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Regionalization of Emergency General Surgery Operations: A Simulation Study

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Abstract

Background: It has been theorized that a tiered, regionalized system of care for emergency general surgery (EGS) patients – akin to regional trauma systems – would translate into significant survival benefits. Yet data to support this supposition are lacking. The aim of this study was to determine the potential number of lives that could be saved by regionalizing EGS care to higher-volume, lower-mortality EGS institutions.

Methods: Adult patients who underwent one of ten common EGS operations were identified in the California Inpatient Database (2010-2011). An algorithm was constructed that “closed” lower-volume, higher-mortality hospitals and referred those patients to higher-volume, lower-mortality institutions (“closure” based on hospital EGS volume-threshold that optimized to 95% probability of survival). Primary outcome was the number of lives saved. 50,000 regionalization-simulations were completed (5000 for each operation) employing a bootstrap resampling method to proportionally redistribute patients. Estimates of expected deaths at the higher-volume hospitals were recalculated for every bootstrapped sample.

Results: Of the 165,123 patients who underwent EGS operations over the 2-year period, 17,655 (10.7%) were regionalized to a higher-volume hospital. On average, 128 (48.8%) of lower-volume hospitals were “closed,” ranging from 68 (22.0%) hospital closures for appendectomy to 205 (73.2%) for small bowel resection. The simulations demonstrated that EGS regionalization would

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prevent 9.7% of risk-adjusted EGS deaths, significantly saving lives for every EGS operation: from 30.8 (6.5%) deaths prevented for appendectomy to 122.8 (7.9%) for colectomy. Regionalization prevented 4.6 deaths per 100 EGS patient-transfers, ranging from 1.3 for appendectomy to 8.0 for umbilical hernia repair.

Conclusions: This simulation study provides important new insight into the concept of EGS regionalization, suggesting that 1 in 10 risk-adjusted deaths could be prevented by a structured system of EGS care. Future work should expand upon these findings using more complex discrete-event simulation models.

Level of Evidence: Level III Epidemiologic Study

Keywords

Regionalization of EGS Operations; Simulation study

BACKGROUND:

The concept of regionalization is founded on the idea that medical and surgical resources should be efficiently allocated, coordinated, and utilized within a well-defined system of care to best optimize patient outcomes for a given geographic region. In our modern medical ecosystem, where value-based care is increasingly being promulgated and endorsed, regionalization in health care is getting a lot of attention. The National Academy of Medicine[1] and the National Quality Forum[2] have both advocated for regionalized approaches to health care, especially for time-sensitive acute medical and surgical conditions. The American College of Surgeons, across multiple surgical disciplines, is likewise advocating for reorganizing and restructuring how and where certain surgical care is delivered, including the integration of surgical care delivery across geographic areas.[3] In addition, major academic hospital systems, including Dartmouth-Hitchcock Medical Center, the University of Michigan Health System, and the Johns Hopkins Hospital and Health System, have banded together to promote regionalization of surgical procedures to higher volume hospitals via the “Take the Volume Pledge” campaign.[4]

In this context, it has been theorized that a tiered, regionalized system of care for emergency general surgery (EGS) patients, with designated and verified “EGS centers,” would translate into significant survival benefits for EGS patents.[5-12] Such a system would change how EGS emergencies are triaged and redefine when and where EGS patients are managed. While there are many reasons to believe that a regional EGS system would improve outcomes in EGS patients, including the national crisis in emergency surgical care,[1,13] surgical workforce shortages,[13] and the increased burden on emergency departments to manage surgical patients,[14,15] data to support the widespread implementation of regional EGS systems are lacking.

Building on our prior work which demonstrated a clear relationship between hospital EGS operative volume and mortality-outcomes[9], the aim of the current study was to determine the potential number of deaths that could be prevented by regionalizing EGS care to higher-volume, lower-mortality EGS institutions. Our prior study, similar to the volume-outcome studies in the field of trauma[16-18] which helped to justify the creation of regionalized trauma care, suggested a potential benefit to regionalizing EGS care to higher-volume hospitals. By simulating a variety of different possible regionalization scenarios, the current study sought to provide EGS thought leaders, stakeholders, policymakers, and clinicians with objective data on the effect of a regionalized system of EGS care aimed at preventing EGS deaths.

