

Use and Outcomes of Laparoscopic-Assisted Colectomy for Cancer in the United States

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Background: Laparoscopic-assisted colectomy (LAC) has gained acceptance for the treatment of colon cancer. However, long-term outcomes of LAC have not been examined at the national level outside of experienced centers.

Objective: To compare use and outcomes of LAC and open colectomy (OC).

Design: Retrospective cohort study.

Setting: National Cancer Data Base.

Patients: Patients who underwent LAC (n = 11 038) and OC (n = 231 381) for nonmetastatic colon cancer (1998-2002).

Main Outcome Measures: Regression methods were used to assess use and outcomes of LAC compared with OC.

Results: Laparoscopic-assisted colectomy use increased from 3.8% in 1998 to 5.2% in 2002 ($P < .001$). Patients were significantly more likely to undergo LAC

if they were younger than 75 years, had private insurance, lived in higher-income areas, had stage I cancer, had descending and/or sigmoid cancers, or were treated at National Cancer Institute-designated hospitals. Compared with those undergoing OC, patients undergoing LAC had 12 or more nodes examined less frequently ($P < .001$), similar perioperative mortality and recurrence rates, and higher 5-year survival rates (64.1% vs 58.5%, $P < .001$). After adjusting for patient, tumor, treatment, and hospital factors, 5-year survival was significantly better after LAC compared with OC for stage I and II but not for stage III cancer. Highest-volume centers had comparable short- and long-term LAC outcomes compared with lowest-volume hospitals, except highest-volume centers had significantly higher lymph node counts (median, 12 vs 8 nodes; $P < .001$).

Conclusions: Laparoscopic-assisted colectomy and OC outcomes are generally comparable in the population. However, survival was better after an LAC than after an OC in select patients.

Arch Surg. 2008;143(9):832-840

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COLON CANCER IS THE THIRD most common malignancy in men and women and the second leading cause of cancer deaths in the United States.¹ Most patients present with localized disease and are eligible to undergo resection. In 1991, laparoscopic-assisted colectomy (LAC) was first reported^{2,3}; however, there were concerns regarding the oncologic appropriateness

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of LAC for malignancy, specifically with regard to port-site metastases, adequacy of resection margins, and the extent of lymphadenectomy.⁴ In addition, the technical complexity of LAC could result in increased morbidity and mortality as a result of iatrogenic injuries, anastomotic

complications, bleeding, and longer operative times.⁵ Moreover, it was uncertain whether there would be a long-term survival difference.

These concerns prompted prospective randomized clinical trials to address the safety and oncologic effectiveness of LAC compared with open colectomy (OC).⁶ Although 1 early single-institution trial suggested that LAC may result in better outcomes than OC,⁷ larger subsequent multi-institutional trials and meta-analyses have not detected considerable differences in either short- or long-term outcomes by surgical approach.⁸⁻¹⁴ These multicenter clinical trials were followed by numerous single-institution trials and cohort studies from centers with high-volume expertise or interest in LAC, most of which also demonstrated comparable results for LAC and OC.^{12,13,15-17}

Although more than 300 articles have described LAC performed by experienced surgeons in clinical trials and at

high-volume centers, to our knowledge no studies have examined long-term outcomes of LAC in the general population to assess the generalizability of results from phase 3 clinical trials. Our objectives were to (1) examine use of LAC in the United States, (2) compare short- and long-term outcomes of LAC and OC in the population, and (3) assess the effect of LAC hospital case volume on outcomes.

METHODS

DATA ACQUISITION AND PATIENT SELECTION

The National Cancer Data Base (NCDB) is a program of the American College of Surgeons, the Commission on Cancer, and the American Cancer Society.¹⁸ The NCDB has been collecting data on incident cancers since 1989 and now contains data on more than 21 million patients. The NCDB records approximately 63% of all colon cancer diagnoses in the United States each year.^{1,18}

Patients with primary colon adenocarcinomas that were diagnosed from 1998 to 2002 were identified from the NCDB using *International Classification of Diseases for Oncology* site and histology codes.¹⁹ Patients were excluded if they had nonadenocarcinoma histology, distant metastases, appendiceal tumors, or were younger than 18 years at the time of diagnosis. Rectal cancers were not included in this study. Patient socioeconomic status is not reported to the NCDB, thus median household income was assessed using the patient's zip code at the time of diagnosis based on 2000 US Census Bureau data.²⁰

