Lymph node counts and hospital survival rates after resection for colon cancer

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Abstract

Context. **Several studies suggest improved survival among patients in whom a higher number of nodes are examined after colectomy for colon cancer. The National Quality Forum and other organizations recently endorsed a 12-node minimum as a measure of hospital quality.**

Objective. To assess whether hospitals that examine more lymph nodes after resection for colon cancer have superior late survival rates.

Design. Using the national Surveillance Epidemiology and End Results (SEER)-Medicare linked database (1995-2005), we first identified all patients undergoing colectomy for non-metastatic colon cancer **(n=30,625)**. We first ranked hospitals according to the proportion of their patients in whom 12 or more lymph nodes were examined and then sorted them into 4 evenly sized groups. We then assessed late survival rates for each hospital group, adjusting for potentially confounding patient and provider characteristics.

Study Participants. US Medicare patients residing in SEER regions.

Main Outcome Measures. 5-year survival

Results. Hospitals with the highest proportions of patients with 12 or more lymph nodes tended to treat lower risk patients and had substantially high procedure volumes. After adjusting for these and other factors, there remained no statistically significant relationship between hospital lymph node examination rates and survival after surgery (adjusted hazard ratio, high vs. low hospital quartile, 0.95, 95% CI 0.88-1.03). Hospital lymph node examination rates were not related to the overall use of adjuvant chemotherapy (26% vs. 25%, high vs. low hospital quartile).

Conclusions. **Lymph node examination rates do not predict hospital survival rates following colectomy for colon cancer. Efforts by payers and professional organizations to increase node counts with this quality indicator may have limited value as a public health intervention.**

Introduction

It may be important that a sufficient number of lymph nodes are obtained and examined at the time of primary resection for colon cancer. More complete node clearance may itself result in lower rates of local or distant cancer recurrence. Obtaining more lymph nodes may also benefit patients to the extent that it allows for more accurate cancer staging and thus more appropriate use of adjuvant chemotherapy for patients with node-positive disease (stage III cancer). Numerous observational studies and a recent systematic review suggest that patients in whom a high number of nodes are examined have considerably lower late mortality after colectomy for colon cancer than patients with fewer nodes examined.[1-5] Such studies have prompted interest in using minimum lymph node counts as a quality indicator for colon cancer resection. **Recently, in collaboration with the American College of Surgeons, the American Society for Clinical Oncology, the National Comprehensive Cancer Network, and other stakeholders, the National Quality Forum (NQF) endorsed a 12-node minimum as a consensus standard for hospital-based performance with colectomy for colon cancer.**[6] **Large private payers have already begun incorporating this measure into its pay-for-performance programs.**[7]

Whether such efforts will ultimately improve patient outcomes with colon cancer remain unclear. Apparent associations between the number of lymph nodes examined and survival after colon resection may reflect confounding patient factors as much as quality of care. There is wide biological variation in the quantity and distribution of mesenteric lymph nodes among patients.[8] Patients with more nodes may have a better prognosis because they mount a stronger immunological response to their cancers.[9] In addition, surgeons may perform more extensive nodal dissections in healthier patients, because they are judged more fit to tolerate a bigger operation or because their greater life expectancy prompts a more "aggressive" procedure, such as dissection down to the base of the ileocolic vessel at its takeoff of the superior mesenteric artery for a right colectomy. Associations between lymph node counts and survival may also be confounded by provider factors. For example, higher lymph node examination rates may be correlated with other provider attributes associated with improved survival after surgery for colon cancer, including hospital volume and physician specialization (both surgeons and pathologists). [10-16]

Using data from the national Surveillance Epidemiology and End Results (SEER)-Medicare database, we performed a retrospective cohort study of patients undergoing resection for colon cancer. To better control for unmeasured confounding by patient factors, we examined relationships between lymph node counts and survival at the hospital level, rather than at the patient level. Specifically, we assessed whether hospitals with higher lymph node examination rates had better late survival rates than hospitals with lower rates, controlling for measurable patient and provider factors.

Methods

<u>Subjects and databases.</u> For this study, we used the 1995-2005 national SEER-Medicare linked database. As detailed elsewhere, these files provide a rich source of information on Medicare patients included in SEER, a nationally representative collection of population-based registries of all incident cancers from diverse geographic areas in the US. [17] By the end of the study period, data from population-based cancer registries represented

approximately 26% of the US population. For each Medicare patient in SEER, the SEER-Medicare linked files contain 100% of Medicare claims from the inpatient, outpatient, physician, home health, and hospice files.