METHODS:

Datasets & Variables:

We conducted a retrospective cohort study of all adult patients (≥18 years) who underwent one of ten EGS operations in the state of California over a 24-month period, from January 1, 2010 to December 31, 2011. The ten operations included: appendectomy; cholecystectomy; colectomy; inguinal & femoral hernia repair (analyzed together); lysis of adhesions (LOA; no bowel resections were performed in the LOA group); necrotizing soft tissue infection (NSTI) excision; repair of perforated peptic ulcer (gastric or duodenal ulcers); small bowel resection; umbilical hernia repair; and ventral hernia repair. Both laparoscopic and open operations were included; trauma operations were excluded.

For the current analyses, only patients undergoing urgent/emergency operations with specific EGS diagnoses were included. Patients were identified using International Classification of Disease, 9th Edition (ICD-9), procedural codes (the full list of procedural ICD-9 codes can be found in our prior manuscript[9]); only patients who were listed in the SID dataset as having undergone one of the ten operations as a primary core operation were included. ICD-9 diagnosis codes identified patients with a specific diagnosis of an EGS condition (the full list of diagnosis ICD-9 codes can be found in our prior manuscript[9]).

The patient populations were chosen as they are among most prevalent emergent surgical procedures/diagnoses requiring operative intervention in the US, and have a non-trivial risk of postoperative morbidity and mortality.[19-21] An operation was defined as being performed urgently/emergently if it was associated with an admission not scheduled at least 24 hours in advance, as defined by the SID unscheduled admission variable.

Two datasets were used. The first was the State Inpatient Database (SID) for California (data from 2010 and 2011). California is the most populous state in the US (population of 37 million in 2011), with a diverse population and varied geography, with both urban and rural areas. The SID is part of a family of datasets developed by the Healthcare Cost and Utilization Project, and sponsored by AHRQ.[22] Data abstracted included patient demographics, chronic health conditions, hospital-based metrics, and in-hospital mortality. The second dataset was the American Hospital Association (AHA) Annual Survey of Hospitals Database for 2010 and 2011.[23] The same California acute care hospitals in the SID and the AHA were paired, thus enabling risk-adjustment at the hospital level.

Acute care hospitals were the only hospital-type included in the analyses. Dedicated pediatric hospitals, rehabilitation hospitals, and government hospitals such as Veteran's Affairs Hospitals were excluded. Only hospitals performing ≥3 of a given EGS operation type over the 2-years were included. We rationalized that this would yield a more consistent, less heterogeneous group of hospitals for comparison.

Statistical Analyses & Outcome Measures:

In a prior manuscript, we found that survival rates for all adult patients undergoing ten different EGS operations were significantly improved when their operations were performed at higher volume hospitals.[9] For each of the ten EGS operations studied, hospital operative volume-thresholds were defined to improve survival; this threshold was the hospital operative volume above which 95% of the hospitals were performing at or above the average mortality rate for that specific operation. By this construct, if a patient were to have an operation at a hospital with an EGS operative volume for that specific surgery greater than the volume-threshold, there would be a 95% chance that that patient’s mortality risk (as defined by hospital mortality proportion) would be lower than the average risk-adjusted mortality for all hospitals performing that same EGS operation.

Prior to running any simulations, an expected, risk-adjusted, pre-regionalization, in-hospital death rate was calculated for each hospital in California. To define this expected mortality, we created hierarchical, Bayesian mixed-effects logistic regression models for each operation separately. A mixed-effects model with hospital-specific intercepts has advantages over the more basic random effects model or a purely fixed effects model.[24] First, it includes an adjustment for both patient-level and hospital-level effects; the inclusion of hospital-level attributes reduces the potential confounding of the patient attribute-risk relation.[24] Second, a mixed effects model allows for the accurate inclusion of smaller hospitals into the analysis by more properly calibrating the estimate of expected death. Our methodology for calculating risk-adjusted expected deaths is described in detail in a prior manuscript.[12]

