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Mortality and morbidity in gastro-oesophageal cancer surgery: initial results of ASCOT multicentre prospective cohort study

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Abstract

Objective To evaluate the effect of comorbidity and other risk factors on postoperative mortality and morbidity in patients undergoing major oesophageal and gastric surgery.

Design Multicentre cohort study with data on postoperative mortality and morbidity in hospital.

Data source and methods The ASCOT prospective database, comprising 2087 patients with newly diagnosed oesophageal and gastric cancer in 24 hospitals in England and Wales between 1 January 1999 and 31 December 2002. Multivariate logistic regression analysis was used to model the risk of death and postoperative complications.

Results 955 patients underwent oesophagectomy or gastrectomy. Of these, 253 (27%) were graded ASA III or IV, and 187 (20%) had a high physiological POSSUM score (≥ 20). Operative mortality was 12% (111/955). Physiological POSSUM score, surgeon's assessment, type of operation, hospital case volume, and tumour stage independently predicted operative mortality. Medical complications were associated with higher physiological POSSUM scores and ASA grade, oesophagectomy or total gastrectomy, thoracotomy, and radical nodal dissection. Stage and additional organ resection predicted surgical (technical) complications.

Conclusions Many patients undergoing surgery for gastro-oesophageal cancer have major comorbid disease, which strongly influences their risk of postoperative death. Technical complications do not seem to be influenced by preoperative factors but reflect the extent of surgery and perhaps surgical judgment. Detailed prospective multicentre cooperative audit, with appropriate risk adjustment, is fundamental in the evaluation of cancer care and must be properly resourced.

Introduction

Oesophageal and gastric cancer are common diseases that pose considerable challenges to surgeons. Most patients present with advanced disease, and curative surgery requires considerable resources in the operating theatre and in critical care. Published data show large variations in practice and outcome from surgical treatment.[1–3] Both the optimal surgical techniques and the role of adjuvant therapy remain controversial because randomised trials have failed to resolve important questions or have not yet been performed. The applicability of data from trials to routine practice in gastro-oesophageal cancer surgery is difficult to determine because of the lack of reliable information about patients and outcomes in routine practice. This information gap obstructs the formulation of hypotheses for randomised trials and frustrates efforts to improve standards of treatment.

We examined the factors associated with postoperative morbidity and mortality after oesophageal and gastric cancer resection.

Methods

Data source

The ASCOT (Assessment of Stomach and Oesophageal Cancer Outcomes from Treatment) database was developed in 1998 to provide comprehensive and accurate data on stage, comorbidity, and outcome for cases of oesophageal or gastric cancer.[4] From 1 January 1999 to 31 December 2002, 32 hospitals in England and Wales (about 10% of all acute trusts doing major cancer surgery) registered with ASCOT on a voluntary basis.

Inclusion and exclusion criteria

We included data on patients undergoing resectional surgery for oesophageal and gastric cancer. We excluded patients who underwent non-surgical treatment (palliative chemotherapy, radiotherapy, endoscopic stenting), patients who underwent surgery without resection (palliative gastrojejunostomy, laparotomy only), and patients whose outcome was not recorded.

End points and risk factors

The primary outcome was overall mortality in hospital after resection of gastric or oesophageal cancer. The secondary end point was morbidity in hospital. We performed separate analyses of complications apparently related to surgical technique (for instance, anastomotic leakage, fistula, abscess, haemorrhage) and other "medical" complications. The risk factors studied included age, sex, comorbid status, tumour site and stage, surgical approach, and annual case volume (defined as the number of oesophageal and gastric resections undertaken in each unit per year and categorised into three groups). We classified tumour site as oesophageal, gastric, or junctional. Data on preoperative health status were collected by using the physiological part of the POSSUM (physiological and operative severity score for the enumeration of mortality and morbidity) score,[5] the ECOG (Eastern Cooperative Oncology Group) performance status,[6] ASA (American Society of Anesthesiology) grade,[7] and a surgeon's simple assessment score.

