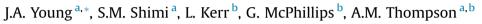
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# Reduction in gastric cancer surgical mortality over 10 years: An adverse events analysis



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#### ABSTRACT

*Background:* The reduction in gastric cancer mortality is due to a reduction in incidence and of surgical mortality. This study was to examine adverse events in patients with gastric cancer dying under surgical care.

*Methods:* Adverse events in surgical care were prospectively audited in patients who died of gastric cancer in Scottish hospitals. A cohort retrospective study examining deaths and contributing adverse events was compared for the periods 1996–2000 and 2001–2005.

*Results:* Between 1996 and 2005, 1083 patients with gastric cancer died on surgical wards in Scottish hospitals. The annual number of deaths under surgical care fell significantly from an average of 128 deaths per annum in years 1996–2000 to 88 deaths per annum in 2001–2005 (p < 0.001). This occurred in parallel with the decline in gastric cancer incidence over the same period. There was an increase in the proportion of gastric cancer resections carried out in 7 major hospitals in Scotland in the second period of the study (p < 0.001). The mean number of deaths in the group of patients, who had gastric cancer resection and palliative surgery, were significantly lower in the second period of the study In addition, when all patients were considered as a group, the mean number of anaesthetic, critical care, medical management and technical surgery adverse events were significantly lower in the second study period. *Conclusion:* There has been a reduction in deaths and adverse events for patients with gastric cancer under surgical care and this has been associated with surgical subspecialisation in oesophago-gastric cancer surgery.

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## 1. Introduction

Gastric cancer is the second leading cause of cancer specific mortality worldwide [1] and the 7th commonest cause of cancer death in Scotland (5th in males and 7th in females) [2]. Over a 10year period, gastric cancer mortality has decreased by 27% [2] mainly as a consequence of declining incidence of gastric cancer [2] but also due to early diagnosis, improvements in staging techniques, technical improvements in surgery and availability of better anti-cancer drugs. Gastrectomy remains the only curative modality in the treatment of invasive cancer. However, the majority of patients have advanced disease at presentation and require palliation.

Several studies have demonstrated an inverse relationship between operative mortality and hospital volume for high risk procedures including major cancer resections [3–6]. In the United Kingdom, the Calman–Hine report [7] commissioned by the Department of Health, in 1995 suggested the establishment of a network of specialised cancer centres, to improve outcomes in upper gastrointestinal cancer. Although the benefits are less clear than those for oesophageal surgery [8-10], it has been recommended that gastric cancer surgery should be performed in high volume units. Over the same period, the surgical community has adopted sub-specialisation in surgical practice with the establishment of specialist oesophago-gastric surgeons. Although the main reason for the decline in gastric cancer mortality is the reduced incidence of gastric cancer, the contribution of surgical subspecialisation and centralisation of gastric cancer resections to units with high volume has not been evaluated as a separate entity. The aim of this study was to compare deaths and adverse events contributing to surgical mortality in patients with gastric cancer dying under surgical care over two periods before and after specialisation in surgical practice and centralisation of gastric cancer surgery.

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# 2. Patients and methods

Patients who died under surgical care from 1994 to 2005 (inclusive) with a diagnosis of gastric cancer (ICD10-C16) or keywords of "gastric" or "stomach" and "cancer" recorded as a cause of death were identified from the Scottish Audit of Surgical Mortality (SASM) database. SASM identifies all deaths that occur in hospital under the care of a surgeon during the patient's last episode of care, whether an operation has taken place or not.

The process reviews the role of a single clinician and clinical teams both surgical and non-surgical in their contribution to the final outcome. The method of case assessment and the review process are well established [11–13]. In brief, deaths occurring within 30 days of an operation or during the patient's last admission are collected via validated surgical and anaesthetic proformas which are anonymously assessed by a surgical assessor and by an anaesthetic assessor (if the patient had a surgical procedure under anaesthesia). The circumstances of death are described in terms of adverse events attributed to clinical issues for an individual, a team or hospital, to resource issues or to other individual causes. An adverse event can be defined as an unintended event caused by medical management, as opposed to the disease process, that results in patient harm (they are not necessarily complications). For patients who died within 30 days of surgery, the individual patient's post-operative time scale was assessed by the case assessors in terms of its bearing on the adverse events that may have occurred in the post-operative course. Due to major changes in adverse event coding by SASM, the adverse events data before 1996 and after 2005 would not allow meaningful comparisons to be made