Using our prior study as a starting point, and to assess our primary aim, we constructed an algorithm that “closed” lower-volume, higher-mortality California hospitals and referred the patients to the remaining higher-volume, lower-mortality institutions. Closure of the under-performing institutions was based on the aforementioned hospital EGS volume-thresholds defined in our prior manuscript[9]: if a given hospital did not achieve the volume-threshold, it was simulated to be closed for that type of operation. Upon closure, patients who had undergone an operation at the closed hospital were then randomly assigned to undergo their operation at a higher-volume hospital, in a manner proportionate to the receiving hospital’s initial pre-regionalization volume; this was the regionalization-simulation. By this construct, the new group of patients undergoing a specific operation type at each post-regionalization hospital was equal to: all pre-regionalization patients at that hospital + new redistributed post-regionalization patients at that hospital. Regionalization-simulations were completed 5000 times for each operation, so 50,000 in total, employing a bootstrap resampling method to redistribute patients.

For every bootstrap resampling, an expected post-regionalization death rate was recalculated at each hospital remaining in the analysis; this was based on the new group of patients undergoing their operation at each hospital after regionalization. As the expected death rate for each operation at each hospital is partly based on patient-level effects, for every single regionalization-simulation, a new expected post-regionalization death rate was calculated based on the redistribution of patients to each hospital.

Our primary outcome was the potential number of deaths prevented, aggregated across hospitals. For every bootstrap resampling, the pre-regionalization death rate was subtracted from the post-regionalization date rate to create a delta death rate – the change from pre-to post-regionalization. If this delta death rate was a negative number, mortality post-regionalization decreased; if this difference was a positive number, mortality post-regionalization increased. To calculate the number of deaths prevented, the delta death rate was multiplied by the total number of patients undergoing each operation type at each hospital for each simulation. This was done as the final step in the individual simulations, meaning 5000 times for each of the ten operations. That number was then averaged to create a mean number of lives saved for every operation.

A two-sided p-value of <0.05 was defined as significant. All statistical analyses were conducting using SAS 9.4 (SAS Institute Inc., Cary, NC). This study was approved by the Human Investigation Committee (HIC) of the Yale University Human Research Protection Program (HRPP) for biomedical research. The HIC is Yale's Institutional Review Board (IRB).

RESULTS:

Over the 2-year study period, 165,123 patients underwent one of the ten EGS operations at 310 different acute care hospitals in California (Table 1). 50,000 regionalization-simulations were run, 5000 for each operation.

For all operations, 17,655 (10.7%) EGS patients were regionalized to higher-volume hospitals; this represented on average 24.9% of patients undergoing each operation type (Table 1). The range in the total number of patients impacted by regionalization varied by operation type: from 470 patients for umbilical hernia repair to 4423 patients undergoing colon resection; the percentage of patients impacted ranged from 3.9% for cholecystectomy to 56.8% for repair of perforated peptic ulcer disease. In terms of hospitals impacted by regionalization, on average 128 acute care hospitals in California were “closed” for each type of surgery; this represented on average 48.8% of hospitals performing each operation type (Table 1). The range in the total number of hospitals impacted by regionalization varied by operation: from 68 hospital closures for appendectomy to 205 for small bowel resection; the percentage of hospitals impacted ranged from 23.9% for cholecystectomy to 77.6% for repair of perforated peptic ulcer disease.

The simulations demonstrated that EGS regionalization would prevent 586.0 risk-adjusted EGS deaths over the two years, equal to 9.7% of the 6047.7 total expected deaths pre-regionalization. Across operation types, the average percentage of deaths prevented was 12.1% (Table 2). For every EGS operation, regionalization away from lower-volume hospitals and to higher-volume hospitals prevented deaths. The range in the total number of deaths prevented by regionalization varied by operation type: from 30.8 deaths prevented for appendectomy to 122.8 for colectomy; the percentage of deaths prevented ranged from 4.7%

for cholecystectomy to 22.2% for umbilical hernia repair. On average, regionalization prevented 4.6 deaths per 100 EGS patient-transfers, ranging from 1.3 deaths prevented per 100 EGS patient-transfers for appendectomy to 8.0 for umbilical hernia repair.