Statistical analysis

Continuous risk factors were grouped into subcategories of increasing operative risk. We used a multilevel logistic regression analysis with backwards stepwise variable selection to identify independent risk factors for operative mortality and morbidity. The standard errors of the model estimates were adjusted for the clustering of patients within hospitals.

The adjusted odds ratios were based on the multivariate analysis of the cases submitted during the first three years of the study (n = 773). The model was then tested on the data from the final year of the study (n = 222).

Results

A total of 2087 cases were submitted. We excluded 836 patients who underwent non-surgical treatment, 255 patients who underwent non-resectional surgery or palliative stenting, and 41 patients whose outcome was not recorded. A total of 669 patients (67%) had complete data for the risk factors included in the multivariate analysis.

Table 1 Demographic data for patients who underwent gastro-oesophageal surgery by site of cancer*

	Gastric	Oesophageal	Junctional
No (%) of cases	502 (53)	229 (24)	207 (22)
Mean age (range)†	70.1 (28.6-95.7)	64.9 (38.9-85.5)	66.4 (33.6-89.1)
No (%) of men‡	323 (64)	168 (73)	162 (78)
Median (IQR) length of stay§ (days)	13 (14)	17 (15)	15 (19)

*17 (2%) cases were not classified by anatomical site.
†Analysis of variance $F_{2,873}$=21.056, P=0.001.
‡χ^2=15.326, 2 df, P=0.001.
§Kruskal Wallis test=18.919, 2 df, P=0.001.

Table 2 Postoperative complications in patients undergoing oesophageal or gastric resection for cancer. Figures are numbers (percentages) of patients

Complication	Gastric (n=590)	Oesophageal (n=365)	P value
Surgical complications:			
Anastomotic leak	19 (3.2)	20 (5.5)	0.096
Leak elsewhere	15 (2.5)	17 (4.7)	0.096
Abscess formation	18 (3.1)	4 (1.1)	0.050
Peritonitis	5 (0.8)	1 (0.3)	0.261
Ileus	9 (1.5)	2 (0.5)	0.143
Wound infection	21 (3.6)	16 (4.4)	0.316
Burst abdomen	1 (0.2)	2 (0.5)	0.326
Intraluminal bleed	12 (2.0)	1 (0.3)	0.313
Extraluminal bleed	8 (1.4)	5 (1.4)	0.313
Pancreatic fistula	7 (1.7)	0 (0)	0.048
Other	59 (10.0)	27 (7.4)	0.172
Required secondary surgery	60 (10.2)	38 (10.4)	0.905
Total	108 (18.3)	72 (19.7)	0.585
Medical complications:			
Cardiovascular	65 (11.0)	57 (15.6)	0.046
Pulmonary	119 (20.2)	148 (40.5)	0.001
Renal	15 (2.5)	13 (3.6)	0.364
Hepatic	3 (0.5)	3 (0.8)	0.419
Other	42 (7.1)	28 (7.7)	0.750
Total	191 (32.4)	190 (52.1)	0.001
Deaths in hospital	61 (10.3)	50 (13.7)	0.115

Surgical treatment

In 23 hospitals 1251/2087 patients (60%) underwent surgical treatment and 955 (46%) underwent tumour resection (table 1). Operative volume ranged between 2 and 39 cases a year. Nine hospitals performed 10 or fewer resections a year and three hospitals performed more than 30 oesophagogastric resections a year. Of the patients, 590 underwent gastric resection (resection rate 54%), 365 underwent oesophageal resection (resection rate for oesophageal or junctional cancers 37%), and 255 underwent non-resectional palliative or exploratory procedures. Only 62 (6%) resections were considered palliative in intent. There were 254 total gastrectomies, 262 distal gastrectomies, and 365 oesophagectomies. The chest was opened in 337 procedures. Overall, 232 (64%) of oesophagectomies incorporated a 2-field lymphadenectomy, and 40% of gastrectomies had "D2" lymphadenectomy. Additional organ resection was performed in 224 patients (23%).

