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Variation in the volume-outcome relationship after rectal cancer surgery in the United States: Retrospective study with implications for regionalization

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ABSTRACT

Background: Previous studies have demonstrated improved outcomes for patients with rectal cancer treated at higher-volume hospitals. However, little is known whether heterogeneity in this effect exists. The objective was to test whether the effect of increased annual rectal cancer resection volume on outcomes is consistent across all hospitals treating rectal cancer.
Methods: Adult stage I to III patients who underwent surgical resection for rectal adenocarcinoma from 2004 to 2016 were identified in the National Cancer Database.
Results: We included 120,522 patients treated at 763 hospitals in this retrospective cohort study. Higher volume was linearly and incrementally related to outcomes in unadjusted analyses. In adjusted models, for an average patient at the average hospital, the effect of increasing the annual caseload of rectal cancer resections by 20 resections per year was associated with 8%, (hazard ratio = 0.92, 95% confidence interval = 0.87, 0.97), 18% (odds ratio = 0.82, 95% confidence interval = 0.70, 0.98), and 16% (odds ratio = 0.84, 95% confidence interval = 0.73, 0.95) relative reductions in 5-year overall survival, 30-, and 90-day mortality, respectively, and with a 19% (odds ratio = 1.19, 95% confidence interval = 1.04, 1.36) relative increase in the rate of neoadjuvant chemoradiation. These effects varied by individual hospitals such that 39% of hospitals do not see any benefit in 5-year overall survival associated with higher volumes. Increased volume was associated with lower positive circumferential resection margin rates at 19% of the hospitals.
Conclusion: This study confirms that higher-volume hospitals have improved outcomes after rectal cancer surgery. However, there exists significant variation in these effects induced by individual within-hospital effects. Regionalization policies may need to be flexible in identifying the hospitals that would achieve enhanced benefits from treating a larger volume of patients.

Introduction

Treatment for non-metastatic rectal cancer involves a multidisciplinary approach utilizing surgery, chemotherapy, and radiation.[1–4] As such, complex treatment decisions need to be coordinated across several physicians in order to effectively care for rectal cancer patients. Unwarranted variations in the delivery and quality of rectal cancer care have been reported, often exposing large discrepancies in patient outcomes between hospitals.[5–8] It is hypothesized that higher volume hospitals experience improved outcomes due to an array of advantages, including greater technical experience, utilization of multidisciplinary care, and adherence to evidence-based guidelines.[9,10]

Policies regarding regionalization of high-risk cancer care to higher volume hospitals have gained attention in the last 3 decades and have been supported by the Leapfrog Group, among others.[11–14] Centralization of rectal cancer care has already been legally enforced in several European countries.[15,16] For example, rectal cancer can only be treated at hospitals in the Netherlands that meet a minimum requirement of 20 resections per year. Yet, it remains to be seen whether these policies can be implemented in the United

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States, where the incentive structure introduces unique barriers. Furthermore, there is still debate regarding the association between higher volume and improved outcomes for colorectal cancer. Although many observational studies have noted a robust volume-outcome relationship, several systematic reviews and meta-analyses have reported mixed results; some have reported no association, whereas others have reported a wide range of effect sizes.[17–20]

An important limitation that has undermined previous studies evaluating the volume-outcome relationship is their reliance on exclusively modeling between-hospital differences in volume effects, inevitably overlooking heterogeneity in volume that can occur within the same hospital. Studies have assumed that the net benefit of higher volume is consistent across all individual hospitals, an assumption that surprisingly has been unchallenged and could explain some of the discrepancies in the literature. Investigating whether the improvements in outcomes associated with increases in volume are heterogenous across individual hospitals by measuring both within- and between-hospital effects could help inform implementation of future policies regarding regionalization.

To address this, we used a hospital-based registry in the United States to characterize variations in hospital-specific effects of higher volume. The objective of this study was to measure the association between annual hospital rectal cancer resection volume with outcomes and test whether this association varies by individual hospitals.