DISCUSSION:

This simulation study provides important new insights into the concept of implementing a tiered, regionalized system of care for common general surgery operations performed emergently in adults at acute care hospitals in California. By simulating the “closure” of lower-volume, higher mortality hospitals and transferring those patients to higher-volume, lower-mortality hospitals, 1 out of every 10 risk-adjusted deaths for all EGS operations was prevented. Our simulated, structured system of EGS care would, on average, reduce the percentage of risk-adjusted deaths by 12.1% for each operation type. This represents a significant drop in mortality across the different types of EGS operations.

Regionalization has long been a hallmark of trauma care. A regionalized trauma system of care is an organized, coordinated network of healthcare resources that provides a broad spectrum of services and definitive medical/surgical care to the acutely injured trauma patient.[25,26] The services and care start at the scene of the injury by local emergency medical services (EMS), and continue from transportation to emergency room to operating room to intensive care unit to hospital floor to rehabilitation to home.[27] The goal of this highly integrated, multi-layered system of injury management is to optimize the chances of survival among trauma victims by reducing the risks, deleterious consequences, and overall burden of injury.[25,26]

The trauma system consolidates the care of the most severely injured patients into a small number of hospitals qualified as “trauma centers.” Trauma centers have a high level of expertise and readiness, as well as extremely specialized resources required for optimal care of injured patients.[27] The three levels of trauma center classification represent a ranking of the resources available at that center to care for injuries: Level I being the highest level of care, with the greatest readiness and the most resources, while Level III has expertise and readiness below that of Level I and II but above that of a standard acute care hospital.[25,26] The trauma center designation is extremely specific, requiring a thorough and complete verification for accreditation based on standards and guidelines established by the American College of Surgeons Committee on Trauma (ACS COT).[25,26]

Based on the success of trauma centers at saving the lives of injured patients, advocates have suggested that a regionalized system of care for EGS patients and operations concentrated at designated “EGS centers” would improve outcomes.[5-12] At present, we have a disjointed system of managing this unique, often physiologically abnormal EGS patient-population, which has resulted in delays to care, widespread practice variation, and disparate outcomes.[19,28-30] The absence of a well-defined EGS system of care has been compounded by the national crisis in emergency surgical care,[1,13] shortages in on-call surgical coverage throughout the US,[13] and increased burden on emergency departments to assess, triage, and initially manage surgical patients[14,15].

We therefore set out to inform one extremely important aspect of a tiered, regionalization system of EGS care: the potential to prevent deaths. Our findings suggest that a regionalized system of EGS care can save lives and decrease mortality. This is true of every EGS operation we studied, from lower-complexity, lower-mortality operations (appendectomy and cholecystectomy) to higher-complexity, higher-mortality operations (colectomy and repair perforated peptic ulcers). The prospect of preventing 12.1% of deaths (ranging from 4.7% to 22.2%, depending on the EGS operation; Table 2) would be a beneficial advancement for the field.

Regionalizing care, however, does not come without consequences, and the potential benefit to patients may be to the detriment of some surgeons, staff, operating rooms, and institutions. Accordingly, “closing” hospitals in a simulation study is very different than having actual operations cease in the operating rooms of smaller, lower-volume hospitals in remote settings of California. While the average proportion of hospitals which were simulated to stop performing EGS operations was over 40% (ranging from 22.0% to 77.6%, depending on the EGS operation; Table 1) it may be that only the highest-risk EGS operations should be stopped at some hospitals rather than all EGS operations; in other words, only the highest-risk EGS patients at the extremes of EGS disease should be transferred. Additionally, a regionalized system has the potential to cause delays to surgical therapy due to longer travel times as well as overwhelm the capacity of the post-regionalization institutions by increasing their volumes and outstripping their resources. These scenarios may negate the survival-benefits of the structured system of EGS care. In this context, the current study represents one additional step on a pathway of investigation for moving EGS away from fragmented delivery systems and towards more coordinated, cooperative, integrated care that prioritizes patient outcomes.