Scottish hospital admission and operation data for gastric cancer for the study period were obtained separately from acute hospital discharge data, the Scottish Morbidity Record 1 (SMR1 returns) which identifies each defined episode of hospital care. Health related information in Scotland is collected in a national database which is managed by The Information and Statistics Division (ISD, Scotland) on behalf of NHS Scotland. ISD collects data from a variety of sources including SMR returns of inpatient admissions. The cancer database is part of this programme [2]. ISD also records deaths in Scotland in a separate but record link accessible death database (GRO) from the General Register Office in Scotland. All data are linked by a unique patient identifier, the Community Health Index number (CHI). The data from the SASM database was manually validated with data from the SMR01 returns and GRO database. Despite this manual validation, it is recognised that coding inaccuracies may occur in multi-sourced data [1415]. For the purposes of this study, the case assessors checked individual case notes when an adverse event was highlighted. For mortalities without an adverse event, validation was checked in 10% of the cases by reference to the case notes.

Data analysis was made using SPSS (SPSS Inc, Chicago, Illinois) in a quasi-experimental design looking at trends over time, accepting the application of events at certain time points. Data was assumed to be non-parametric and the dependence of categorical factors such as year and admission type was examined using two-way Chisquared tests. Frequencies in categories were tested for equality with one-way Chi-squared tests. Statistical significance was accepted when the test statistic *p* was less than 5%.

#### 3. Results

Between 1996 and 2005 the incidence of gastric cancer registrations in Scotland declined progressively from 988 patients in 1996 to 795 in 2005 (p < 0.001). In addition, the recorded mortality from gastric cancer declined from 699 patients in 1996 to 590

patients in 2005 (p < 0.001). During the same period, the annual number of gastric cancer surgery procedures recorded in Scottish hospitals decreased from 380 operations in 1996 to 221 operations in 2005 (p < 0.001). However, there was a significant increase in the proportion but not the absolute numbers of cases operated on in the seven main cancer hospitals from 144/380 (38%) in 1996 to 146/221 (66%) in 2005 (Fig. 1).

# 3.1. Deaths

Over the study period, 1083 deaths (12% of the reported deaths) with a diagnosis of gastric cancer were audited by SASM. The annual number of deaths under surgical care fell significantly from an average of 128 deaths per annum in years 1996–2000 to 88 deaths per annum in the years 2001–2005 (p < 0.001). As a proportion of all gastric cancer deaths reported to ISD, the annual proportion of patients dying in hospital under surgical care has decreased significantly from 18% in 1996 to 12% in 2005 (p < 0.001). The median age at death was 74 years (range 22–101) and 61% of the patients were male. The majority of patients who died with gastric cancer were admitted to the surgical service as an emergency (54%) and the proportion of elective admissions decreased from 26% in 1996 to 20% in 2005.

Overall, 40% of patients with gastric cancer who died on a surgical ward were found to have advanced cancer and this has risen over the study period from 36% in 1996 to 59% in 2005 (p < 0.001). Other co-morbidities were also found commonly in this cohort of patients (22% of patients had cardiovascular disease and 15% respiratory disease).

The mean number of deaths in the group of patients, who had gastric cancer resection and palliative surgery, were significantly lower in the second period of the study (Table 1).

#### 3.2. Adverse events

Between 1996 and 2005 inclusive a total 1083 patients died following admission to the surgical wards in Scottish hospitals. One hundred and sixty five of these deaths (15%) were coded to have encountered 279 adverse events before death. The majority of deaths with adverse events had either a cancer resection (99/185 deaths, 175 events) or a palliative operation (47/179 deaths, 84 events). In addition, 4 adverse events were encountered in 4/75 deaths following endoscopy (2 diagnostic and 2 therapeutic), in 7/43 deaths (8 events) who had a surgical procedure unrelated to gastric cancer and in 8/601 deaths (8 events) who had no diagnostic or interventional procedure during their final admission.