According to *Registry Operations and Data Standards*²¹ site-specific procedure coding, patients were limited to those who underwent a colectomy, specifically excluding patients who had local procedures (eg, a polypectomy). The surgical approach variable for colon cancer distinguishes whether the procedure was primarily performed using the laparoscopic or open approach.²¹

HOSPITAL CLASSIFICATION

The Commission on Cancer divides hospitals into teaching/research hospitals and community centers based on case volume and access to cancer-related services and specialists. Academic centers must be primarily affiliated with a medical school or be a designated National Cancer Institute (NCI) cancer center.¹¹ Hospitals that report to the NCDB include 32 of 37 NCI-designated comprehensive cancer centers and 67 of 121 major inpatient Veterans Affairs hospitals. The hospital type variable compared NCI, other academic (academic but not an NCI center), Veterans Affairs, and community hospitals. In addition, hospitals were divided into 5 groups (quintiles) based on mean annual hospital LAC volume with approximately equal numbers of patients in the 5 groups.

LAC USE

The χ^2 test for trends was used to assess LAC use over time. Multiple logistic regression was used to assess patient, tumor, and hospital factors predicting LAC. Factors examined include sex, age (<55, 55-65, 66-75, 76-85, >85 years), race/ethnicity (white, black, Asian, Hispanic, and other), median income quartiles, cancer stage (I-III), hospital type, and year of diagnosis. Odds ratios with 95% confidence intervals (CIs) were generated. The Hosmer-Lemeshow goodness-of-fit test and the C statistic of the receiver operating characteristic curve were used to assess the model.

Table 1. Characteristics of Patients Undergoing Laparoscopic-Assisted Colectomy vs Open Colectomy for Cancer

Characteristic	No. (%) of Patients	
	Laparoscopic-Assisted Colectomy (n=11 038)	Open Colectomy (n=231 381)
Sex		
F	5463 (49.5)	120 763 (52.2)
M	5575 (50.5)	110 618 (47.8)
Age, median (interquartile range), y	72 (62-79)	73 (53-80)
Race/ethnicity		
White	9038 (81.9)	194 117 (83.9)
Black	1127 (10.2)	22 844 (9.9)
Asian	265 (2.4)	4226 (1.8)
Hispanic	439 (4.0)	7218 (3.1)
Other	169 (1.5)	2976 (1.3)
Median income, \$		
≥ 46 000	4502 (42.8)	81 708 (37.1)
36 000-45 999	2859 (27.2)	63 505 (28.8)
30 000-35 999	1681 (16.0)	42 379 (19.2)
< 30 000	1486 (14.1)	32 576 (14.8)
Insurance status		
Uninsured	150 (1.4)	4207 (1.8)
Private	2613 (23.7)	44 271 (19.1)
Medicaid	185 (1.7)	4972 (2.1)
Medicare	6302 (57.1)	140 997 (60.9)
Government	249 (2.3)	4203 (1.8)
Other/not otherwise specified	1539 (13.9)	32 731 (14.1)
Tumor location		
Cecum	2409 (21.8)	55 444 (24.0)
Ascending/hepatic flexure	2301 (20.8)	59 309 (25.6)
Transverse	948 (8.6)	22 441 (9.7)
Splenic flexure/descending	1105 (10.0)	22 541 (9.7)
Sigmoid	3937 (35.7)	64 957 (28.1)
Overlapping/not otherwise specified	338 (2.1)	6689 (2.9)
Surgery		
Hemicolectomy	10 450 (94.7)	219 342 (94.8)
Total abdominal colectomy	221 (2.0)	4875 (2.1)
Colectomy with contiguous organ resection	205 (1.9)	3856 (1.7)
Other/not otherwise specified	162 (1.5)	3308 (1.4)
Chemotherapy		
Administered	2617 (23.7)	64 064 (27.7)
Not administered	8421 (76.3)	167 317 (72.3)
Cancer stage		
I	4071 (36.9)	60 023 (25.9)
II	3717 (33.7)	92 126 (39.8)
III	3250 (29.4)	79 232 (34.2)
Hospital type		
National Cancer Institute	437 (4.0)	7734 (3.3)
Other academic	2428 (22.0)	49 923 (21.6)
Veterans Affairs	236 (2.1)	3798 (1.6)
Community	7134 (64.6)	156 785 (67.8)
Other	803 (7.3)	13 141 (5.7)
Census region		
Northeast	832 (7.6)	16 709 (7.3)
Atlantic	1822 (16.7)	38 033 (16.6)
Southeast	2225 (16.7)	48 980 (21.4)
Great Lakes	1786 (16.3)	43 028 (18.8)
South	587 (5.4)	14 949 (6.5)
Midwest	485 (4.4)	18 004 (7.9)
West	982 (9.0)	17 675 (7.7)
Mountain	390 (3.6)	5842 (2.6)
Pacific	1815 (16.6)	25 208 (11.0)

