Failure to Rescue Patients After Reintervention in Gastroesophageal Cancer Surgery in England

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Importance: Gastroesophageal cancer resections are associated with significant reintervention and perioperative mortality rates.

Objective: To compare outcomes following operative and nonoperative reinterventions between high- and low-mortality gastroesophageal cancer surgical units in England.

Design: All elective esophageal and gastric resections for cancer between 2000 and 2010 in English public hospitals were identified from a national administrative database. Units were divided into low- and high-mortality units (LMUs and HMUs, respectively) using a threshold of 5% or less for 30-day adjusted mortality. The groups were compared for reoperations and nonoperative reinterventions following complications.

Setting: Both LMUs and HMUs.

Participants: Patients who underwent esophageal and gastric resections for cancer.

Exposure: Elective esophageal and gastric resections for cancer, with reoperations and nonoperative reinterventions following complications.

Main Outcomes and Measures: Failure to rescue is defined as the death of a patient following a complication; failure to rescue–surgical is defined as the death of a patient following reoperation for a surgical complication.

Results: There were 14,955 esophagectomies and 10,671 gastrectomies performed in 141 units. For gastroesophageal resections combined, adjusted mortality rates were 3.0% and 8.3% (P < .001) for LMUs and HMUs, respectively. Complications rates preceding reoperation were similar (5.4% for LMUs vs 4.9% for HMUs; P = .11). The failure to rescue–surgical rates were lower in LMUs than in HMUs (15.3% vs 24.1%; P < .001). The LMUs performed more nonoperative reinterventions than the HMUs did (6.7% vs 4.7%; P < .001), with more patients surviving in LMUs than in HMUs (failure to rescue rate, 7.0% vs 12.5%; P < .001). Overall, LMUs reintervened more than HMUs did (12.2% vs 9.6%; P < .001), and LMUs had lower failure to rescue rates following reintervention than HMUs did (9.0% vs 18.3%; P = .001). All P values stated refer to 2-sided values.

Conclusions and Relevance: Overall, LMUs were more likely to reintervene and rescue patients following gastroesophageal cancer resections in England. Patients were more likely to survive following both reoperations and nonsurgical interventions in LMUs.


IN 2011, THERE WERE 462,000 NEW CASES OF ESOPHAGEAL CANCER1 AND 988,000 NEW CASES OF GASTRIC CANCER DIAGNOSED WORLDWIDE.2 SURGERY IS THE MAINSTAY FOR A CURE. ESOPHAGEAL AND GASTRIC CANCER RESECTIONS, HOWEVER, ARE ASSOCIATED WITH SIGNIFICANT POSTOPERATIVE MORTALITY, WITH NOTABLE VARIABILITY AMONG CENTERS. THE VOLUME-OUTCOME RELATIONSHIP HAS BEEN DEMONSTRATED IN UPPER GASTROINTESTINAL CANCER SURGERY,3,4 WHICH HAS LED TO CENTRALIZATION OF SERVICES IN ENGLAND.

Another major determinant of outcome is the quality of postoperative complication management. The relationship between a hospital's complication rate and its mortality rate is not a linear one. It has been shown that hospitals that rank as the worst for mortality are not necessarily those that rank as the worst for the number of complications accrued, which suggests that the complication rate is not the only determinant of outcome following postoperative complications.5 In colorectal surgery, it has been shown that, despite similar surgical complication rates, variability in outcome following the management of these complications occurs between high- and low-mortality hospitals; this is termed failure to rescue–surgical, which is defined as the death of a patient following reoperation for a surgical complication.6 This metric is thought to represent a marker of how well postoperative surgical complications are managed. It may explain to a degree why such mortality differences and variability occur among colorectal cancer surgical
units. In gastroesophageal cancer surgery, such a relationship between reinterventions and postoperative outcomes has not been examined.

Our hypothesis is that units with lower overall postoperative mortality reintervene more often and are subsequently more successful than units with high mortality. Our study aims to ascertain if differences in patient survival following reoperations for complications occur between high- and low-mortality hospitals undertaking gastroesophageal cancer resections in England. Furthermore, our study also aims to assess the use of and the subsequent outcome following nonoperative interventions, such as the use of endoscopic and interventional radiological therapy between high- and low-mortality gastroesophageal cancer surgical units in England.