Methods

Data source and study population

This study was granted institutional review board exempt status by the Rush University Medical Center Institutional Review Board because it was a secondary analysis of de-identified data. We queried the National Cancer Database participant user file for patients $\geq$18 years old who were diagnosed with American Joint Committee on Cancer (AJCC) stage I–III rectal cancer (International Classification of Diseases for Oncology, third edition codes C19.9 and C20.9) between 2004 and 2016 and who underwent potentially curative resection at participating hospitals. We limited the sample to patients with adenocarcinoma. Patients with missing data were excluded. Most variables had complete data, and no variable had more than 6% of missing values, suggesting that a complete case analysis was appropriate. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines.

Exposure

Hospital volume was defined as the annual number of rectal cancer resections performed at each hospital during the study period. Thus, hospital volume could vary within each hospital year by year. Hospital volume was modeled as a continuous variable, and the assumption of linearity was verified graphically. While hospital volume is commonly categorized into categories (eg, tertiles), this practice can lead to a loss in statistical power while artificially inducing bias, which is why the STROBE guidelines do not recommend categorization. For these reasons, hospital volume was treated as a continuous variable allowing for the risk in outcomes to change incrementally for every increase in annual volume of 1 patient. This 1-unit effect is additive, so it can be scaled to any contrast for presentation. We scaled this variable to present the change in risk associated with each increase in annual hospital volume of 20 patients (eg, 10 versus 30, 20 versus 40, 25 versus 45, etc).

Outcomes

Five-year overall survival (5-year OS) was the primary outcome and was defined as the interval between the date of surgery and the date of death while being censored at last contact or at 5 years, whichever came first. Secondary outcomes included 30-day postoperative mortality, 90-day postoperative mortality, positive circumferential resection margin (CRM, $\leq$1 mm to the margin), and receipt of neoadjuvant chemoradiation (stage II and III patients only).

Potential confounders

Adjustment was made for the following confounders: sex, age, race/ethnicity, AJCC stage, facility type, great circle distance to hospital, geographic location of hospital, insurance status, education, income, Charlson/Deyo comorbidity score, emergency resection, year of diagnosis, and surgical approach.

Statistical analysis

Median volumes by baseline characteristics and dichotomous outcomes were compared using correlation coefficients and Kruskal-Wallis analysis of variance tests as appropriate to the data. For unadjusted survival analyses evaluating the association between continuous hospital volume and 5-year OS, we generated a scatterplot of survival probabilities by hospital volume.

For adjusted survival analyses, we fit a 2-level survival model (patients clustered in hospitals) with an exponential baseline hazard function to estimate the adjusted association between hospital volume and 5-year OS. Because annual volume changes over time within each hospital, this approach fits individual submodels relating volume and outcome within each hospital and borrows power from other hospital sub-models. This unique feature of partitioning between and within hospital variation in an effect estimate gives multilevel models their appeal and offers superior inferences compared to standard approaches that only fit one model for all hospitals.

The survival model included both a random intercept and a random coefficient for hospital volume using the PUF_FACILITY_ID as the clustering variable. The random intercept accounts for between-hospital variation in the baseline 5-year risk of death and allows hospitals to have varying intercepts for the baseline risk. The variance of this random intercept effect, σ_1, was estimated from the model. The random coefficient for hospital volume, on the other hand, allows the hazard ratio (HR) for higher volume (increase of 20 resections) to vary by individual hospitals as opposed to assuming that increasing volume at every hospital by 20 resections would lead to the same net benefit. This random effect represents the level of heterogeneity between hospitals in the effect of increasing annual volume after accounting for individual within-hospital volume effects. The variance of this random coefficient effect, σ_2, was estimated from the model. The 2 variances of the random effects (random intercepts and random coefficients) were allowed to be correlated, allowing for the estimation of their covariance, σ_{CV}.