Preoperative fitness assessment

Most patients undergoing resection had unrelated systemic disease, and in many this was severe enough to

Table 3 Multivariate* analysis of risk factors associated with operative mortality after oesophagogastric surgery. Presented variables are those selected by model

Risk factor	%	OR (95% CI)
Possum physiological score:		
11-14	6.5	1
15-20	10.0	1.72 (0.87 to 3.37)
20-30	18.5	4.12 (1.99 to 8.54)
>30	24.0	6.46 (2.06 to 20.27)
Surgeon's assessment:		
1	7.3	1
2/3	19.0	2.62 (1.47 to 4.68)
Cancer stage:		
Stage I	8.3	1
Stage II	12.4	1.39 (0.63 to 3.06)
Stage III	11.8	1.54 (0.81 to 2.95)
Stage IV	18.7	2.49 (1.03 to 5.98)
Type of surgery:		
Partial gastrectomy	8.3	1
Total gastrectomy	13.8	2.43 (1.26 to 4.70)
Oesophagectomy	12.8	2.41 (1.27 to 4.56)
Annual volume:		
0-10 (n=9)	16.7	1
11-20 (n=10)	12.7	0.50 (0.24 to 1.05)
21-39 (n=4)	10.3	0.49 (0.24 to 0.97)
Level 2 variance (SE)		0.61 (0.097)

*Other variables entered into model were age, sex, ECOG (Eastern Cooperative Oncology Group) status, ASA (American Society of Anesthesiology) grade, operative intent, surgical approach, resection of additional organ, lymphadenectomy.

Table 4 Multivariate analysis of risk factors associated with all complications in oesophagogastric surgery. Presented variables are those selected by model

Risk factor	%	OR (95% CI)
Sex:		
Female	41.9	1
Male	51.8	1.45 (1.07 to 1.99)
Possum physiological score:		
11-14	40.3	1
15-20	50.1	1.51 (1.00 to 2.28)
20-30	56.8	2.23 (1.28 to 3.91)
>30	56.0	2.55 (0.91 to 7.15)
ASA grade:		
I	41.0	1
II	48.3	1.23 (0.88 to 1.92)
III	54.5	1.74 (1.09 to 2.78)
IV	72.7	3.20 (0.74 to 13.8)
Surgical approach:		
Abdominal	18.2	1
Thoracic	19.2	1.57 (1.15 to 2.15)
Additional organ:		
Not resected	44.7	1
Resected	61.6	1.48 (0.99 to 2.21)
Lymphadenectomy:		
Non-radical	43.0	1
Radical	55.7	1.43 (0.99 to 2.05)
Type of surgery:		
Partial gastrectomy	36.6	1
Total gastrectomy	52.0	1.90 (1.23 to 2.92)
Oesophagectomy	55.8	1.17 (0.62 to 2.21)
Level 2 variance (SE)		0.41 (0.22)

*Other variables entered into model were age, ECOG status, surgeon's assessment, operative intent, cancer stage, annual volume.

compromise survival from major surgery. The median "physiological" POSSUM score was 17 (range 12-56, n = 757), 187 (20%) patients had a score of over 20, 253 (27%) patients were ASA grade III or IV, and 164 (14%) had an ECOG score of ≥ 2; 18 patients (2%) were classified by the surgeon as either severely compromised or unfit for any elective surgery. Over half (145, 57%) of the patients who received non-resectional treatment were rejected on fitness grounds.

Postoperative adverse events

The overall mortality from resection was 111/955 (12%). Mortality was 8% (13/166) in ASA grade I patients compared with 9% (44/491) in grade II, 18% (44/242) for grade III, and 27% (3/11) in grade IV. Among 590 patients undergoing gastric resection, 254 (43%) developed at least one complication. The commonest problems were respiratory infection or failure (20%) and cardiac failure, arrhythmia, or ischaemia (11%). Ten percent of patients needed a second operation: 34 patients (6%) had an anastomotic or other enteric leak (table 2).

Fifty patients (14%) undergoing oesophageal resection died in hospital, and 219 (60%) had at least one complication. Technical or surgical complications affected 72 (20%) patients; 148 (41%) had respiratory and 57 (16%) had cardiac complications (table 2).