### Patients and Methods

#### Study Design

Our study was a retrospective national cohort study of all patients who received a diagnosis of gastric or esophageal cancer and who underwent an elective primary major surgical resection between April 2000 and March 2010 inclusive in England. Data were obtained from the Hospital Episodes Statistics (HES) database. We obtained approval under Section 251 granted by the National Information Governance Board for Health and Social Care (formerly Section 60 by the Patient Information Advisory Group). We obtained approval from the South East Research Ethics Committee. The HES database is an administrative database covering all English public hospitals known as National Health Service (NHS) hospitals and treatment centers from 1989, with more than 15 million new records added each year, and has been described previously. Demographic, diagnostic, and procedural interventions are reported routinely for each patient episode. Each patient record now contains a primary diagnosis field and up to 19 secondary diagnoses fields, as well as up to 24 procedural (including operative) fields. These are reported using International Statistical Classification of Diseases, 10th Revision (ICD-10) and Operating and Procedural Codes version 4 (OPCS-4) coding, respectively. Anonymized patient level outcome measures can be derived, and this data set has been extensively used for such purposes previously. Linkage of HES data with the UK Office of National Statistics was performed to identify patients who had died within 30 days of admission to the hospital.

#### Patient Selection

All patients who underwent a primary resection for esophageal or gastric cancer in England were included in the analysis. The ICD-10 codes were used to identify these patients. The OPCS-4 procedure codes used to identify esophagectomy and gastrectomy were G01, G02, G03, G27, and G28.

#### High- and Low-Mortality Group Selection

Units were stratified according to overall risk-adjusted mortality. A cutoff of 5% was chosen as an arbitrary threshold for combined mortality of a unit’s esophageal and gastric 30-day mortality rate. This figure was chosen because high-volume centers worldwide reportedly reproduce such rates for patients undergoing elective resections for cancer. Units with an adjusted mortality of 5% or lower were termed low-mortality units (LMUs), and those units with a higher adjusted mortality (>5%) were termed high-mortality units (HMUs).

### Complications and Reoperations

Reinterventions were only counted if specific surgical pathologies were found. The reoperative procedures were selected as those that most likely reflect serious surgical complications rather than planned “re-looks.” Thus, reoperations in this context can be thought of as a surrogate for serious surgical complications for patients who underwent an intervention. The reoperations broadly fall under 3 categories: thoracotomy, laparotomy, and laparoscopy. Examples of indications for reoperation include bleeding, organ space infections, and bowel obstruction. Common procedures included under the heading “laparotomy” were drainage of abscess/collection, bowel resection and/or stoma formation, and washout of abdominal cavity. Patients who unexpectedly underwent 1 or more operative procedures subsequent to the index procedure during the primary admission were deemed to have undergone a reoperation.

#### Nonoperative Reinterventions (Radiological/Endoscopic)

Any patient who did not undergo a reoperation but who underwent a radiologically guided percutaneous drainage procedure or an upper gastrointestinal endoscopic procedure postoperatively were identified and were deemed to have undergone a nonoperative reoperation. Procedures that were performed before midnight on the day of the index operation were excluded because these procedures may have been planned procedures that were undertaken as a part of the primary resection. Reasons for undertaking these reinterventions are not discernible from the database. However, radiologically guided drainages and endoscopies that were performed after the day of surgery are likely to reflect a surgeon’s desire/threshold to investigate any deviations from a “normal” recovery. Thoroscopic interventions were also considered, but none were identified as reinterventions.

#### Outcome Measures

The outcome measures were (1) mortality following reoperations and (2) mortality following nonoperative reintervention (endoscopic and radiological).

#### Outcome Measures and the Modified Clavien-Dindo Surgical Complication Classification

The validated modified Clavien-Dindo classification of surgical complications stratifies surgical complications according to 7 grades, I to V, with 2 subgrades for grades III and IV (subgrades IIIa and IIIb and subgrades IVa and IVb) (eTable 1, jamasurg.com). For our study, we were specifically interested in subgrade IIIa and subgrade IIIb complications. Our primary outcome measure was failure to rescue a patient after nonoperative reintervention; it would represent outcome following Clavien-Dindo grade IIIa complications, and FTR-S would represent outcome following Clavien-Dindo grade IIIb complications (eTable 1). Of note, the original failure to rescue definition would have considered deaths following Clavien-Dindo grades I through IVb complications together.

#### Statistical Analysis

Risk adjustment was performed by creating a multiple regression model to predict the likelihood of binary outcomes with the covariates of sex, patient age (considered in bands of <60,
scores of (SPSS Inc). All rate. Statistical analyses were performed with SPSS version 18.0 predicted deaths and multiplying by the national crude death hospital by dividing the hospital’s observed deaths by its model-
analyses. Unit-level adjusted death rates were obtained for each on bivariate analysis were included in the multiple regression analyses. Unit-level adjusted death rates were obtained for each hospital by dividing the hospital’s observed deaths by its model-predicted deaths and multiplying by the national crude death rate. Statistical analyses were performed with SPSS version 18.0 (SPSS Inc). All P values stated refer to 2-sided values.