This allowed us to estimate a hospital-specific HR for the effect of hospital volume on 5-year OS, accounting for confounders, and clustering on the intercept and volume coefficient. All covariates were centered at the cluster means. As such, the model estimates, for the same average patient, the effect of increasing hospital volume by 20 rectal cancer resections per year *within each hospital* in the study. Regardless of their observed annual volume, the model simulates every hospital treating an average patient and increasing the volume by 20. This allows heterogeneity in the effect of increasing annual hospital volume by specifying individual models within each hospital, thus estimating a separate HR for each. The higher the σ_2, the more the HRs vary.

For the secondary outcomes, which were all dichotomous, we conducted similar analyses as discussed earlier except that we used 2-level logistic regression models instead. We generated distributions of hospital-specific odds ratios (ORs) for the effect of volume on secondary outcomes, accounting for confounders, and clustering on the intercept and volume coefficient. Data management and descriptive analyses were conducted with SAS Version 9.4. Multivariable analyses and modeling were conducted in Version 4.0.3 of R Statistical Software, with the *coxme* and *lme4* packages, while figures were generated with *ggplot2*.

Results

A total of 120,522 patients treated at 763 hospitals met inclusion criteria, with a median annual hospital volume of 17 (interquartile range [IQR] = 27–10 = 17) rectal cancer resections per year. The study population had more males (59%) and included 17% nonwhite patients; 45% had private insurance, and 22% were treated in the South Atlantic, the most represented geographical region. Overall, 37% of patients had stage III disease, and 47% of patients were treated at a comprehensive community cancer center. Hospital volume varied across individual characteristics (complete demographic data available in Table I), but especially across hospital type and hospital geographic location. Figure 1 presents a heatmap of geographic regions by volume, indicating that the West South Central region had the highest volumes of patients. Rates of 30-day mortality, 90-day mortality, positive CRM, and receipt of neoadjuvant chemoradiation were 1.8%, 3.3%, 15.5%, and 41.9%, respectively.

Figure 2 presents a scatterplot of unadjusted survival probabilities by hospital volume. The median follow-up was 54 months (IQR = 60–28 = 32 months). Survival rates improved over time; in 2004–2006, 2007–2009, 2010–2012, and 2013, the 5-year OS rates were 67%, 69%, 69%, and 71%, respectively. The unadjusted 5-year OS of stage I–III rectal cancer patients differed by hospital volume in a dose-response manner. For example, patients treated at hospitals with an annual volume of 40 resections had a survival probability of 78%, whereas patients treated at hospitals with an annual volume of 20 resections had a survival probability of 70%. The incremental survival margin associated with higher volume follows a linear pattern, suggesting that categorization of volume would be biased.

In the adjusted multilevel model for 5-year OS, increasing annual hospital volume by 20 resections per year was associated with an 8% relative reduction in the 5-year risk of death (HR = 0.92, 95% CI = 0.87, 0.97) for the average patient at the average hospital. The between-hospital variation ($\sigma_2 = 0.26$) in the volume effect (ie, HR) was high and statistically significant, suggesting that the HRs that represent the effect of increasing volume on 5-year OS were substantially different between individual hospitals. Figure 3 depicts this between-hospital variation by reporting the hospital-specific HRs and their corresponding 95% CIs, sorted by increasing HR (not by volume). The distribution of these HRs indicates that most hospitals had HRs clustered around the HR for the average hospital. The best performing hospital had an HR of 0.46, indicating that increasing volume by 20 resections at this hospital would be associated with a 54% relative reduction in the 5-year risk of death. This specific hospital had varying annual volumes that ranged between 12 and 24 over the study period. Among the 763 hospitals, 467 hospitals (61%) had varying volume effects that were statistically significantly associated with reductions in 5-year OS, 188 hospitals (25%) would not achieve any benefit from increasing volume, while 108 hospitals (14%) would have worse outcomes if they experienced higher volume. Hospitals that had volume effects that were associated with better survival compared to those with worse survival had similar annual volumes (median = 23 vs 22). Hospitals that had volume effects associated with worse survival were more likely to be in the South Atlantic region and were more likely to be comprehensive community cancer centers and less likely to be academic centers.

