Original article

Complications of intestinal stomas

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Background: **Stomal complications are prevalent and associated with considerable morbidity. This study examined the incidence and potential risk factors for their development.**

Methods: **The time of onset and presence of ten specific complications were recorded for patients with an intestinal stoma over 10 years at two urban hospitals. A database was established with 20 explanatory variables (such as common medical co-morbidities) derived from the stomatherapy and medical records. Univariable and multivariable analyses were performed to identify potential risk factors for the development of complications.**

Results: **Some 1216 patients (mean age 64 years) with a minimum of 2 years' follow-up were included, of whom 544 (44·7 per cent) underwent surgery for malignancy and 647 (53·2 per cent) had a colostomy formed. There were 1219 complications in total; 807 major complications (excluding excoriation and slough) occurred in 564 patients (46·4 per cent), of which the commonest was parastomal hernia (171, 14·1 per cent). On multivariable analysis, musculoskeletal co-morbidity (odds ratio (OR) 1·79, 95 per cent confidence interval 1·05 to 3·07; $P = 0·032$), cancer (OR 1·48, 1·13 to 1·93; $P = 0·004$) and high American Association of Anesthesiologists score (OR = 3·80, 2·14 to 6·75; $P < 0·001$) were associated with an increased risk of complications. Preoperative siting was associated with a reduced risk (OR 0·59, 0·39 to 0·90; $P = 0·014$).**

Conclusion: **Intestinal stomal complications are common, occurring in almost half of patients. There are certain irremediable risk factors, allowing appropriate preoperative counselling.**

Presented to meetings of the Association of Surgeons of Great Britain and Ireland, Glasgow, UK, May 2009, the Association of Coloproctologists of Great Britain and Ireland, Harrogate, UK, June 2009, and the European Society of Coloproctology, Prague, Czech Republic, September 2009; and published in abstract form as *Colorectal Dis* 2009; **11**(Suppl 1): 37 and *Colorectal Dis* 2009; **11**(Suppl 2): 36

Paper accepted 13 July 2010

Published online 24 September 2010 in Wiley Online Library (www.bjs.co.uk). **DOI:** 10.1002/bjs.7259

Introduction

The creation of an intestinal stoma (usually ileostomy or colostomy) brings a wide range of physical and psychological challenges. Physical complications directly related to a stoma have been reported widely in the medical literature[1,2] and are often exacerbated by a suboptimal stoma (for example difficulty securing an appliance, leakage, and change in body image associated with a parastomal hernia)[3]. Furthermore, problems dealt with by stomatherapists do not always reach the surgeon's attention, and reported complications based on medical records may underestimate their frequency[1,2]. Prospective studies to date have been short term or involved small numbers of patients[4–6]. Retrospective studies have reported larger numbers[1,2,7–16] but solid data on risk factors are lacking. The aim of this study was to determine, in a large population, the incidence of, and risk factors for, intestinal stomal complications.

Methods

The study comprised a review of stomatherapy and medical records of adult patients who had undergone creation of an intestinal stoma over a 10-year period at two urban general hospitals up to 2006. A dedicated database was established in which information regarding timing and

presence of specific complications, and multiple patient variables at the time of stoma construction, were recorded systematically. The study had ethics committee approval; all data were anonymized and stored in compliance with the Data Protection Act 2003.

In total, 20 explanatory variables were recorded. These included information on demographics, indications, co-morbid and surgical factors: age, sex, body mass index (BMI), history of smoking, diabetes, musculoskeletal co-morbidity (recorded when a preoperative entry had been made in the medical notes of the presence of rheumatoid or significant osteoarthritis limiting mobility or daily functions), neurological co-morbidity, cardiac co-morbidity, respiratory co-morbidity, abdominal co-morbidity, American Society of Anesthesiologists (ASA) physical status, presence of sepsis, nutritional compromise (derived from the nursing nutritional score calculation chart), previous abdominal surgery, specialty and grade of surgeon, indication for and timing of surgery, preoperative siting by an enterostomal nurse, and type of stoma. Also recorded were ten dependent (outcome) variables: excoriation, slough, parastomal hernia, bleeding (recorded on at least one occasion), obstruction (irrespective of whether intra-abdominal, or in relation to a parastomal hernia, and documented in the medical records), ischaemia (severity not specified), fistula, retraction, prolapse and stenosis.

Statistical analysis

In statistical terms complication data following surgery are time dependent. Therefore, life-table analyses are the most appropriate method of analysis. However, in a data set that suffers from loss to follow-up (including death), a high level of data censorship makes such methods impracticable for analysing risk factors. Nevertheless, some attention must be paid to establishing a point at which the majority of complications are manifest to avoid underestimation. Therefore, a random sample of 400 patients was analysed initially to determine the time of onset of first complication, and thus to determine the minimum appropriate follow-up interval.

