].

The aim of the present study was to identify risk factors for complications, and in particular to determine whether operations performed by trainees carry a higher risk of complications than other operations.

MATERIAL AND METHODS

To obtain a homogenous group and to minimize confounders, only patients undergoing LI closure following an open-approach LAR for rectal cancer were included. Patients operated at Copenhagen University's Hospital at Hvidovre in the period from January 2002 to December 2008 were included in the study. In this period, laparoscopic LAR had not yet been introduced at our department. Patient data were obtained from the National Danish Colorectal Cancer Database. The data were crosschecked with the hospital register to ensure inclusion of all patients. The surgeon's grade (level of specialization) was obtained from the homepage of the National Danish Board of Health and Medicines (www.sst.dk).

Statistical analysis

The SPSS programme version 18 was used for analysis of data. For the univariate comparison of dichotomous data, we employed the Pearson χ^2-test or Fisher's exact test, as appropriate. Continuous data were compared with the Mann-Whitney U-test. Continuous variables were dichotomized at their median value. Multivariate logistic regression analysis was employed to identify independent predictors of outcome. The dependent variable was complication (yes = 1, no = 0). As covariates, we entered variables into the model that showed a difference in the univariate analysis at a p-value of < 0.05. A two-sided p value below 0.05 was considered statistically significant.

Definition of complications

Postoperative complications are those which occurred within 30 days after LI closure with the exception of incisional hernia which was reported whenever it was encountered during the follow-up. Complications were defined prior to data collection as follows:

Small bowel obstruction: Combination of three or more of the following findings: abdominal distension, abdominal pain, vomiting, absolute constipation or the presence of multiple air fluid level on plain abdominal radiography in the postoperative period.

Prolonged postoperative ileus: The inability to tolerate oral intake for a minimum of five days postoperatively in the absence of other symptoms of bowel obstruction.

Wound infection: Infection necessitating drainage or antibiotic treatment.

Anastomotic leak: Radiological evidence of fistula or fluid collection with clinical symptoms [4, 9].

Incisional hernia and para-stomal hernia as well as medical complications (cardio-pulmonary, cerebro-

TABLE 1

Possible surgical risk factors of postoperative complications after loop ileostomy closure in 159 patients who had low anterior resection for rectal cancer.

	Patients, n (%)	Complications, n (%)	p-value, univariate analysis	Odds ratio (95% CI)	p-value, logistic regression
Gender					
Female	52 (32.7)	16 (30.8)	0.02	1	0.032
Male	107 (67.3)	16 (15)		2.545 (1.083-5.979)	
Age, years					
< 65	77 (48.4)	13 (16.9)	0.323	1	0.142
≥ 65	82 (51.6)	19 (23.2)		1.031 (0.990-1.073)	
Interval between low anterior resection and loop ileostomy closure, weeks					
< 18	73 (45.9)	10 (13.7)	0.049	1	0.029
≥ 18	86 (54.1)	22 (25.6)		1.022 (1.002-1.041)	
Alcohol consumption (> 14 glasses/week)					
No	136 (85.5)	28 (20.6)	0.724	1	0.158
Yes	23 (14.5)	4 (17.4)		1.022 (0.992-1.054)	
Smoking (> 15 cigarettes/day)					
No	131 (82.4)	27 (20.6)	0.742	1	0.911
Yes	28 (17.6)	5 (17.9)		1.003 (0.952-1.056)	
Technique of closure					
Simple closure	118 (60.2)	18 (15.3)	0.009	1	0.022
Resection & anastomosis	41 (39.8)	14 (34.1)		0.368 (0.156-0.868)	
Body mass index, kg/m²					
< 24	59 (37.1)	13 (22)	0.645	1	0.670
≥ 24	100 (62.9)	19 (19)		0.974 (0.864-1.099)	
Surgeon's grade					
Trainee	47 (29.6)	6 (12.8)	0.134	1	0.226
Specialist	112 (70.4)	26 (23.2)		1.887 (0.675-5.273)	
Co-morbidity					
No	96 (60.4)	20 (20.8)	0.784	1	0.351
Yes	63 (39.6)	12 (19)		0.652 (0.265-1.603)	
Complication after low anterior resection					
No	81 (50.9)	15 (18.5)	0.606	1	0.701
Yes	78 (49.1)	17 (21.8)		0.843(0.352-2.016)	
Anastomosis					
Hand-sewn	151 (95)	28 (18.5)	0.031	1	0.232
Stapled	8 (5)	4 (50)		2.761 (0.522-14.591)	

CI = confidence interval; LAR = low anterior resection; LI = loop ileostomy closure.

vascular and other) were also registered. LI closure was carried out under general anaesthesia. A single dose of parenteral antibiotics was administered to all patients at induction of anaesthesia.