Table 2. Factors Associated With Undergoing Laparoscopic-Assisted Colectomy vs Open Colectomy for Cancer

Characteristic	Patients Undergoing Laparoscopic-Assisted Colectomy, %	Adjusted Odds Ratio (95% Confidence Interval) ^a
All patients	4.6	
Sex		
M	4.8	1 [Reference]
F	4.3	0.95 (0.91-0.98)
Age, y		
<55	5.0	1 [Reference]
55-75	4.8	0.97 (0.91-1.04)
>75	4.2	0.90 (0.83-0.97)
Race		
White	4.4	1 [Reference]
Black	4.7	1.11 (1.04-1.19)
Asian	5.7	0.95 (0.83-1.09)
Hispanic	5.8	1.17 (1.06-1.30)
Other	5.5	1.15 (0.98-1.35)
Median income, \$		
≥36 000	4.8	1 [Reference]
<36 000	4.0	0.86 (0.82-0.90)
Insurance status		
Private	5.6	1 [Reference]
Uninsured	3.5	0.66 (0.55-0.79)
Medicaid	3.6	0.67 (0.57-0.78)
Medicare	4.3	0.90 (0.85-0.95)
Government	5.5	0.74 (0.59-0.93)
Other/not otherwise specified	4.5	0.89 (0.83-0.95)
Tumor location		
Cecum	4.1	1 [Reference]
Ascending/hepatic flexure	3.7	0.91 (0.85-0.96)
Transverse	4.0	0.98 (0.90-1.06)
Splenic flexure/descending	4.7	1.14 (1.06-1.23)
Sigmoid	5.8	1.36 (1.28-1.43)
Overlapping/not otherwise specified	4.9	1.24 (1.09-1.40)
Cancer stage		
I	6.4	1 [Reference]
II	3.8	0.59 (0.56-0.62)
III	3.9	0.60 (0.57-0.63)
Hospital type		
National Cancer Institute	5.4	1 [Reference]
Other academic	4.7	0.76 (0.68-0.85)
Veterans Affairs	5.8	1.04 (0.81-1.34)
Community	4.3	0.70 (0.63-0.78)
Census Region		
Midwest	2.6	1 [Reference]
Northeast	4.8	1.80 (1.60-2.03)
Atlantic	4.5	1.70 (1.53-1.89)
Southeast	4.4	1.66 (1.49-1.84)
Great Lakes	3.9	1.44 (1.30-1.60)
South	3.8	1.50 (1.32-1.70)
West	5.2	2.07 (1.84-2.32)
Mountain	6.2	2.47 (2.15-1.85)
Pacific	6.7	2.63 (2.36-2.93)

^aOdds ratios less than 1 indicate a lower likelihood of undergoing a laparoscopic-assisted colectomy. Adjusted for year of diagnosis.

OUTCOMES AND STATISTICAL ANALYSIS

Margin status was reported as clear (R0), microscopic (R1), or gross/macroscopic (R2) involvement.²¹ Margin status was compared using the χ^2 test. The total number of nodes examined

are also reported to the NCDB. Median node counts were compared using the Mann-Whitney *U* test. Margin status (R0 vs R1/R2) and lymph node evaluation (≥ 12 vs < 12 nodes) were assessed using multiple logistic regression to adjust for potential confounders, including age, sex, race/ethnicity, median income, cancer stage, hospital type, and year of diagnosis.

Perioperative mortality was assessed as death from any cause 30 days after the index operation. Recurrence was defined as any locoregional or distant recurrence after a documented disease-free period. Patients who were never disease-free postoperatively were excluded from the recurrence analysis. Multiple logistic regression was used to assess the effect of surgical approach (LAC vs OC) on perioperative mortality and recurrence while adjusting for age, sex, race/ethnicity, median income, cancer stage, hospital type, and year of diagnosis.