Individual major and minor complications were recorded. To assist in designing an appropriate multivariable model, univariable logistic regression analyses were performed to determine associations. Variables with $P < 0{\cdot}050$ in these analyses were used in a multiple logistic regression model with appropriate use of indicators where required. Subanalyses between specific complications and explanatory variables determined *a priori* were performed. $P < 0{\cdot}050$ was taken to indicate statistical significance. Stata® version 10.0 (StataCorp, College Station, Texas, USA) was used for statistical analysis.

Table 1 Individual major complications

	No. of patients ($n = 1216$)
Parastomal hernia	171 (14·1)
Bleeding	156 (12·8)
Obstruction	116 (9·5)
Ischaemia	100 (8·2)
Fistula	74 (6·1)
Retraction	72 (5·9)
Prolapse	66 (5·4)
Stenosis	52 (4·3)

Values in parentheses are percentages.

Table 2 Univariable analysis of risk factors for major stomal complications

	Odds ratio	*P**
Cardiac co-morbidity	1·69 (1·18, 2·42)	0·004
Musculoskeletal co-morbidity	2·56 (1·61, 4·04)	< 0·001
Diabetes	1·73 (1·13, 2·65)	0·011
History of smoking	1·14 (1·01, 1·29)	0·032
ASA III or IV	4·33 (2·60, 7·23)	< 0·001
Cancer (*versus* other indications)	1·49 (1·18, 1·87)	0·001
Preoperative siting	0·50 (0·35, 0·72)	< 0·001
Planned (*versus* emergency)	0·54 (0·39, 0·75)	< 0·001
End ileostomy (*versus* other)	1·30 (1·03, 1·63)	0·025

Values in parentheses are 95 per cent confidence intervals. ASA, American Society of Anesthesiologists physical status score. *Logistic regression analysis. Body mass index, malnourished state, sepsis, age, respiratory co-morbidity, neurological co-morbidity, abdominal co-morbidity, sex, previous surgery, specialty of surgeon (colorectal *versus* other) and grade (consultant *versus* trainee) were not significant.

Table 3 Multivariable logistic regression analysis of risk factors for major stomal complications

	Odds ratio	*P*
Musculoskeletal co-morbidity	1·79 (1·05, 3·07)	0·032
ASA III or IV	3·80 (2·14, 6·75)	< 0·001
Cancer *versus* other indications	1·48 (1·13, 1·93)	0·004
Preoperative siting*	0·59 (0·39, 0·90)	0·014

Values in parentheses are 95 per cent confidence intervals. *Planned *versus* emergency surgery was removed on the basis of almost complete collinearity with preoperative siting (a similar but less strong negation of risk was shown by replacing this variable with planned surgery). ASA, American Society of Anesthesiologists physical status score. Cardiac co-morbidity, diabetes, history of smoking, and ileostomy *versus* other were not significant.

Table 4 Risk factors for parastomal hernia

	Univariable analysis*		Multivariable analysis*	
	Odds ratio	*P*	Odds ratio	*P*
Respiratory co-morbidity	2·38 (1·53, 3·70)	< 0·001	2·37 (1·50, 3·74)	< 0·001
Cancer (*versus* other indications)	1·92 (1·38, 2·66)	< 0·001	1·84 (1·31, 2·58)	< 0·001
Diabetes	1·97 (1·18, 3·26)	0·009	2·01 (1·18, 3·43)	0·010
History of smoking	1·20 (1·03, 1·40)	0·021		
End colostomy (*versus* other)	1·44 (1·04, 1·99)	0·029	1·43 (1·02, 2·00)	0·038
BMI > 25 kg/m^2	1·92 (1·06, 3·44)	0·030	2·04 (1·11, 3·70)	0·021

Values in parentheses are 95 per cent confidence intervals. BMI, body mass index. Only statistically significant results are shown. *Logistic regression analysis.

Results

The initial sample of 1408 patients (670 men) had a mean age of 64 (range 19–100) years. The random sample of 400 patients was representative of the whole in respect of the percentage of patients who had least one complication in the study period (51·7 *versus* 56·0 per cent). Within the sample, the median time to the first complication was 85 days, two-thirds of complications had arisen by 6 months and 83·8 per cent (of the 51·7 per cent) by 2 years. Accordingly, 192 patients whose follow-up was less than 2 years for any reason (including death and reversal of loop stoma) were excluded from further analysis, leaving a total of 1216 patients for risk analysis with a follow-up of 24–118 (median 40) months.

Data were complete for all variables other than BMI (238 data points) and ASA status (475 data points), which were recorded inconsistently. Of the 1216 patients, 567 (46·6 per cent) had an end colostomy, 80 (6·6 per cent) a loop colostomy, 520 (42·8 per cent) an end ileostomy and 49 (4·0 per cent) a loop ileostomy. Indications for surgery were cancer in 544 patients (44·7 per cent), inflammatory bowel disease in 343 (28·2 per cent), diverticulitis in 154 (12·7 per cent), faecal incontinence in 82 (6·7 per cent), trauma in 68 (5·6 per cent) and familial adenomatous polyposis in 25 (2·1 per cent). The stoma was sited before operation in 1087 patients (89·4 per cent); all but 23 were sited by a clinical nurse specialist trained in stoma care. Surgery was elective in 1039 patients.