Future work should expand upon these findings using increasingly complex simulation models based on advanced triage algorithms. For example, discrete-event simulation models can compare triage criteria, incorporate hospital resources and time to definitive care, and study the impact on access to care for resource-limited populations. In the present study, we were not able to assess if a hospital has an acute care surgery service. This is important, as recent evidence points to the significant mortality benefits of the acute care surgery practice paradigm to manage EGS operative emergencies as compared with the traditional general surgery service model; specifically, the multi-institutional study found a 31% reduction in 30-day mortality in EGS cases when managed under an acute care surgery service.[31] Accordingly, incorporating such hospital-level attributes into more advanced triage algorithms and simulation models should be explored.

The present study has limitations. First, the patients in our simulations were proportionally yet randomly assigned to new hospitals at which to have their operations; this may not accurately simulate a logical EGS system of care. Second, we used a retrospective administrative dataset, and our conclusions are thus constrained by their intrinsic limitations and biases, such as selection bias and misclassification bias. Third, the data are from the state of California, and generalizations to other areas of the United States or to a national level may not be valid.

In conclusion, this regionalization-simulation study provides important new insight into the concept of EGS regionalization, suggesting that 1 in 10 risk-adjusted deaths could be prevented by a structured system of EGS care. Our findings provide EGS thought leaders, stakeholders, policymakers, and clinicians with evidence suggesting a mortality benefit for regionalized EGS care. Future work should expand upon these findings by increasing the complexity and decision-making algorithms of the simulation models.

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Table 1:

Characteristics of 165,123 Patients and 310 Hospitals Impacted by Regionalization-Simulations in California, by Operation Type

Operation	Patient Characteristics			Hospital Characteristics		
	Number operations	Number of patients "moved"	% of patients "moved"	Number hospitals	Number of hospitals "closed"	% of hospitals "closed"
Appendectomy	52905	2285	4.3	305	68	22.0
Cholecystectomy	69052	2668	3.9	310	74	23.9
Colectomy	12574	4423	35.2	292	192	65.8
Inguinal & Femoral Hernia	3757	483	12.9	265	91	34.3
Lysis of Adhesions	9343	1110	11.9	292	110	37.7
Necrotizing Soft Tissue Infection Excision	2616	767	29.3	228	126	55.3
Repair of Perforated Peptic Ulcer Disease	2231	1267	56.8	245	190	77.6
Small Bowel Resection	7447	3450	46.3	280	205	73.2
Umbilical Hernia	1737	470	27.1	209	107	51.2
Ventral Hernia	3461	732	21.1	259	121	46.7
Average (by column)	--	--	24.9	268.5	128.4	48.8
Total	165123	17655	--	--	--	--

Table 2:

Impact of Regionalization on Preventing Deaths After EGS Operations, Based 50,000 Bootstrap Resampled Simulations

Operation	Number deaths prevented, over 2 years	Standard deviation of average	% of deaths prevented	Rate of deaths prevented, per 100 patient transfers
Appendectomy	30.8	0.1	6.5	1.3
Cholecystectomy	49.1	0.1	4.7	1.8
Colectomy	122.8	0.9	7.9	2.8
Inguinal & Femoral Hernia	31.5	0.3	12.3	6.5
Lysis of Adhesions	62.7	0.5	9.4	5.6
Necrotizing Soft Tissue Infection Excision	41.7	0.5	12.1	5.4
Repair of Perforated Peptic Ulcer Disease	67.4	0.8	17.0	5.3
Small Bowel Resection	99.0	0.9	11.0	2.9
Umbilical Hernia	37.4	0.4	22.2	8.0
Ventral Hernia	43.6	0.4	17.7	6.0
Average (by column)	--	0.5	12.1	4.6
Total	586.0 *	--	--	--

* The total number of risk-adjusted deaths was expected to be 6047.7 before regionalization, and 5461.7 after regionalization -- a decrease of 9.7%.