Furthermore, there was significant heterogeneity in the baseline risk of death across all hospitals. The between hospital-level variance in baseline survival was large (ie, $\sigma I = 0.17$), and the covariance was −0.57. The negative sign of the covariance between the 2 variances of the random effects indicates that hospitals that had large variation in the baseline risk of death for the average patient had diminished volume heterogeneity.

Table II reports the multivariable results for all outcomes. For an average patient at the average hospital, the effect of increased volume was associated with 18% (OR = 0.82, 95% CI = 0.70–0.98) and 16% (OR = 0.84, 95% CI = 0.73–0.95) relative reductions in 30- and 90-day mortality, respectively, and with a 19% (OR = 1.19, 95% CI = 1.04–1.36) relative increase in the rate of neoadjuvant chemoradiation, while not being associated with positive CRM ($P = .75$). As with 5-year OS, the effect of increasing volume by 20 on all secondary outcomes varied substantially by individual hospitals (Figure 4). For example, the range of hospital-specific ORs for receipt of neoadjuvant chemoradiation was (0.95, 2.97), with 42% of hospitals achieving statistically significant increases, but with a subset of hospitals without any benefit seen or associated with lower rates of neoadjuvant chemoradiation. For positive CRM, most hospitals did not see any changes in positive CRM associated with higher volumes consistent with the average hospital, but 19% did see lower rates of positive CRM.

Discussion

The volume-outcome relationship has been one of the most studied and debated topics in high-risk surgery. In rectal cancer, studies evaluating outcomes in relation to hospital volume are as abundant as they are conflicting. In this national study of patients with rectal cancer, we have shown that a dose-response relationship exists between hospital volume and improved outcomes, but this relationship varies drastically by individual hospitals. While most hospitals see a net benefit from higher volumes, a subset of high- and low-volume hospitals do not see benefit from increased volumes. These patterns were true for all hospital types and regions. Taken together, the results of our study support regionalization as higher volume was associated with improved outcomes, but the amount of benefit varies substantially between hospitals, suggesting within-hospital volume effects strongly influence outcomes. Regionalization may not need to be restricted to hospitals that currently have higher volumes; lower volume hospitals could achieve improved outcomes if the opportunity presented itself.

Several international health systems have successfully centralized rectal cancer care to high-volume hospitals, but these efforts have not been formally implemented in the United States. Proponents of centralization often support the belief that superior technical skill and processes of care at higher-volume hospitals enhance their benefit and impact long-term outcomes. This has gained new attention in the United States with the recent development of The National Accreditation Program for Rectal Cancer (NAPRC), a quality improvement initiative formed by the OSTRiCh Consortium (Optimizing the Surgical Treatment of Rectal Cancer) and the Commission on Cancer of American College of Surgeons.[21,22] The goal of the NAPRC is to improve rectal cancer