Complication rates

A total of 1219 complications occurred in 681 (56·0 per cent) of the 1216 patients; some individuals had multiple complications. Of the ten types of complication recorded, two (excoriation and slough) occurred in 412 patients (33·9 per cent), and frequently reflected the presence of other more 'major' complications (coexisting in 295 of these). On the basis that these were deemed less clinically important than the other eight (*Table 1*), and that their inclusion would significantly (by collinearity) skew analyses, these were omitted from the multivariable model. There were thus 807 'major' complications among 564 (46·4 per cent) of the 1216 patients (*Table 1*).

Table 5 Risk stratification in patients undergoing elective surgery with stoma

Factor(s) present	Risk (%)
Baseline	35
Surgery for cancer	45
Musculoskeletal co-morbidity	49
Musculoskeletal co-morbidity + cancer	59
ASA > II	68
ASA > II + cancer	76
Musculoskeletal co-morbidity + ASA > II	79
All three factors	85

Based on preoperative siting of stoma and a median follow-up of 40 months. ASA, American Society of Anesthesiologists physical status score.

Univariable and multivariable analyses of risk factors for major stomal complications are shown in *Tables 2* and *3*, and analyses of risk factors specific to parastomal hernia in *Table 4*.

Discussion

Over 20 000 stomas are created in England each year[8] for a wide range of pathologies and in all age groups. This study has demonstrated a high prevalence of a variety of stomal problems, with significant risk factors identifiable for complications. Complication rates from the present and other studies in the medical literature are summarized in *Table S1* (supporting information). The overall major complication rate here was 46·4 per cent, which echoes reported rates of 21–60 per cent[9,13,14,17–20]. The reported prevalence of parastomal hernia ranges from 0·8 to 30·6 per cent, and was 14·1 per cent in the present series.

In the present study, efforts were made to reduce the potential bias imposed by the inclusion of patients with a limited duration of follow-up. Nevertheless, the methodology used will still underestimate the complication risk compared with actuarial analysis[9,13]. Furthermore, although recorded independently by the enterostomal nurses, data accrual from the medical records was retrospective and for some variables incomplete. This severely limits interpretation. For example, a BMI over 25 kg/m^2 was found to be a risk factor for the development of parastomal hernia but BMI was measured in only a fifth of patients. Outcomes may also have been influenced by other explanatory variables that were not recorded, such as chemotherapy, corticosteroid administration or collagen vascular disease.

Several retrospective studies have reported stomal complication rates in large cohorts[1,2,7–16], but only two have attempted to determine potential risk factors for the development of complications using appropriate statistical methodology[1,2]. These demonstrated the protective influence of a preoperative stomatherapist visit, and identified loop stoma formation, surgery for inflammatory bowel disease and BMI exceeding 30 kg/m^2 as risk factors[1,2]. In the present study, logistic regression analysis demonstrated musculoskeletal co-morbidity, poor ASA status and surgery for cancer (*versus* other indications) to be independent risk factors for stomal complications, and preoperative marking by an enterostomal nurse to be protective. The vast majority of patients (88·7 per cent) were counselled before surgery by an enterostomal nurse, and the stoma was sited before almost all elective operations. There was thus almost complete collinearity between preoperative siting and elective surgery. The beneficial effect of preoperative siting is in accordance with other studies, even when a preoperative enterostomal nurse visit had been less common (26 per cent) and the rate of emergency surgery much higher (66 per cent)[2]. Respiratory co-morbidity, diabetes and formation of an end colostomy, in addition to surgery for malignancy, were found to be risk factors for parastomal hernia development.

Even in the elective situation, when some optimization may be possible, there will be irremediable independent risk factors for a stomal complication. Furthermore, certain medical co-morbidities and intraoperative difficulties secondary to significant obesity may promote the use of a stoma in patients who can least afford another medical problem. The present data affirm the significant overall risk of stomal complications, and the need for preoperative siting to try to limit these. In patients in whom preoperative discussion and counselling are possible, it would be desirable to have some broad indication of risk to facilitate discussion. The odds ratios presented in the results of multivariable analysis are unwieldy for the clinician, and do not correspond mathematically with risk in a linear fashion. They can, however, be used to generate some simple percentage risk estimates. Thus, based on the data for the present group of 1216 patients, the risk of major complications in the 533 patients with ASA performance status I or II and no musculoskeletal co-morbidities, whose stoma was sited before operation and who were undergoing surgery for indications other than cancer, is about 1 in 3 (35 per cent, odds ratio 0·55). As all the significant co-variables are binary, the effect of these variables on overall risk can be determined relatively easily (*Table 5*). As a rule of thumb, a relatively fit patient with cancer has an almost 1 in 2 chance of a stomal complication at approximately 3 years' follow-up. Impaired mobility and/or operative performance status increases this risk to about 75 per cent.

Acknowledgements

A.M. was funded partly by Hollister UK. The authors declare no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article.

Table S1 Incidence of individual major complications (Word document)

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