From these files, we identified all patients aged 65 to 99 undergoing major resection for colon cancer between 1995 and 2002. All Medicare patients with incident cases of these cancers were identified by the appropriate cancer codes from the SEER files. Those patients undergoing colectomy were identified from the Medicare Inpatient file using the appropriate procedure codes from the *International Classification of Diseases*, version 9. Because lymph node counts are less relevant for this population, we excluded patients with distant metastases (stage IV disease). We also excluded the small proportion of patients who received preoperative radiation therapy, which may confound lymph node counts.

<u>Node examination rates</u>. **We identified all US hospitals at which SEER-Medicare patients underwent colectomy during the study period.** We then characterized each hospital according to the proportion of patients in whom at least 12 lymph nodes were examined (the standard endorsed by NQF), as determined from the appropriate field within the Patient Entitlement and Diagnosis Summary File (PEDSF) from SEER. Hospitals were ranked and sorted into four approximately evenly sized patient groups (quartiles). We repeated our analysis after grouping hospitals by their median lymph node counts, rather than proportions over 12. Because the two exposures measures were highly correlated (coefficient 0.78), results from this sensitivity analysis were nearly identical to those of the baseline analysis and are not presented here.

<u>Analysis</u>. Our primary outcome measure was mortality, determined at five years from the date of resection or through December 31, 2005, which is the end of our follow-

up period. We used Cox proportional hazards models to examine relationships between hospital node counts and mortality, adjusting for patient characteristics, censoring at the end of the follow-up period. We used the patient as the unit of analysis, with the exposure (node examination quartile) measured at the hospital level. We adjusted for age group (65-69, 70-74, 75-79, 80-84, 85+), gender, race (black, non-black), year of procedure, acuity of the index admission (elective, urgent, emergent), tumor location (right, transverse, left, sigmoid colon), and patient comorbidities. **We also adjusted for tumor category (Tis, T1, T2, T3, T4).** Comorbidities were identified using information from the index admission and inpatient encounters from the preceding 6 months, based on methods described by Elixhauser et al. [18] Risk factors were assessed for colinearity, over-fitting and interactions.

Although we subsequently stratified our results by tumor stage, we did not adjust for this variable to avoid introducing bias into our baseline analysis. Hospitals that examine more lymph nodes may appear to have more node-positive patients, even if their patient populations are identical to those at hospitals examining fewer nodes. Risk adjustment would artifactually reward those former hospitals for their "sicker" patients and create a bias toward over-estimating the survival benefit of examining more nodes. As described elsewhere[19], inpatient, outpatient and physician claims files were used to identify patients receiving adjuvant chemotherapy, defined as therapy occurring within 6 months before or after surgery. We did not adjust for receipt of adjuvant chemotherapy in our baseline analysis. Chemotherapy for node-positive patients is hypothesized to be part of the causal pathway underlying potential relationships higher lymph node counts and improved survival and thus not a true confounder. We did, however, adjust for provider characteristics potentially associated with improved late survival after cancer surgery, including hospital teaching status, hospital volume, and surgeon volume.

Since patients admitted to the same hospital may have correlated outcomes, we used marginal survival models that accounted for clustering by hospital. [20] We first assessed within-cluster correlations in patient failure times and derived robust variance-covariance estimators. These estimators were then incorporated into our multivariate Cox proportional hazard models assessing relationships between hospital lymph node examination rates and survival. All p-values are two-tailed. The institutional review board of the University of Michigan approved the study protocol.

Results

Although age and gender did not vary markedly across hospital quartiles, hospitals with highest proportions of patients with 12 or more lymph nodes tended to treat **fewer black patients and more patients admitted electively.** As expected, hospitals with the highest lymph node examination rates had a slightly lower proportion of patients with stage II (node negative) disease (38% vs. 39% at hospitals with lowest rates) and a higher proportion of patients with stage III disease (32% vs. 28%, respectively). **Although statistically significant, there were no clinically important differences in the overall use of adjuvant chemotherapy (26% vs. 25% at hospitals with the highest vs. lowest node rates, respectively).** (Table 1)

Hospitals with the highest lymph node examination rates were more likely to be teaching hospitals than hospitals with lowest rates (58% vs. 33%, respectively) and more likely to be high volume centers (43% vs. 20%, respectively). Surgeon volume did not vary considerably across the hospital quartiles. (Table 1)