Table I
Patient, tumor, and hospital characteristics by hospital volume

	All Patients N (%)	Hospital Volume Median (Quartile 1, Quartile 3)
Overall	120,522	17 (10, 27)
Age, y	Median (Quartile 1, Quartile 3) = 64 (55, 74)	Correlation= −0.08, $P = .02$
Distance, miles	Median (Quartile 1, Quartile 3) = 10 (5, 26)	Correlation= 0.14, $P < .001$
Sex		
Male	70,678 (59)	17 (10, 27)
Female	49,844 (41)	17 (10, 27)
MIS versus open		
MIS	88,461 (73)	17 (11, 27)
Open	32,061 (27)	17 (10, 27)
Insurance		
Not insured	3,894 (3)	16 (10, 25)
Private	54,033 (45)	18 (11, 29)
Medicaid	6,096 (5)	16 (9, 26)
Medicare	55,326 (46)	16 (10, 26)
Other government	1,173 (1)	19 (11, 30)
Charlson/Deyo Score		
0	87,475 (73)	17 (11, 27)
1	24,522 (20)	17 (10, 27)
2	6,011 (5)	17 (11, 26)
≥3	2,514 (2)	17 (10, 27)
Stage at diagnosis		
Stage I	36,060 (30)	17 (10, 27)
Stage II	39,361 (33)	17 (10, 26)
Stage III	45,101 (37)	18 (11, 28)
Race		
White	99,533 (4)	18 (10, 29)
Black	9,432 (8)	17 (10, 26)
Hispanic	6,367 (5)	18 (11, 28)
Other	5,190 (83)	17 (10, 27)
Average zip code household income		
<$38,000	20,836 (17)	18 (11, 28)
$38,000–$47,999	28,835 (24)	17 (10, 27)
$48,000–$62,999	32,372 (27)	17 (10, 26)
≥$63,000	38,479 (32)	18 (11, 28)
Percent no high school degree		
≥21%	20,615 (17)	17 (10, 27)
13%–20.9%	31,721 (26)	17 (10, 27)
7%–12.9%	39,831 (33)	17 (10, 27)
<7%	28,355 (24)	18 (11, 27)
Emergency case type		
No	110,130 (91)	17 (10, 27)
Yes	10,392 (9)	15 (9, 24)
Year of diagnosis		
2004	9,619 (8)	17 (11, 25)
2005	9,558 (8)	17 (11, 25)
2006	9,493 (8)	17 (10, 26)
2007	9,398 (8)	17 (10, 25)
2008	9,297 (8)	16 (10, 27)
2009	9,076 (8)	16 (10, 27)
2010	9,216 (8)	17 (10, 26)
2011	9,175 (8)	18 (10, 27)
2012	9,085 (8)	17 (10, 28)
2013	8,949 (7)	17 (10, 29)
2014	9,457 (8)	17 (11, 29)
2015	9,333 (8)	19 (10, 29)
2016	8,866 (7)	19 (11, 28)
Facility Region		
New England	6,231 (5)	16 (8, 25)
Middle Atlantic	19,166 (16)	19 (11, 29)
South Atlantic	26,535 (22)	18 (11, 29)
East North Central	21,106 (18)	16 (9, 26)
East South Central	8,675 (7)	18 (12, 27)
West North Central	10,848 (9)	19 (12, 28)
West South Central	10,126 (8)	21 (11, 35)
Mountain	5,047 (4)	15 (11, 22)
Pacific	12,788 (11)	13 (9, 21)
Facility Type		
Community cancer	5,217 (4)	6 (4, 8)
Comprehensive community cancer	56,090 (47)	15 (10, 28)
Academic	43,047 (35)	24 (16, 35)
Integrated cancer network	16,168 (13)	17 (10, 25)

MIS, minimally invasive surgery.

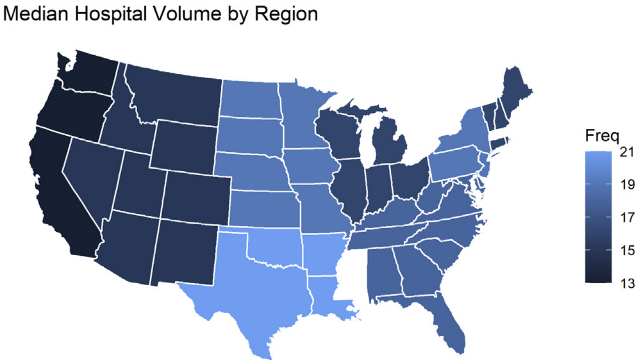

Figure 1. Heatmap of median volumes by geographic region.

outcomes by delivering the highest quality of care provided by the centers that adopt national standards. While the NAPRC does not have a volume threshold, it does endorse the view that higher volume hospitals are associated with superior outcomes. This program inspired a re-examination of the volume-outcome literature, given that it may directly impact future policies.