RESULTS

A total of 25,626 patients were electively admitted to 141 NHS units in England over the 10-year period and were included in our study. The demographic characteristics of the patients are shown in eTable 2, as are the odds ratios of 30-day mortality as independently predicted by the considered covariates. Patients older than 80 years of age, more socially deprived patients (ie, those with a higher Carstairs index), and patients with more comorbidities (ie, those with a Charlson score of >2) were more likely to die in the hospital within 30 days (with odds ratios of 5.00, 1.36, and 1.84, respectively, and P < .05 for all 3 groups of patients) (eTable 2).

MORTALITY RATES

There were 1348 deaths in the whole cohort, giving an overall crude death rate of 5.3% for esophageal and gastric resections combined. The crude death rates were 5.1% (758 of 14955) for patients who underwent an esophagectomy and 5.5% (590 of 10671) for those who underwent a gastrectomy.

MORTALITY BY GROUP (LMUs VS HMUs)

When the units are stratified using a risk-adjusted mortality threshold of 5%, 65 units with 11,803 patients (46.1%) appear in the LMU group (=5% adjusted mortality), and 76 units with 13,823 patients (53.9%) appear in the HMU group (>5% adjusted mortality).

PATIENT DEMOGRAPHICS

The demographic characteristics of the 2 groups are shown in eTable 3. There were no statistical differences between the 2 groups in terms of the type of resection performed (esophageal or gastric; P = .20), patients’ presenting ages (P = .77), or patients’ sex (P = .34). There were relatively more socially deprived patients (indicated by a higher Carstairs index) in the HMUs than in the LMUs (P < .001). There were also more comorbid patients (indicated by a higher Charlson score) in the LMUs than in the HMUs (P < .001). More patients in LMUs than HMUs underwent procedures with a minimally invasive approach (985 vs 792 patients; P < .001). Teaching hospital status by mortality group was not statistically different between LMUs and HMUs (10 vs 14 units; P = .40).

REINTERVENTION AND MORTALITY RATES

The LMUs and the HMUs had equivalent reoperation rates for surgical complications (thoracotomy, laparotomy, and laparoscopy combined) (5.4% vs 4.9%; P = .11). The LMUs and the HMUs had significantly different nonoperative reintervention rates, with the LMUs performing more nonoperative reinterventions (6.7% vs 4.7%; P < .001).

Patients were significantly more likely to die after reoperations in HMUs than in LMUs (ie, the failure to rescue–surgical rate, 24.1% vs 15.3%; P < .001). Patients were more likely to die after a nonoperative reintervention in the HMUs (12.5% vs 7.0%; P < .001).

Eighty-two patients underwent both nonoperative and operative reinterventions that were coded under the operative category. These were equally distributed between the mortality groups (P = .18).

FAILURE TO RESCUE AND UNIT CASE VOLUME

Overall failure to rescue rates did not appear to be related to total unit case volume (Figure). Statistical outliers (>2 SDs from the population mean) are seen in both high- and low-volume centers.

COMMENT

Using English national administrative data, we have shown that, when surgical units undertaking esophageal and gastric cancer resections are grouped according to adjusted mortality, index admission reoperation rates for complications are equivalent between LMUs and HMUs. However, the LMUs are more likely to nonoperatively intervene and are more likely to rescue patients from subsequent death after both reoperative and nonreoperative reinterventions.

What our study reiterates is that variability in outcome following management of serious complications does also occur in patients undergoing an upper gastrointestinal resection. This is in keeping with the current literature in other specialties. Our study also demonstrates that failure to rescue–surgical rates differ by mortality grouping, as in lower gastrointestinal surgery. Although the concept that LMUs rescue patients after reoperations more fre-
sequently than HMUs do may not be novel, the present study is the first to demonstrate this concept in patients' undergoing upper gastrointestinal cancer surgery. Theoretically, if all the patients undergoing an operation in an HMU were undergoing the operation in an LMU, approximately 50 more patients per year would have been alive. Through analysis of nonoperative reinterventions, and subsequent outcome, we are able to reflect on those aspects of surgical care that are encountered when surgeons are faced with serious surgical complications in HMUs and LMUs. In those circumstances, surgeons have the option of watchful waiting and/or medical therapy, nonoperative intervention (radiological drainages/endoscopic therapy), or reoperation. What determines the treatment path taken is dependent on many factors, including the patient's morbidity and physiological reserve and the available resources and experience. Ultimately, surgeons bear the responsibility on the final decision taken.