Survival was based on the time from surgery to death or to last contact. Median follow-up was 45 months. Patients receiving diagnoses from 1998 to 2000 were used in the survival analyses, as they had at least 5 years of follow-up data reported to the NCDB. Survival was estimated by the Kaplan-Meier method and compared using the log-rank test.²² Relative survival was also calculated by adjusting the observed survival rates for differences in sex, age, and race/ethnicity based on 2000 US Census Bureau data.²⁰ Relative survival currently serves as the best estimate of disease-specific survival using data from cancer registries.

Cox proportional hazards modeling was used to evaluate the association between surgical approach and survival while adjusting for potential confounders, including patient, tumor, treatment, and hospital factors.²³ The proportional hazards assumptions were confirmed graphically. Hazard ratios (HRs) with 95% CIs were generated.

The logistic regression and Cox models accounted for clustering of outcomes within hospitals using robust variance estimates.²⁴ The level of statistical significance was set at $P < .05$. All *P* values reported are 2-tailed. Statistical analyses were performed using SPSS, version 14 (SPSS Inc, Chicago, Illinois), and Intercooled Stata, version 9.0 (Stata Corp, College Station, Texas). The Northwestern University institutional review board approved this study.

RESULTS

Of the patients with colon adenocarcinoma diagnosed from 1998 to 2002, 11 038 patients underwent LAC at 1223 hospitals, and 231 381 underwent OC at 1681 hospitals (**Table 1**). Of the patients who underwent LAC, 36.9% had stage I, 33.7% had stage II, and 29.4% had stage III cancer. Of those who had an LAC, 4.0% underwent surgery at an NCI-designated hospital, 22.0% underwent surgery at other academic hospitals, 2.1% underwent surgery at Veterans Affairs facilities, and 64.6% underwent surgery at community hospitals.

LAC USE

From 1998 to 2002, use of LAC increased from 3.8% to 5.2% ($P < .001$ for trend). Overall, 4.6% of patients from 1998 to 2002 underwent LAC, and 95.4% underwent OC. In the multivariable analysis, patients were significantly more likely to undergo LAC compared with OC if they were male, younger than 75 years old, black or Hispanic, living in areas with higher median incomes, or using private insurance (**Table 2**). Patients were also significantly more likely to undergo LAC if the tumor was located in the sigmoid colon or if they had stage I disease

(vs stage II or III). Patients were significantly more likely to have an LAC if they were undergoing surgery at an NCI-designated cancer center or a Veterans Affairs hospital compared with community hospitals and other academic centers. Patients undergoing surgery in the West, Mountain, and Pacific census regions were more likely to undergo LAC compared with patients in the Midwest or on the East Coast.

SHORT-TERM OUTCOMES

On univariate analysis, perioperative mortality was lower after an LAC compared with an OC (2.4% vs 3.0%, $P = .001$); however, when adjusted for patient, tumor, and hospital factors, there was not a significant difference in the risk of death within 30 days (HR, 0.91; 95% CI, 0.80-1.03). The median node count was lower in patients who underwent LAC compared with those who had an OC (10 vs 11 nodes, $P < .001$), even after adjusting for differences in patient, tumor, and hospital factors (odds ratio, 0.95; 95% CI, 0.91-0.99). From 1998 to 2002, the proportion of patients with 12 or more regional lymph

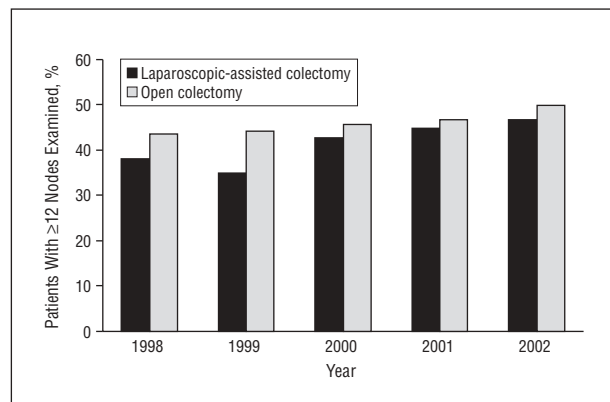


Figure 1. Examination of 12 or more regional lymph nodes in patients who underwent laparoscopic-assisted or open colectomy from 1998 to 2002. $P < .001$ for each year.

nodes examined increased for both those undergoing LAC (from 38.2% to 46.7%) and those undergoing OC (from 43.5% to 49.9%), and the difference in the adequacy of nodal evaluation for LAC compared with OC decreased over time from 5.3% to 3.2% (**Figure 1**). The overall margin-positive resection rate was similar for LAC compared with OC (3.0% vs 2.9%, respectively; $P = .39$) (**Table 3**).