Our study contributes to this ongoing discussion in several ways. First, while it does not evaluate the effect that a formal regionalization policy would have on outcomes, it does suggest that using a strict volume threshold using current volume standards would regionalize care to a subset of higher volume hospitals that have inferior outcomes and away from a subset of lower volume hospitals that have improved outcomes. For all outcomes evaluated, significant heterogeneity in the volume effect was observed between hospitals, and the subset of hospitals that had muted effects included equal shares of higher and lower volume hospitals. Whether a net benefit would be caused by shifting care to all current higher volume hospitals versus including current lower volume hospitals and accommodating increases to their volume should be further investigated. This is an important practical issue that should be considered given that volume varies widely by geographical region and hospital type. Improved outcomes associated with increases in volume could be achieved by many lower volume community cancer centers. Understanding which processes and factors improve hospital-specific outcomes at all hospitals is of utmost importance, given that continuous quality improvement will be needed to achieve better outcomes.

Second, our study results suggest that the discrepancy in previous studies regarding the volume-outcome relationship in rectal cancer might have been driven by heterogeneity that exists in the volume effects at individual hospitals. This is the first study to test whether the effect of increasing hospital volume varies by individual hospitals using a multilevel random coefficient model. We found compelling evidence that volume effects in rectal cancer may not be static, and previous studies likely introduced bias by assuming that volume effects were consistent among hospitals. This information will be useful for quality improvement programs to consider throughout implementation. Lastly, our study provides interesting data regarding "medium-volume" hospitals, which are often excluded from consideration. Because we used a continuous variable for volume, our results apply to the entire continuum of hospitals without arbitrary categorization. Identifying which hospitals would improve their outcomes with a modest increase in volume should be investigated.

An important point of contention that remains to be resolved relates to the structural and market-based barriers that would have to be overcome to undergo regionalization in the Unites States. A recent study[23] showed that only a small subset of United States' hospitals meets NAPRC standards, and they treat a highly selected group of patients. They also reported that volume was a stronger predictor of survival than adherence to process measures. Thus, NAPRC accreditation will remain difficult to achieve unless standards are loosened or if the variability in volume effects is addressed. Finally, consideration of geographical and urban/rural