Before adjusting for potentially confounding variables, hospitals with the highest node examination rates had higher survival rates after resection than hospitals with the lowest rates. (Figure 1) Unadjusted 5-year survival probabilities for the two hospital groups were 55% and 51%, respectively (p<0.001). Relative to hospitals with low node examination rates, the unadjusted hazard ratio of mortality associated with high lymph node examination rates was 0.88 (95% CI, 0.84-0.93). After adjusting for confounding patient and provider factors, however, hospital lymph node examination rates were no longer associated with survival after surgery (adjusted hazard ratio, highest vs. lowest, 0.95, 95% CI 0.88-1.03). (Table 2) **After adjusting for potential confounding by tumor category, we found that depth of penetration of the tumor had no effect on mortality rates (adjusted HR 0.94, 95% CI 0.87-1.02). In addition to the small differences in survival between hospital groups at the extremes (hospital quartiles 1 and 4), we found no evidence of a "dose-response" effect in the intermediate quartile comparisons. Though none of these differences were statistically significant, hospital quartile 2 had slightly worse survival than quartile 1 (lowest node rates); hospital quartile 4 (highest node rates) had slightly worse survival than quartile 3. (Table 2)**

Table 2 also summarizes relationships between survival and hospital lymph node examination rates in various patient subgroups. As suggested in previous studies, adjusted hazard ratios of mortality between the hospitals with highest nodes counts and lowest node counts were lowest among patients with stage II disease (adjusted HR 0.85, 95% CI 0.74-0.96), compared with those for stage I disease (adjusted HR 0.92, 95% CI 0.78-1.09) and stage III disease (adjusted HR 0.98, 95% CI 0.86-1.11). Patient age and **tumor location** were not important modifiers of the relationship between hospital lymph node examination rates and late survival after surgery. (Table 2)

Discussion

Our study raises questions about the importance of examining a large number of lymph nodes in patients with colon cancer. Using SEER-Medicare data, we profiled hospitals according to how frequently they achieved the 12-node minimum suggested by many experts and then assessed late survival according to this measure. In addition to reducing risks of patient selection bias within hospitals, comparison at the hospital level most directly simulates survival differences that would be observed if lymph node counts were used as a hospital quality indicator for colon resections. Although hospitals with high lymph node counts had higher observed survival rates than hospitals with low counts, absolute survival differences were considerably smaller than previously estimated by patient-level analyses. Moreover, these survival differences largely disappeared after adjusting for confounding patient and provider characteristics.

Our main findings are consistent with one previous hospital-level analysis, which similarly failed to detect a survival benefit associated with higher node counts in a small cohort of patients undergoing colectomy in Canada.[5] However, our findings differ from those of most previous studies, all based on patient-level comparisons, which have suggested that more extensive nodal examination improves patient outcomes.[1-3, 21] A recent systematic analysis summarized data from 17 studies examining the impact of lymph node counts on survival after colectomy for colon cancer.[4] It included population-based studies, single institution retrospective cohort studies, and nested cohort studies which included prospectively gathered data from clinical trials. These studies were too heterogeneous with regards to study populations, outcome measures and node cut-points to allow for formal meta-analysis. However, survival differences between patients with high and low lymph node counts were apparent in most studies. In several, patients in whom the greatest numbers of nodes were examined had hazard ratios of mortality below 0.70, relative to patients with the fewest nodes.

Although their study populations and analytic methods vary widely, previous studies share several limitations that may lead to overestimating the true benefits associated with more extensive lymph node dissection. First, as described earlier, prior studies assessing relationships between lymph node counts and survival may have failed to fully account for confounding patient characteristics. In this study, higher node counts were associated with fewer comorbidities, lower admission acuity, and right-sided colon cancers. Although differences in case mix were relatively small in magnitude, they were sufficient to explain small differences in survival rates associated with hospital lymph node examination rates. Moreover, differences in measurable risk factors increase the likelihood of additional confounding by unmeasured variables. It is plausible that surgeons perform more extensive nodal dissections in healthier patients, because they are judged more fit to tolerate potential complications or because their greater life expectancy prompts the surgeons to be more "aggressive." By focusing on hospital-level comparisons, our study was designed to minimize patient selection bias within hospitals.

Of course, this design does not deal with confounding by unmeasured differences in case mix across hospitals. To this extent, our study no doubt underestimates the extent to which relationships between hospital lymph node examination rates and survival are confounded by patient characteristics.