The timely diagnosis of a major surgical complication and the performance and reliability of surgical teams are of vital importance. Perhaps a more rapid identification of actual or potential complications underlies some of the observed differences. Supportive care such as intensive therapy units, physiotherapy, and dietetic input may contribute toward the successful rescue of a patient. A greater understanding of the quality and capabilities of such services between HMUs and LMUs may uncover some of the observed outcome differences. Similarly, structural factors such as out-of-hours radiology services and nurse-patient ratios may vary between LMUs and HMUs. Although the hospital volume-mortality relationship has been shown previously in esophageal surgery and, to a lesser extent, gastric surgery, no relationship has been investigated with regard to the hospital volume–failure to rescue–surgical rate relationship in gastrointestinal cancer surgery. We found failure to rescue outliers at both high and low volumes, which suggests that unit volume does not predict ability to rescue patients following reintervention. Future studies are needed to examine the relationship between failure to rescue rates in different surgical units and the aforementioned factors that determine the treatment path chosen and the outcomes encountered.

We specifically chose to analyze the modified Clavien-Dindo group III types of complications for several reasons. First, certain postoperative complications may be present on admission, such as pneumonia or deep vein thrombosis, which are not necessarily discernible from administrative databases and are subsequently discovered in the postoperative period. This would influence failure to rescue rates, and, although important, if they cannot be adjusted for, this would not faithfully reflect the actual care given by a unit. The interventions that we have chosen are not open to variability of definition. Certain postoperative complications, such as respiratory tract infections and wound infections, may be underreported owing to differences in definitions between LMUs and HMUs. It must be noted that the absolute complication rate is not represented here. Nor can the total complication rate be assumed from the reintervention rate presented. There are likely to have been some serious surgical complications and interventions, such as the failure of a cervical anastomosis (where the opening up of a neck wound on the ward would have been the treatment) or the insertion of chest drains by the bedside. Such “rescue” would not have been discerned from our study. Although underestimating the true serious surgical complication rate by using reoperations as a proxy, of the patients who underwent a reoperation, differences are still observed among units with different mortality statuses. Our study has clearly defined complications in that patients were either returned to the operating theater or not, and in that patients either underwent postoperative endoscopies or drainages or they did not. Finally, Clavien-Dindo grade III complications are arguably those that most likely represent surgical technical quality and anastomotic complications. In gastroesophageal cancer surgery, these are factors that have important implications perioperatively for survival.

Our study is based on an administrative data source. Any coding errors may potentially influence the results. Systemic underreporting of reinterventions by disparate organizations within the same mortality grouping over the study period could, in theory, lead to reporting bias. However, this is unlikely. A more general coding error could have influenced the results. Again, however, this is unlikely given the proven accuracy of this data set in recording diagnostic fields. Data on site of anastomosis and histology are not available from the database and may influence the risk adjustment and, hence, subsequent outcome. However, we have no evidence to suggest that geographically disparate hospitals grouped as HMUs or LMUs would collectively perform more procedures of one type than another, or perform operations for patients with similar histological features rather than for patients with different histological features. Unfortunately, the HES database does not capture cancer stage (although the Charlson score includes metastases, which data were included in the adjustment model), and this may well have an influence on perioperative outcome, as will a case mix not fully adjusted for using the available data. However, it is unlikely that patients with stage IV disease would be undergoing major surgery, unlike in colorectal cancer for which some patients with obstructing colon cancer are stented as a bridge to elective (albeit expedited) surgery.

A strength of our study is that it is not subject to reporting bias. Another strength is that, over similar time periods, the HES database has been shown to record more deaths than a voluntarily recorded clinical registry. Given the sample size and the number of years considered, our study truly reflects the national outcome from gastroesophageal cancer surgery.

Reoperation following gastroesophageal cancer surgery has been repeatedly associated with poor perioperative outcomes in the literature. Such findings may influence contemporary decision making by surgeons faced with the difficulties of managing postoperative surgical complications. The implications of our study raise the question of whether more aggressive and appropriate reinterventions can in fact confer better outcomes. Surgeons should interpret these findings within the context and limitations of their own units. With centralization of services, commissioners should ensure the availability of interventional endoscopy and radiology services to complement the surgical service. Improved outcome from gastroesophageal cancer surgery is more complex than just
the volume-outcome relationship. Complication rates have repeatedly been shown to be equivalent between HMUs and LMUs in different specialties. Complication management is becoming more widely recognized as an important discriminator of surgical outcome. Surgeons should be supported with all the facilities and expertise necessary to ensure that all facets of the care that they deliver are optimal. The focus and priority of future research should be to identify whether quality, expertise, or familiarity with re-intervention is the causal factor in the association with LMUs.

In conclusion, there is variability in outcome following serious surgical complications necessitating reoperations among gastroesophageal cancer surgical units in England. Units with lower overall mortality re-intervene more often and are subsequently more successful than units with higher overall mortality. Future work should focus on why such variability occurs and should identify methods for mitigating this variability.

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REFERENCES