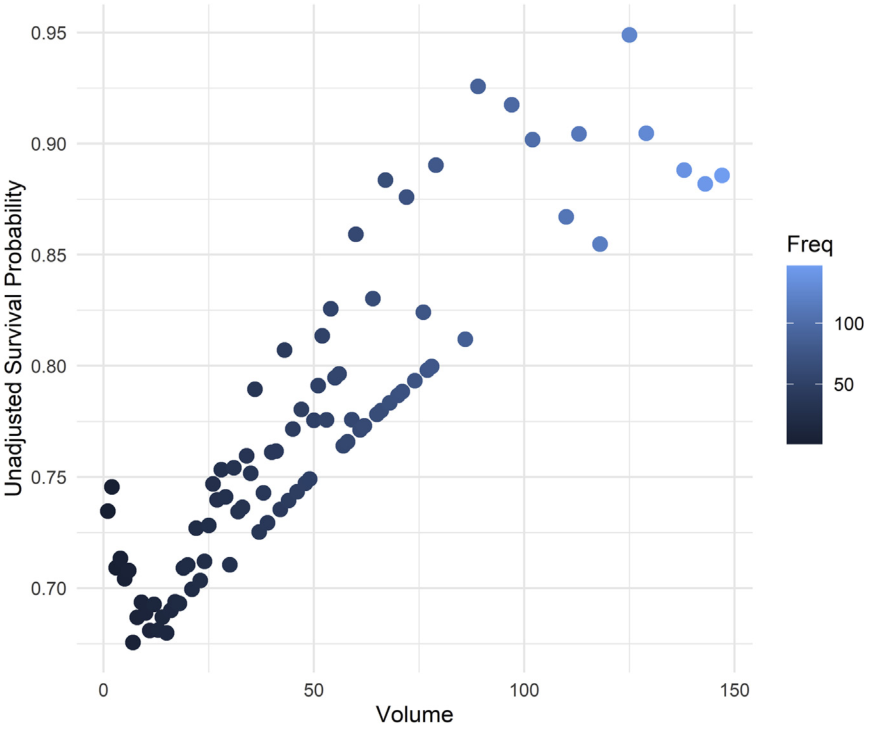

Figure 2. Unadjusted survival probabilities by hospital volume.

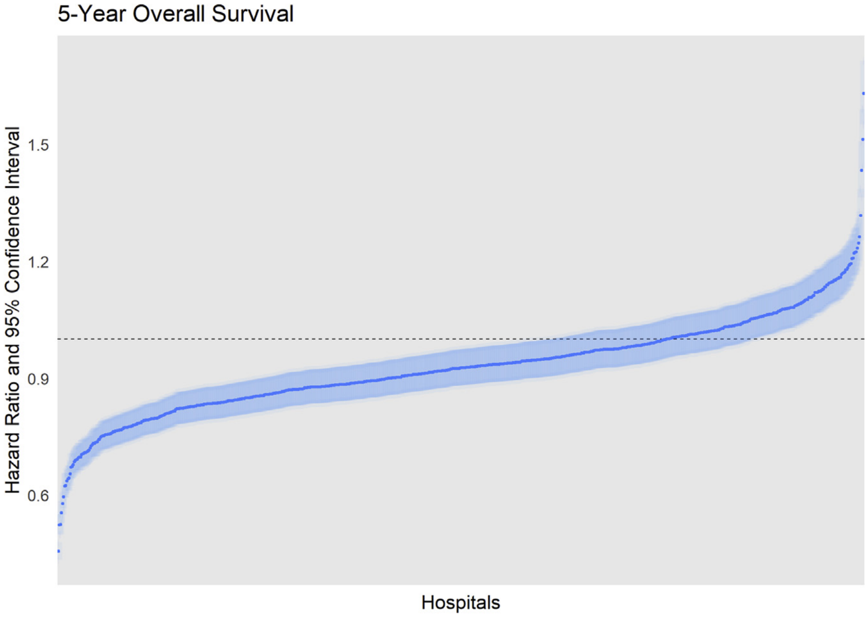

Figure 3. Hospital-specific hazard ratios for 5-year overall survival.

Table II
Results from multilevel models

	Variance of random intercept, Σ_1	Variance of random slope, Σ_2	Covariance, Σ_{cv}	Range of hazard ratios/odds ratios
5-year overall survival	0.17*	0.26*	−0.57*	0.46–1.63
30-day mortality	0.04*	0.16*	0.01	0.54–1.38
90-day mortality	0.04*	0.18*	−0.33*	0.44–1.22
Positive CRM	0.27*	0.44*	0.13*	0.22–8.96
Neoadjuvant chemoradiation	0.18*	0.74*	0.20*	0.15–7.34