Analysis of prognostic factors

Multivariate analysis showed significant associations of mortality in hospital with both physiological POSSUM score and the surgeons' assessment but not with ASA grade or ECOG score (table 3). Tumour stage and type of operation were also significant predictors; patients undergoing partial gastrectomy were at significantly less risk than others. Using the multivariate model, we observed a 51% reduction in the risk of operative mortality for those hospitals with over 20 resections a year compared with hospitals with fewer than 10 a year. Table 4 gives details of the variables selected for all complications. For postoperative complications sex, type of operation (both the type of resection and the approach), physiological POSSUM score, and ASA grade were predictive, but not patient's age. Additional organ resection and stage IV disease were independent predictors for surgical complications, while radical node dissection gave an odds ratio of 1.44 and nearly reached significance (see bmj.com). Physiological POSSUM score, ASA grade, surgical approach, extent of node dissection, and type of operation all independently predicted medical complications. The multivariate models developed for operative mortality and morbidity showed good predictive value when we applied them to the data from the final year of the study (see bmj.com).

Discussion

In Britain, surgical outcomes are currently under unprecedented public scrutiny. Because the information routinely collected by the NHS is completely inadequate for reliable risk adjusted comparisons, most British surgeons have neither accurate information about their own results nor any grasp of how these compare with their peers. For gastro-oesophageal cancer, controversial recommendations about techniques, operative mortality, and unit case volumes have been based on systematic literature reviews.[8] Detailed accurate information is needed to allow appropriate responses both to public scrutiny and to demands for organisational change. We used a large and detailed prospective dataset to determine the factors associated with adverse outcomes for this kind of surgery.

The mortality we report compares unfavourably with that reported in many recent studies,[9–11] although the contemporary Scottish national audit reported a similar mortality (13%) for gastrectomy.[12] The ASCOT contributors were self selected and may therefore be unrepresentative of UK practice overall, but they represent a wide spectrum of large and small, rural and urban, and specialist and generalist departments from England and Wales. The validity of direct comparisons between multicentre cohorts such as ASCOT and some other types of study is doubtful. Mortality in hospital, which we report, is up to 50% higher than the 30 day mortality reported in many studies. International comparisons are confounded by major differences in populations of patients, and both randomised trials and case series from specialist centres commonly report superior treatment effects because of selection and publication biases.

Contributing factors

Factors that may contribute to high operative mortality include a high frequency of unrelated systemic disease, liberal selection criteria for operation, low case volumes in individual units, poor quality or inappropriately radical surgery, and inadequate standards of postoperative care. Occult cardiac disease is higher in the United Kingdom than in many other European countries,[13] and, by international standards, UK surgeons work with limited postoperative nursing and intensive care unit support.[14 15] Patients of surgeons who operate on a high proportion of referred cases have higher mortality,[16] but the 46% curative resection rate in this series was not unusually high.

We found that factors related to patients—the stage and site of the tumour and general health and fitness—were the strongest predictors of postoperative death and complications. "Medical" complications were predicted by two measures of patient fitness, by sex, and by more extensive surgery, but surgical complications were predicted only by tumour stage and additional organ resection, although radical node dissection came close to independent significance. Thus the robustness of the patient is not a factor in predicting these complications.

High case volumes in specialist cancer surgery units are associated with superior outcomes in other healthcare systems,[4 17 18] but evidence about this association in the UK context is limited. The Scottish audit did not find a clear effect of case volume on mortality,[12] while an audit in the South West region found an effect that just achieved significance.[19] We found a trend in favour of a weak volume effect compatible with the latter study. The presence of an association does not prove causality, and the proposition that increasing average unit case throughput would improve mortality remains unproved. The test set results showed the reliability of the model developed from the first three years of data by their confirmation of the predictive associations noted.