The methods of loop ileostomy construction and closure

The decision to construct LI during LAR was dependent on the surgeon's peri-operative judgement. For LI construction, a circular skin incision was made at a pre-operatively defined site. A cross form incision was made in the rectus abdominis muscle fascia, the terminal ileum was passed through it, and then three quarters of its circumference were incised so that the oral part became the largest one. The bowel segment was fixed using absorbable 3-0 sub-epidermal sutures, and the oral part was inverted and fixed. The ideal aim was to construct a 2-cm LI.

For LI closure, a circumferential incision around LI was used; then a careful dissection around the bowel to the intra-peritoneal level was made. The bowel was closed with a hand-sewn two-layer anastomosis with absorbable 3-0 suture. The first layer was through the entire bowel wall, while the second layer was through the sero-muscularis part only (standard technique in our department). In case of stapled anastomosis, a functional end-to-end anastomosis was created using a linear stapler GIA 80. After mobilization of the ileal segment which involved the stoma, an enterotomy was created at the base of the nipple valve allowing insertion of both branches of the stapler into afferent and efferent limbs. This was the technique used in our department at time of this study.

Then the fascia was closed with absorbable 2-0 suture and the skin was closed with non-absorbable suture using a circumferential sub-cuticular wound approximation technique. If the surgeon deemed that ostomy closure would carry a risk of postoperative stenosis, then resection and an end-to-end hand-sewn two-layer anastomosis was recommended.

Trial registration: not relevant.

RESULTS

Among the 159 patients, 107 (67. 3%) were men. The median age was 65 years (range 39-88) and the median body mass index (BMI) was 24 kg/m^2 (range 16.4-35.9 kg/m^2). Sixty-three patients (40%) had one or more chronic disease (diabetes, cardio-vascular, thrombo-embolic, liver or lung diseases). The median interval between LI construction and closure was 18 weeks (range 8-137 weeks). A total of 47 patients (30%) had an American Society of Anesthesiologists (ASA) score of I, 102 (64%) ASA II and 10 (6%) ASA III. In all, 40 (25%) received preoperative radio- or chemoradiotherapy prior to LAR. The median duration of hospitalization after LI closure was four days (range 1-88). Specialists performed 112 (70%) of the closure operations and supervised their trainees in 17 (11%) operations. The assignment of surgeons to operations takes place by convention and in accordance with department's policy of providing training without compromising optimal patient care. In case of supervision, it was with direct hands-on assistance to the trainees in the operation theatre. Unsupervised trainees, usually surgeons in an advanced phase of their specialization training, performed 30 operations (19%). In specialist-performed operations, 26 patients (23.2%) had complications in contrast to six (12.8%) in trainee-performed operations with and without supervision (p = 0.13). The median follow-up time was 95 weeks (range 1-242 weeks). Sixteen patients (10%) had stoma-related complication after LI construction (two prolapses, two fistulas, six severe skin reactions, two self-limited bleedings and four parastomal hernias); most of these complications were self-limiting. Regarding the ileostomy closure, 117 (74%) had simple closure, while 41 (26%) had a small-bowel resection and anastomosis. And 23% of those 41 patients had a stapled anastomosis and 35 a hand-sewn anastomosis. Small-bowel resection and anastomosis were associated with an increased risk of complications compared with simple closure 14 (34.1%) versus 18 (15.3%) (p = 0.009). Prolonged postoperative ileus was the main complication associated with small bowel resection (p = 0.02). All patients had a circumferential skin incision and primary wound closure using circumferential subcuticular wound approximation. Patient data and risk factors are summarized in **Table 1**.

There was no postoperative mortality within 30 days after LI closure. A total of 32 patients developed complications (20.1%). Surgical complications occurred

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in 27 (17%) patients. Overt anastomotic leak accounted for four (2.53%), while small-bowel obstruction treated surgically accounted for five (3.1%) complications. Incisional hernia and wound infection were the most frequent events (they were each encountered in eight (5%) cases), followed by prolonged postoperative ileus which occurred in six (3.84%) cases.