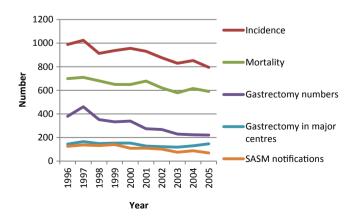


Fig. 1. Annual incidence, mortality and gastric cancer surgery statistics in Scottish Hospitals including SASM notifications of surgical deaths 1996–2005.

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Period	Deaths in gastric resection group.	Deaths in group with no procedure.	Deaths in palliative surgery group.	Deaths in unrelated surgery group.	Deaths in diagnostic endoscopy group.	Deaths in therapeution endoscopy group.
1996-2000						
Number	126	340	115	19	23	18
Mean	25.2	68	23	3.8	4.6	3.6
Range 2001–2005	(25–30)	(59–76)	(19–27)	(2–5)	(2-6)	(1–7)
Number	59	261	64	24	21	13
Mean	11.83	52.2	12.8	4.8	4.2	2.6
Range	(8-13)	(45-60)	(7-18)	(1-6)	(2-7)	(0-6)
p	< 0.05	NS	< 0.05	NS	NS	NS

 Table 1

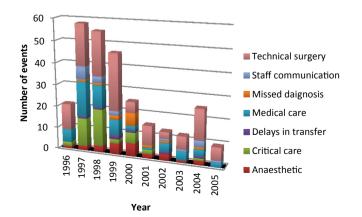
 Mean number (Range) of adverse events (AEs) in gastric cancer patients dying in surgical care according to procedure performed in the two periods of the study.

Adverse events grouped by processes of care (Fig. 2) demonstrated that 120/279 events were related to surgical technique including anastomotic leaks, post-operative bleeding, or inappropriate extent of surgery (approach, method, under or over treatment). A further 59/279 events were attributed to post-operative medical care (aspiration pneumonia, delays in recognising medical complications) and another 42/279 events were attributed to critical care (including availability and use of critical care facilities). Fifty eight miscellaneous events occurred in patients who did not have surgery and these included 3 adverse events due to bleeding or iatrogenic perforation following therapeutic endoscopy. There was a significant reduction in the total number of adverse events between the two study periods.

In 185 patients who had gastric cancer resection surgery and subsequently died (Fig. 3), 175 adverse events were recorded in 99 patients. The number of adverse events in this group decreased over the period of the study (p < 0.001) principally due to significant decreases in adverse events related to post-operative medical care (p = 0.042) and adverse events related to post-operative critical care (p = 0.002). Adverse events related to surgical technique also decreased over the period of the study (p = 0.061) with 51 events attributed to post-operative complications and 36 events attributed to surgical decision making.

In patients who had non-resection palliative surgery (Fig. 4), adverse events related to technical surgery and post-operative medical care decreased over the period of study but this did not reach statistical significance. Eighty four adverse events were recorded in 47/179 patients who had palliative surgery with 23/84 attributed to decision making and 6/84 adverse events to post-operative complications.

In 185 patients who died after gastric cancer resections (90 total gastrectomies, 74 partial gastrectomies and 21 oesophagogastrectomies), there were 34 post-operative anastomotic leaks that



**Fig. 2.** Adverse events in all patients who died during a surgical admission with gastric cancer from 1996–2005.

contributed to death (15 oesophageal, 11 gastric, 3 duodenal stump, 5 colonic injuries). In patients who died following gastric cancer resection, the annual incidence of anastomotic leaks varied between 6% and 38%. In addition there were 4 post-operative anastomotic leaks in the group which had palliative bypass surgery.

In addition, when all patients were considered as a group, the mean number of anaesthetic, critical care, medical management and technical surgery adverse events were significantly lower in the second study period. In the group of patients who had cancer resection surgery, the mean number of anaesthetic, critical care, medical management and technical surgery adverse events were significantly lower in the second study period. In the group of patients who had palliative surgery, the mean number of critical care, medical management and technical surgery adverse events were significantly lower in the second study period. In the group of patients who had palliative surgery, the mean number of critical care, medical management and technical surgery adverse events were significantly lower in the second study period (Table 2).