CRM, circumferential resection margin.
* P value <0.001

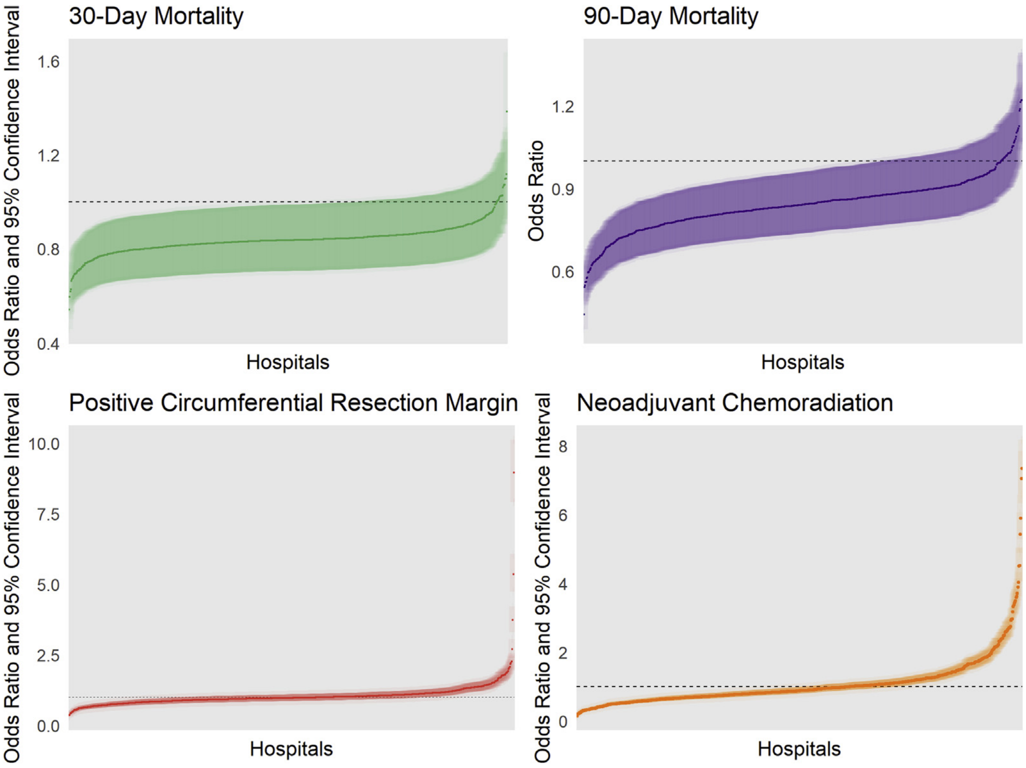

Figure 4. Hospital-specific odds ratios for secondary outcomes.

barriers in designing standards for regionalization will be needed but have yet to be considered within a comprehensive national framework. Our study may directly inform how to optimally allocate hospitals that perform well. Specifically, we noted that hospitals that had volume effects associated with worse survival were more likely to be in the South Atlantic and were more likely to be comprehensive community cancer centers. Hospitals that meet these criteria could be thoroughly evaluated to discern whether such volume effects are truly detrimental.

Our study is not without limitations. We categorized patients based on the hospital at which they underwent surgery. Given that patients may be referred across multiple hospitals and are often cared for at different hospitals depending on the treatment modality, ascribing effects to a single hospital may bias our understanding of hospital volume. Further, our study is an observational study that is subject to well-known National Cancer Database limitations in coding accuracy, lack of disease-free survival data, and potential for unobserved confounding and selection bias. We attempted to mitigate this limitation by adjusting for a comprehensive list of patient, tumor, and hospital characteristics in a model that appropriately modeled the between- and within-hospital variation in volume effects associated with outcomes. This allowed us to address an important conceptual limitation, namely that all previous studies had assumed that there was no variation in volume effects by individual hospitals. Finally, the database does not contain any information on surgeon volume and characteristics, which likely influence survival and other outcomes. Future studies are needed to discern whether variation in surgeon volume effects exists and whether they explain the hospital level volume effects that we report.

In conclusion, in this national study of non-metastatic rectal cancer patients, we have shown that patients treated at higher-volume hospitals experienced improved outcomes. However, the story is more complex and nuanced. The effect of increased volume varied widely such that some hospitals experienced enhanced volume effects, but a subset did not experience any improvement in outcomes. This variation is heterogeneous in a linear fashion along the volume continuum. Our results suggest that future regionalization policies should include current lower volume hospitals that could achieve better outcomes if increased patient referral is feasible, as well as those current higher volume hospitals that are already achieving optimal outcomes.

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Conflict of interest/Disclosure

The authors do not have any conflicts of interest or other disclosures to report.

Supplementary materials

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