LONG-TERM OUTCOMES

The overall recurrence rate was higher in patients undergoing OC compared with those undergoing LAC (19.7% vs 17.7%, $P < .001$) (Table 3). However, after adjusting for patient, tumor, treatment, and hospital factors, there was not a significant difference in recurrence rates (odds ratio, 0.99; 95% CI, 0.95-1.04). Five-year survival was significantly better with an LAC than an OC (observed: 64.1% vs 58.5%, $P < .001$; relative: 84.8% vs 78.7%, $P < .05$), even after adjusting for potential confounders (HR, 0.91; 95% CI, 0.87-0.96) (Table 3 and **Figure 2**). Five-year survival was significantly better in patients with stage I cancer (observed: 77.0% vs 71.1%, $P < .001$; relative: 98.4% vs 95.6%, $P < .05$; HR, 0.84; 95% CI, 0.76-0.92) and patients with stage II cancer (observed: 63.2% vs 60.3%, $P = .01$; relative: 86.2% vs 83.0%, $P < .05$; HR, 0.92; 95% CI, 0.85-0.99) undergoing LAC compared with those undergoing OC, but there was not a significant difference in survival by surgical approach for stage III disease (observed: 48.4% vs 47.2%, $P = .23$; relative: 63.3% vs 61.9%, $P < .05$; HR, 0.97; 95% CI, 0.91-1.05).

EFFECT OF HOSPITAL LAC CASE VOLUME ON OUTCOMES

From 1998 to 2002, 1223 hospitals reported performing at least 1 LAC. The 34 hospitals in the highest-volume quintile performed 9 or more LACs per year. There were no significant differences by LAC case volume for

Table 3. Overall and Stage-Specific Outcomes for Laparoscopic-Assisted Colectomy (LAC) Compared With Open Colectomy (OC) for Cancer

Characteristic	%				Adjusted Hazard Ratio for Death Within 5 y, (95% Confidence Interval) ^b
	Positive Resection Margins	Recurrence Rate	5-y Survival		
			Observed	Relative ^a	
Overall					
LAC	3.0	17.7 ^c	64.1 ^c	84.8 ^c	0.91 (0.87-0.96) ^c
OC	2.9	19.7	58.5	78.7	1 [Reference]
Stage I cancer					
LAC	0.8 ^c	5.6 ^c	77.0 ^c	98.4 ^c	0.84 (0.76-0.92) ^c
OC	0.5	7.5	71.1	95.6	1 [Reference]
Stage II cancer					
LAC	2.6	17.2	63.2 ^c	86.2 ^c	0.92 (0.85-0.99) ^c
OC	2.6	16.0	60.3	83.0	1 [Reference]
Stage III cancer					
LAC	6.2	33.8	48.4	63.3 ^c	0.97 (0.91-1.05)
OC	5.4	33.2	47.2	61.9	1 [Reference]

^aRelative survival is an estimate of disease-specific survival.

^bHazard ratios less than 1.0 indicate a lower risk of death with LAC.

^c $P < .05$ compared with OC.