Female gender was associated with an increased risk of overall postoperative complications (p = 0.02). Eight (50%) of the 16 female patients with complications had different degrees of intestinal obstruction.

Age, radio(chemo)therapy, ASA score, co-morbidity, alcohol, smoking, BMI, complications after LAR and complications after LI construction did not correlate with an increased complication rate after LI closure. This result, however, cannot be used to draw conclusions, and large epidemiological studies are needed.

DISCUSSION

After construction of an LI in LAR, LI closure is most often undertaken eight to 12 weeks later, which allows the patient sufficient time for recovery from the initial resection, softening of intra-abdominal adhesions and resolution of inflammation and oedema within the abdomen and around the stoma orifice [8]. However, the median interval between construction and closure in this study was longer, which reflects a traditional reluctance to early closure. A recent review recommends LI closure as early as two weeks after stoma construction [14]. The review showed a tendency towards a higher complication rate in patients who had their LI closed after a longer interval (p = 0.049). In multivariate analysis, a longer interval between LAR and LI closure appeared to be a negative predictor of outcome (i.e. more complications). But in those who had delayed LI closure, a significant association was observed between the delayed LI closure and complications after LAR: 51(59.3%) versus 27 (37%) p = 0.005. Consequently, these results cannot be considered supportive of early closure due to confounding factors.

The rate of complications in our study was lower than the rates reported in two recent reviews [8, 10] and lower than in another Danish study [15], but higher than in a recent Danish study in which a cohort of 997 patients was analysed [13].

LI closure performed by trainee surgeons was reported as a risk factor in one study [12], while other studies investigating this factor found no such correlation [16, 17].

In our study, the trainee-performed operations showed no association with a higher rate of complications; in fact, there were more complications in the specialist-performed operations, probably due to the complexity of those operations that were performed by the specialists. However, there was not sufficient data in the patients' records to confirm this assumption.

Our study showed that small-bowel resection and anastomosis is associated with a higher risk of complications than simple closure, a finding which confirms a previous study [18]. Small-bowel resection is most often done when simple closure is not technically possible due to adhesions, and is thus performed in difficult cases which may explain the increased complication risk. The decision on whether or not to perform small-bowel resection was left to surgeon's peri-operative judgment. No conclusion could be drawn from the analysis of patient records concerning the reasons for choosing small-bowel resection. The routine procedure in our department during the study period was a hand-sewn anastomosis, but at the end of the study period, the stapled anastomosis was introduced and it has gradually replaced hand-sewn anastomosis. The learning curve may explain the higher complication rate in the few stapled anastomoses performed; but due to the small size of this group, no definite conclusions can be drawn. Pokorny et al's study [12] on a similar population showed a significant risk of surgery-related complications in patients who had a stapled anastomosis. A Cochrane review concluded that the present evidence is insufficient to demonstrate the superiority of the stapled to hand-sewn technique in colorectal anastomosis, independently of the level of anastomosis. The decision on which technique to be used must be judged on the basis of previous experience, clinical circumstances and available resources [19].

The association of female gender with an increased risk of overall postoperative complications reported in our study has not – to our knowledge – been reported before. A recent Japanese study found an increased risk of wound infections in male patients undergoing LI closure [17]. An explanation may partly be found in the difference of smoking habits and consumption of alcohol between the Japanese and Danish women, but the analysis of alcohol and smoking habits revealed no association with increases in complication rate. A larger data set is required to evaluate such association.

Wound infection accounted for only 5% of the complications in this study. This may be owed to the circumferential sub-cuticular wound approximation used in almost all operations, as this technique is associated with a lower incidence of wound infection [20].

CONCLUSION

Female gender, small-bowel resection with anastomosis and a long interval between construction and closure of LI were associated with an increased risk of complications, but confounding factors limit the possibility of drawing conclusions. No statistically significant association was found between the complication rate and surgeon's grade or level of specialization. This study of closure of LI is based on a homogenous group of patients having an LI after an AR for rectal cancer. The low incidence of serious complications following LI closure justifies the use of such closure after AR. Large randomised controlled trials are necessary to evaluate the correlation between complications and the timing of LI closure.

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