# 4. Discussion

Over the study period there has been a reduction in the incidence of surgical deaths with gastric cancer by 61%. However, the annual incidence and mortality related to gastric cancer in Scotland have declined in contrast to the specific rise in cardia cancers that may be related to obesity and gastro-oesophageal reflux disease [16]. The number of gastric resections in Scotland has declined by 48% with proportionately more gastric resections carried out in major Scottish hospitals, reflecting increased reliance on specialist multi-disciplinary teams, increasing surgical sub-specialisation as well as improvement in diagnostic and staging technologies leading to better case selection. In addition, there have been synchronous improvements in anaesthesia, analgesia and interventional radiological techniques and expertise.

Overall 45% of deaths in this study had undergone an interventional procedure with 18% a cancer resection, 17% a palliative

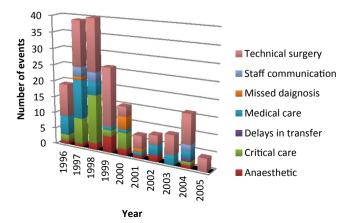


Fig. 3. Adverse events in patients who died during a surgical admission with gastric cancer after gastrectomy from 1996–2005.

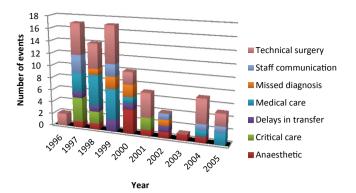


Fig. 4. Adverse events in patients who died during a surgical admission with gastric cancer after palliative surgery from 1996–2005.

operation that did not remove the cancer, 4% an operation unrelated to gastric cancer and 7% a diagnostic or therapeutic endoscopy. The low rate of resection probably reflects the advanced stage of the disease found in this study in patients reported as unsuitable for surgery [17]. The high proportion of patients with advanced disease at presentation is likely due to delay in presentation with subsequent acute presentations of symptomatic disease (bleeding, obstructive symptoms, malnutrition and cancer fatigue) and to improvements in cancer staging by new imaging technology (especially multi-slice CT scanning, PET CT) and better adoption of laparoscopy in staging. In addition, many patients were found to have multiple comorbidities, including malnutrition, and presented as an emergency with acute symptoms. All of these are adverse factors and are known to reduce the resection rate [18–20]. While 15% of all patients who died on surgical wards with gastric cancer had an adverse event (compared to 10% overall in the NHS [21,22]), the proportion of patients with adverse events increased with the severity and complexity of the surgical procedure undertaken with 54% of the adverse events recorded were after a gastric cancer resection.

During the study period, there was a significant reduction in deaths in the groups that had gastric resection surgery and palliative surgery. The reduction in deaths following surgery either curative or palliative may be associated with the increased subspecialisation and centralisation in the management of these patients. The reduction in deaths following palliative procedures has not been reported previously as a function of improved surgical workup with regards to assessment of fitness and clinical staging, surgical sub-specialisation and other improvements which occurred over the past 15 years. During the study period, there was a significant reduction in adverse events relating to anaesthetic, technical, medical care and critical care between the early and late periods. This expected improvement may be associated with centralisation of oesophago-gastric resection surgical services and increasing surgical sub-specialisation as well as improvements in anaesthesia, analgesia, interventional radiological techniques and better case selection. However, these associations remain speculative since they are beyond the remit of this paper. It is noteworthy that technical adverse events following gastric resection and suboptimal surgical decision-making in those who have had palliative surgery remained relatively high. The most significant reduction in the total number of adverse events occurred in the year 2000 mainly due to a reduction in technical surgery adverse events and although this coincides with the establishment of subspecialisation, this remains speculative.