Second, previous studies have failed to fully account for confounding provider attributes. In our study, hospitals with higher lymph node counts were more likely to be teaching hospitals and had higher hospital procedure volumes. A growing number of studies suggest that higher hospital volumes are associated with improved survival after cancer surgery. [10, 16] Some would argue that obtaining more lymph nodes may be part of the causal pathway underlying apparent relationships between volume and late survival, and thus that we should not have treated volume as a confounder in this study (and adjusted for it). However, our previous analyses suggest that volume and late survival associations are largely independent of lymph nodes counts, implying that volume exerts its effects by a myriad of other processes. [10]

Finally, to avoid biases associated with cancer upstaging at hospitals with high node examination rates, our study focused primarily on overall survival among all patients with non-metastatic colon cancer, not stage-specific survival. However, consistent with findings from previous studies, we found that node examination rates appeared to be most important in patients with stage II (node-negative) disease. This result is not surprising. Hospitals that examine more lymph nodes will tend to find more patients with node-positive disease [22] and more accurately classify node-negative patients. In contrast, more patients classified as stage II at hospitals with low node examination rates may truly be node-positive and experience lower survival. To the extent that it improves cancer staging, higher node examination rates may be valuable in providing stage I or II patients with more accurate prognoses. However, a true survival benefit associated with higher lymph node counts should be evident in improved survival among all patients undergoing colon cancer resection. We failed to detect such benefits in our analysis.

Our study has several limitations. First, our study was limited to Medicare patients over 65 years of age, who represent approximately two-thirds of patients with new diagnoses of colon cancer.[23] The use of SEER-Medicare data, compared to SEER data alone, allowed us to account for patient comorbidities, admission acuity, and provider attributes, all important confounders of relationships between lymph node counts and survival after cancer surgery. In stratified analyses, we found no significant evidence that patient age is an important modifier of relationships between survival and hospital node examination rates. Nonetheless, the generalizability of our findings to patients under 65 years of age is unknown.

Second, our hospital-level comparisons essentially ignore wide variations in the number of nodes examined among patients within hospitals. It is unlikely that such variation is primarily attributable to differences of quality of care within hospitals. At most hospitals, surgical specimens from gastrointestinal resections are evaluated by a small number of pathologists, if not by a single physician. Although there may be variation in surgical technique among surgeons at the same hospital, our conclusions were unaltered when we assessed lymph node examination rates at the surgeon level rather than at the hospital level. For these reasons, we believe that within-hospital variation in the numbers of lymph nodes examined primarily reflects patient factors related to tumor biology and immunology, not quality of care.

Although our study documents wide variation in node examination rates across hospitals, it does not provide insights into why some hospitals are more successful than others in this regard. Although we cannot rule out variation in surgical technique, practices related to processing and evaluation of surgical specimens in the pathology department may also be responsible. Recent studies have suggested that wide variation in the quality of gross specimen preparation and node extraction, tasks which are often performed by technicians.[24] Pathologists may also vary in their skill or diligence in identifying nodes.[25] A better understanding of mechanisms underlying variation in hospital node examination rates with colon cancer would be essential for increasing node counts.

Using lymph node counts as a hospital quality indicator is gaining momentum **from stakeholders in the health care community**. For instance, as part of their pay for performance programs, several large private payers have already begun to hold providers accountable for recovering at least 12 nodes following resection for colon cancer.[7] Our study also suggests that the potential gains in patient outcomes associated with improvements in this process of care may be smaller than many believe. Further studies based on datasets with more clinical detail would be useful for confirming or refuting our findings, and for identifying more effective levers for improving quality of care in patients with colon cancer.

Disclosures

Author contributions. Dr. Birkmeyer had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Birkmeyer, Hollenbeck, and Wong

Acquisition of data: Birkmeyer

Analysis and interpretation of data: Birkmeyer, Ji, Baser, and Wong

Drafting of the manuscript: Birkmeyer, Wong

Critical revision of the manuscript for important intellectual content: Birkmeyer, Baser, Hollenbeck, Morris, and Wong

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Figure legend

Figure 1. Kaplan-Meier plot describing 5-year survival among patients undergoing resection for colon cancer, according to hospital lymph node examination rates. Based on data from the SEER-Medicare linked database, 1995-2005.

Table 1. Characteristics of patients undergoing resection for colon cancer, according to hospital lymph node examination rates. Based on data from the 1995-2005 SEER-Medicare database.