Problems with data collection

Submission of data to ASCOT was voluntary and essentially unfunded, and, not surprisingly, the completeness of data recording varied considerably. Rates of omission of clinical data were reduced by internal verification work to between 5% and 10%.[20] Overall, ASCOT recorded two thirds of the cases recorded by hospital episode statistics (see bmj.com), although figures for individual trusts varied considerably. Comparison of mortality data with figures from hospital episode statistics showed no evidence of overall bias, even among trusts who contributed few cases to ASCOT. The uneven quality of the hospital episode statistics data reflected the experience of others.[21]

Our study was limited in scope to the elucidation of factors associated with death and complications. Systems like ASCOT will permit the development of accurate predictive scoring models and of risk adjusted comparisons of performance between hospitals and surgeons, but for these purposes near complete data will be required. We have shown both the potential value and the problems of large prospective databases as tools for surgical audit and research. Resources should be provided to improve the ability of multidisciplinary teams to record complete, comprehensive, and accurate data on all patients undergoing major surgery for cancer.

What is already known on this topic

Gastro-oesophageal cancer resections carry the highest mortality among elective general surgical procedures, but reported results vary widely between institutions

Units with higher case volumes are associated with better results in some non-UK settings and in an English region with only one high volume centre, but not in Scotland

What this study adds

In a large sample of English hospitals, morbidity and mortality remain high and are influenced more by the preoperative condition of the patient than by unit volume

Prospective collection of risk adjusted data allows evaluation of the factors affecting operative outcome and requires a multidisciplinary input with adequate resources to ensure complete and accurate data collection

The ASCOT project was developed by the membership of the British Oesophago-gastric Cancer Group. We thank all the consultants who contributed patients to the study and the data collection officers for their assistance. Abdullah Jibawi, David Corless, and David Cade of the Surgical Research Group at Leighton Hospital, Crewe, provided and prepared the HES data for external validation of the ASCOT dataset.A list of the trusts registered with ASCOT can be found on bmj.com

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Operative mortality in colorectal cancer: prospective national study

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The statistical model used by the Association of Coloproctology of Great Britain and Ireland and a list of hospitals participating in data collection appear on bmj.com

Abstract

Objective To develop a mathematical model that will predict the probability of death after surgery for colorectal cancer.
Design Descriptive study using routinely collected clinical data.
Data source The database of the Association of Coloproctology of Great Britain and Ireland (ACPGBI), encompassing 8077 patients with a new diagnosis of colorectal cancer in 73 hospitals during a 12 month period.
Statistical analysis A three level hierarchical logistic regression model was used to identify independent predictors of operative mortality. The model was developed on 60% of the patient population and its validity tested on the remaining 40%.
Results Overall postoperative mortality was 7.5% (95% confidence interval 6.9% to 8.1%). Independent predictors of death were age, American Society of Anesthesiology (ASA) grade, Dukes's stage, urgency of the operation, and cancer excision. When tested the predictive model showed good discrimination (area under the receiver operating characteristic curve = (0.775) and calibration (comparison of observed with expected mortality across different procedures; Hosmer-Lemeshow statistic = 6.34, 8 df, P = 0.610).
Conclusions Clinicians can predict postoperative death by using a simple numerical table derived from the statistical model of the ACPGBI. The model can be used in everyday practice for preoperative counselling of patients and their carers as a part of multidisciplinary care. It may also be used to compare the outcomes between multidisciplinary teams for colorectal cancer.

Introduction

Surgeons and the units in which they work are now clearly accountable for clinical outcomes.[1] Consent to surgery cannot be truly informed unless operative risk is estimated by considering the patient's comorbid condition, extent of disease, and complexity of the proposed treatment. Patients and carers may then make decisions with greater awareness of the risks involved.

We describe the development of a dedicated model for colorectal cancer that estimates the operative risk for individual patients while providing an example of the general problem of quantifying surgical risk.

Data and methods

Data sources

The colorectal cancer study of the Association of Coloproctology of Great Britain and Ireland (ACPGBI) was conducted prospectively in 73 hospitals. Data were collected using the standardised ACPGBI dataset[2] or equivalent. The contributing hospitals reported a total of 8077 new cases of colorectal cancer over a 12 month period between 1 April 1999 and 31 March 2001.

We excluded patients with a diagnosis of colorectal cancer who did not undergo surgery and patients of whom only the name and demographic details were recorded on the database, without information on outcomes or risk factors.

Study end point and risk factors

The primary outcome was operative mortality, defined as death occurring within 30 days of an operative pro-