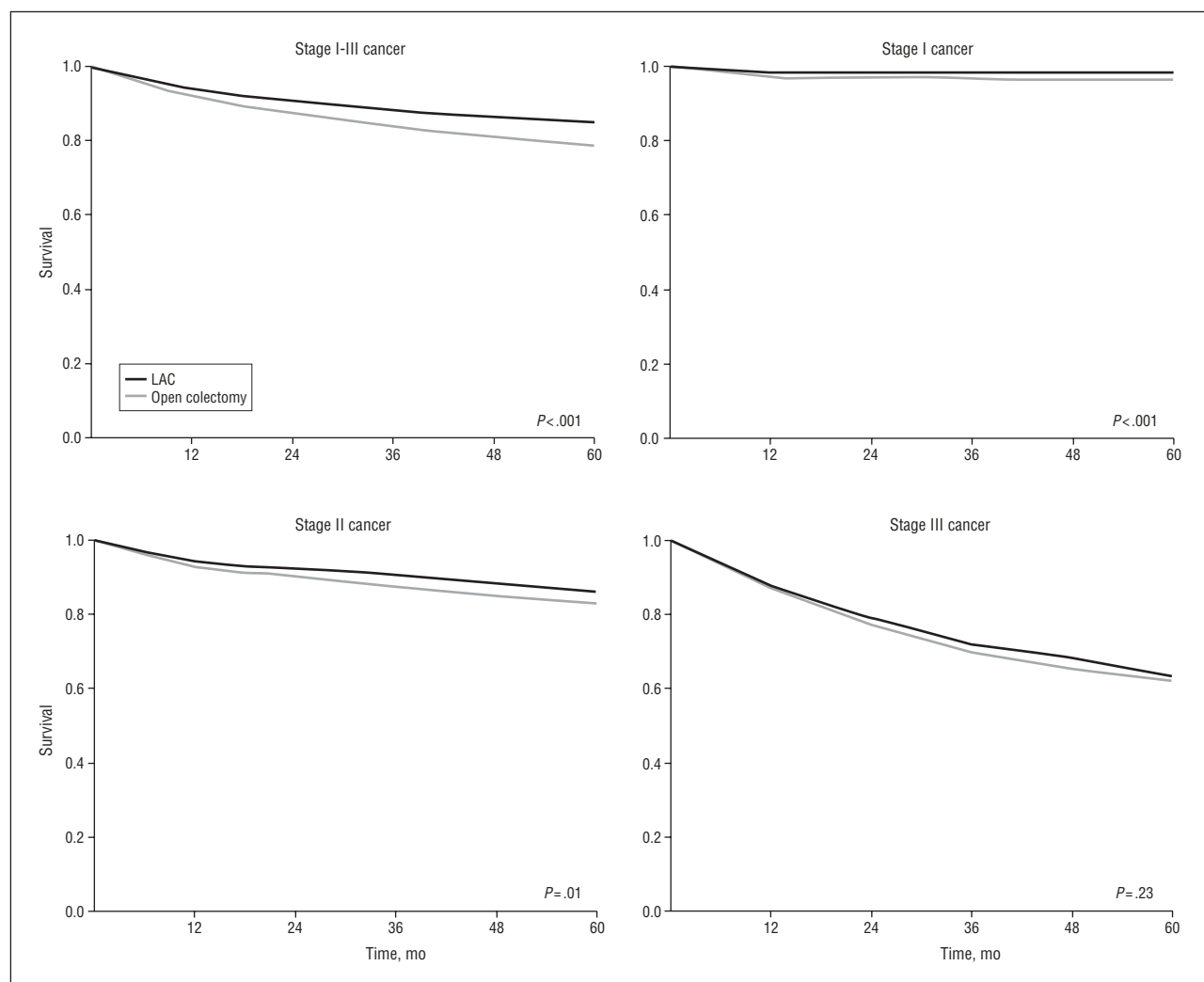


Figure 2. Relative survival by cancer stage comparing laparoscopic-assisted colectomy (LAC) with open colectomy.

Table 4. Effect of Laparoscopic-Assisted Colectomy Case Volume on Outcomes

Measure	Hospital Volume Quintile ^a				
	Highest	High	Moderate	Low	Lowest
Case volume thresholds, cases/y	≥9	6-8	3-5	1-2	≤1
Positive resection margins, %	3.1	3.1	3.2	3.4	3.2
≥12 Nodes examined, % (median nodes examined) ^b	52.3 (12)	44.9 (11)	40.6 (10)	37.3 (9)	33.7 (8)
Perioperative mortality, %	2.1	2.4	2.6	2.2	3.5
Recurrence rate, %	17.2	14.8	15.7	16.8	16.7
5-y observed survival, %	61.3	66.4	65.5	64.2	63.2

^aBased on mean annual hospital laparoscopic-assisted colectomy volume.