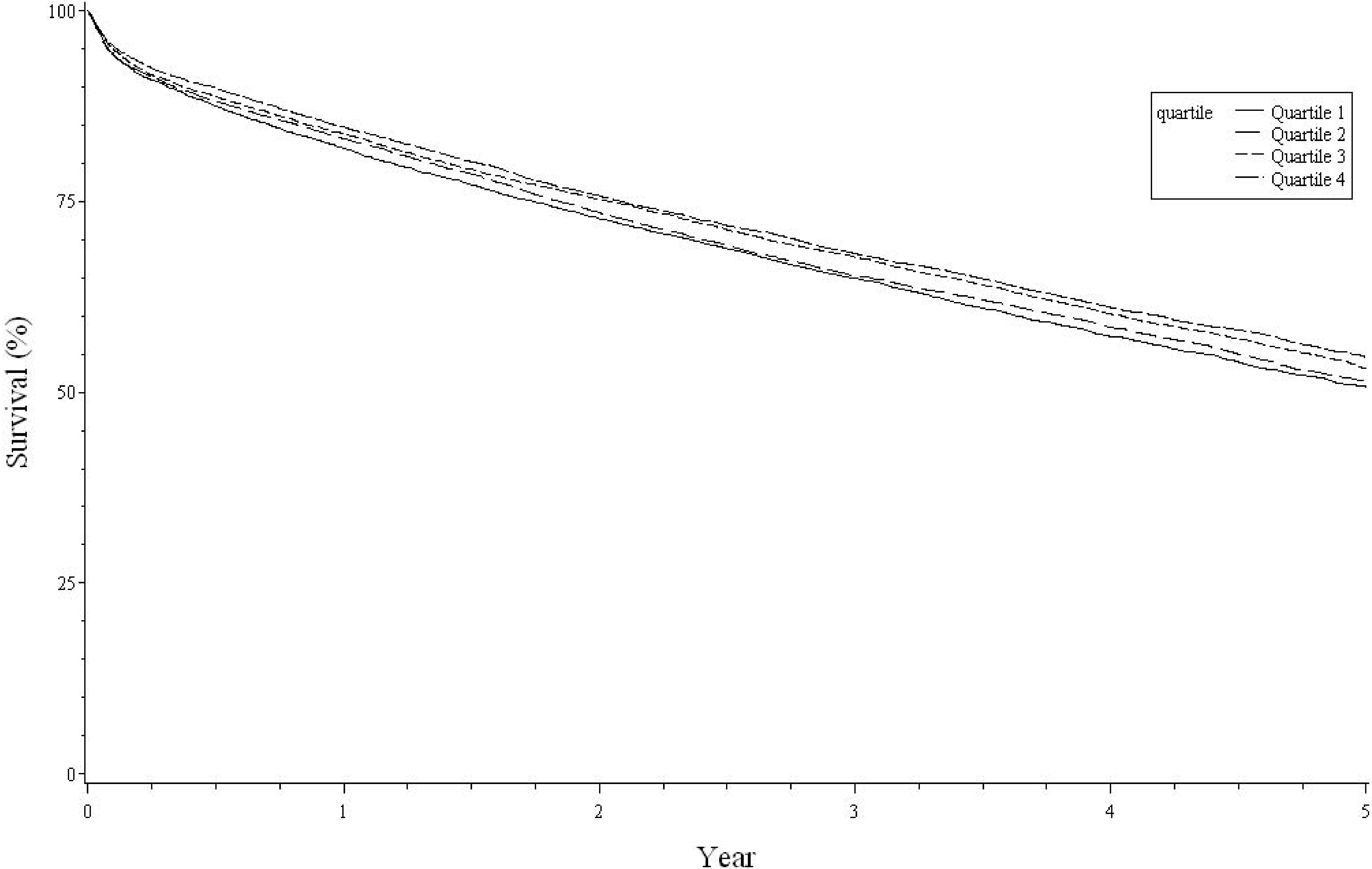
	Hospital lymph node examination rates (Quartile)					
	1st quartile	2nd quartile	3rd quartile	4th quartile	p-value	Hazard ratio of mortality associated with variable (95% CI)
Number of patients	7526	7633	7513	7953		
Number of hospitals	233	225	153	289		
Median number of lymph nodes examined	6	8	10	13		
Mean of lymph nodes examined	5.9	7.7	9.5	14.9		
Proportion of patients with at least 12 lymph nodes examined	**16.2%**	**31.2%**	**43.4%**	**60.7%**		
Patient characteristics						
Age (%)					0.46	
65-69	14.6	15.0	15.2	15.8		1
70-74	21.1	21.5	21.1	21.4		1.28(1.19,1.37)
75-79	23.9	24.4	24.9	24.8		1.59(1.49,1.69)
80-84	21.3	20.3	20.4	20.1		2.20(2.06,2.34)
85+	19.1	18.8	18.4	18.0		3.44(3.23,3.66)
Gender (% female)	56.4	56.4	57.1	56.1	0.71	0.93(0.90,0.96)
Race (% black)	8.1	7.0	9.4	5.4	<.001	1.17(1.10,1.24)
Admission acuity (%)					<.001	
Elective	53.8	57.9	60.2	63.7		1
Urgent	25.2	22.8	17.1	17.9		1.62(1.56,1.69)
Emergent	21.0	19.3	22.7	18.4		2.28(2.19,2.37)
Comorbidity (% 2+)	64.2	63.1	64.2	61.7	0.003	1.99(1.91,2.06)
Tumor location					<.001	
Right	54.9	55.9	56.4	58.7		1
Transverse	9.9	9.9	9.9	9.7		1.04(0.98,1.11)