A published audit of the outcomes of oesophago-gastric cancer surgery in Scotland showed mortality was high after gastric cancer surgery (14.1%) [23,24] compared to rates of less than 1% in Japan [25] and between 3 and 11% in Europe and America [24,26–30]. In the present study the number of adverse events in patients who died after gastric resection decreased over time. Surgical adverse events related to technical surgery and poor decision making in the first period of the study were most common due to the complications of anastomotic leaks, bleeding and other organ injuries during resection surgery. These factors, in combination, may be possible indicators of low hospital volumes. Indeed, the results from this study show a reduction in technical factors between the two study periods. Whether this is a result of sub-specialisation or centralisation or other factors remain unproven. Increasing subspecialisation and centralisation across Scotland may partly explain the reduction in deaths and adverse events the second periods of the study. Additionally, effective specialist multidisciplinary teams [31] developed in major hospitals which became established in Scotland during the second period of the study [32]. The multi-disciplinary assessment and recommendations may have contributed to the decline in poor decisions over the latter period of the study. The high proportion of anastomotic leaks is likely to be due to a combination of the surgical challenges of mal-nourished patients with comorbidities combined with a reduction in other causes of deaths. The anaesthetic adverse events mainly related to pre-operative assessment and are probably a reflection of the high proportion of emergency admissions within this group of patients. Adverse events were infrequent in patients who died following endoscopy with only a single perforation at therapeutic endoscopy. It is noteworthy that gastric cancer patients dying following endoscopic treatments are not included in the audit if they are not an inpatient on the surgical wards. As such, the true rate of adverse events and deaths after endoscopic treatment in Scotland remains unknown. In the first study period, there were a number of adverse events related to the lack of use of critical care beds following gastric cancer surgery, particularly after major resections. This was highlighted by the Scottish Audit of Surgical Mortality (SASM) annual reports and resulted in improvement of

Table 2

Mean number (range) of adverse events (AEs) in all patients who died up to 30 days after surgical admission with gastric cancer and after gastric resection or palliative surgery in the two periods of the study.

	Period	Anaesthetic AEs	Critical care AEs	Delays in transfer AEs	Medical care AEs	Missed diagnosis AEs	Staff communication AEs	Technical surgery AEs
Mean (range)								
All patients	1996-2000	3.4 (1-6)*	7.8 (2-17)*	1.0 (0-2)	8.2 (2-16)*	2.0 (0-6)	2.2 (0-6)*	16.4 (5-26)*
-	2001-2005	1.6 (0-3)	0.6 (0-2)	0.4 (0-1)	2.8 (1-4)	0.6 (0-1)	1.2 (0-3)	7.6 (3–14)
After gastric	1996-2000	2.2 (1-5)*	6.4 (2-15)*	0(0)	4.8 (1-12)*	1.0 (0-4)	1.2 (0-3)	12.2 (3-18)*
cancer resection	2001-2005	0.8 (0-2)	0.2 (0-1)	0.2 (0-1)	1.8 (0-3)	0.2 (0-1)	0.4 (0-2)	5.2 (3–9)
After palliative	1996-2000	1.2 (0-4)	1.6 (0-4)*	1.0 (0-2)	2.8 (0-5)*	1.0 (0-3)	1.0 (0-3)	3.8 (2-6)*
surgery	2001-2005	0.8 (0-1)	0.4 (0-2)	0.2 (0-1)	0.6 (0-2)	0.2 (0-1)	0.6 (0-1)	2.0 (0-4)

\* = statistically significant difference (p < 0.05).

critical care provision in larger hospitals. Adverse events related to the use of critical care beds have subsequently significantly decreased.

The limitations of this study are that this is a cohort retrospective study based on multi sourced data with inherent limitations. Some of the data items were obtained by record linkage. This is dependent on the accuracy of coding of individual data items and despite manual validation of a proportion (10%) of the coded items, there remains a possibility of miscoding error of approximately 12%.

There has been a reduction in deaths and adverse events for patients with gastric cancer under surgical care in Scotland. This has been associated with surgical sub-specialisation and partial centralisation of gastric cancer surgery to larger hospitals with improved post-operative facilities and care. However, challenges remain to further reduce surgical (technical) adverse events and to achieve an earlier presentation for elective surgery. Reduction of technical surgical adverse events could be realised by better case selection, enhanced hospital and surgeon's case volume, earlier diagnosis of complications and a responsive interventional service to deal with these complications early, promptly and with minimal insult. It is the combined effect of addressing all these challenges rather than an individual challenge will bring about a reduction of adverse events in this category. Earlier presentation for elective surgery could be realised by improving public awareness and a lower threshold for investigations in patients with alarming symptoms.

# Contributors

The manuscript has been read and approved by all authors. All persons listed as authors have contributed to preparing the manuscript. All authors, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

# **Competing interest**

All authors have completed the Unified Competing Interest form at www.icmje.org/coi\_disclosure.pdf and declare: no financial relationships with any organisation that might have an interest in the submitted work in the previous five years; and no other relationships or activities that could appear to have influenced the submitted work.

## Strobe

This manuscript satisfies all criteria set out in the STROBE checklist.

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