Left	8.8	9.8	9.7	9.2		1.06(0.99,1.13)
Sigmoid	26.4	24.4	24.1	22.5		0.92(0.88,0.96)
Tumor stage (modified AJCC)					<.001	
Stage 0/I	32.5	31.5	30.7	29.9		1
Stage II	39.4	40.2	39.5	38.3		1.41(1.35,1.47)
Stage III	28.1	28.3	29.8	31.7		2.26(2.16,2.36)
Adjuvant therapy						
Chemotherapy	25.2	27.8	25.2	26.4	<.001	0.94(0.90, 0.97)
Provider characteristics						
Teaching (%)	32.5	38.2	49.4	58.3	<.001	0.98(0.95,1.02)
Hospital procedure volume (%)					<.001	
Low	45.7	38.0	22.2	27.7		1
Medium	34.8	31.4	38.0	29.2		0.93(0.89,0.97)
High	19.5	30.5	39.8	43.0		0.90(0.86,0.93)
Surgeon procedure volume (%)					<.001	
Low	31.7	35.4	34.6	31.8		1
Medium	32.7	33.3	32.6	34.6		1.02(0.97,1.07)
High	35.6	31.3	32.8	33.6		1.08(1.02,1.13)

Table 2. Association between hospital node examination rates and late survival after colectomy for colon cancer, with adjustment for patient and provider characteristics.

	Adjusted hazard ratio of mortality according to hospital node examination rates, (95% CI)			
	Referent group: 1st quartile (lowest lymph node counts)	2nd quartile versus 1st quartile	3rd quartile versus 1st quartile	4th quartile versus 1st quartile
All patients	1.0	1.04 (0.96,1.12)	0.94 (0.87,1.02)	0.95 (0.88,1.03)
Age				
65-69	1.0	1.02 (0.82,1.26)	0.92 (0.73,1.15)	0.90 (0.72,1.11)
70-74	1.0	1.00 (0.84,1.21)	0.93 (0.77,1.13)	0.96 (0.79,1.16)
75+	1.0	1.05 (0.96,1.14)	0.95 (0.87,1.04)	0.95 (0.87,1.04)
Stage				
0/I	1.0	1.04 (0.88,1.21)	0.88 (0.75,1.04)	0.92 (0.78,1.09)
II	1.0	0.99 (0.88,1.13)	0.94 (0.82,1.06)	0.85 (0.74,0.96)
III	1.0	1.06 (0.93,1.20)	0.91 (0.80,1.04)	0.98 (0.86,1.11)
Tumor location				
Right	1.0	1.00 (0.90,1.12)	0.92 (0.82,1.03)	0.94 (0.84,1.06)
Left/sigmoid	1.0	1.12 (0.98,1.29)	0.97 (0.84,1.12)	0.99 (0.85,1.14)

Adjusted for the following patient and provider characteristics: age, sex, race, year of procedure, admission acuity, patient comorbidities, location of tumor, hospital teaching status, hospital volume, and surgeon volume



Survival (%)
100
75
50
25
0
0
1
2
3
4
5
Year
quartile
Quartile 1
Quartile 2
Quartile 3
Quartile 4