^b $P < .001$ for each pairwise comparison of the proportion with 12 or more nodes examined and median node counts. No significant difference across the volume strata for perioperative mortality, resection margin status, recurrence, or survival.

perioperative mortality, margin-positive resection rates, recurrence, or long-term survival by univariate or multivariable analysis, even when comparing highest- and lowest-volume centers (**Table 4**). However, patients undergoing LAC were 2-fold less likely to have 12 or more regional lymph nodes resected and examined at lowest-volume hospitals compared with those at highest-volume centers (52.3% vs 33.7%, $P < .001$; median, 12

vs 8 nodes, $P < .001$; odds ratio, 0.50; 95% CI, 0.43-0.57).

COMMENT

Over the last decade, numerous clinical trials and cohort studies have examined outcomes after LAC and OC

and the results are comparable.^{9,12-14,17} These studies have typically come from large institutions with an interest in and a large case volume of laparoscopic colon surgery. However, long-term outcomes have not been examined in the general population. This is particularly important, as most patients in the United States undergo colon surgery at low-volume community hospitals. Minimally invasive techniques for colectomy will continue to diffuse into the general population.

USE OF LAC

Laparoscopic-assisted colectomy was first described in 1991,^{2,3} and LAC outcomes from members of the Clinical Outcomes of Surgical Therapy (COST) study group were first presented in 1996 and showed acceptable short-term results for the procedure.^{6,25} In 2004, the COST group published the results of their randomized trial, demonstrating that long-term outcomes for LAC were not inferior to those for OC. For patients with localized colon cancer diagnosed from 1998 to 2002, we found that use of LAC for cancer increased by a factor of 33% from 3.8% to 5.2%. When laparoscopic cholecystectomy was introduced in the late 1980s, it was adopted relatively rapidly, as most cholecystectomies performed in the United States shifted from the open to the laparoscopic approach within 3 years.²⁰ However, the technical complexity of LAC, the steep learning curve, longer operative times, and concerns regarding oncologic appropriateness have slowed widespread use of minimally invasive colectomies.¹⁷ Thus, approximately 10 years after the description of the respective minimally invasive procedures for gallbladder and colon surgery, only 5% of colectomies were performed laparoscopically compared with 75% of cholecystectomies.

We found that patients were more likely to undergo LAC compared with OC if they were male, younger, black or Hispanic, living in higher-income areas, or using private insurance or had descending or sigmoid colon tumors or stage I cancer. The factors associated with undergoing LAC likely reflect selection of a lower-risk population, based on both patient and tumor factors, early in the LAC experience. Studies have specifically addressed the applicability of LAC irrespective of age, lesion location along the colon, or stage of disease; thus, most patients are likely eligible for LAC.^{8,26-28} Although black patients were statistically more likely to undergo LAC, the absolute difference is likely not clinically relevant.

LAC VS OC OUTCOMES

A systematic review of short-term outcomes from randomized trials found that LAC and OC resulted in similar margin-negative resection rates and nodal evaluation, but perioperative mortality was significantly lower after LAC.¹⁴ Although some individual studies have suggested better long-term outcomes with the laparoscopic approach,^{7,15} pooled results from 4 prospective randomized trials showed that there was not a significant difference in survival between patients who underwent LAC and those who underwent OC.⁹ A recent meta-analysis of 10 prospective randomized controlled trials also dem-

onstrated that there was not a significant difference in oncologic outcomes for LAC compared with OC; however, there were trends toward lower recurrence rates and longer disease-specific survival rates with LAC.¹² In examining a large, national population of LAC cases, we found that perioperative mortality, positive-margin resection, and recurrence rates were comparable between patients undergoing LAC and those undergoing OC in the general population. Conversely, a higher proportion of patients undergoing LAC had an inadequate lymph node evaluation compared with patients undergoing OC, though this difference decreased over time. Similar differences by hospital volume and type have been shown in a cohort of patients undergoing open colectomy.²⁹ In addition, survival was significantly better after LAC than after OC, particularly for stage I disease. There may be physiologic explanations for why a laparoscopic approach may result in better outcomes than an open approach,³⁰ and it is possible that trials have been underpowered to detect superiority of LAC, particularly the COST study, which was a noninferiority trial.^{8,10} However, the differences in long-term survival observed in our study may likely be a result of patient selection, in which lower-risk patients were chosen to undergo elective LAC. This may particularly be the case for the difference seen in patients with stage I disease—if a polyp were removed via colonoscopy and a close margin necessitated colectomy, those patients may have been preferentially offered LAC.

EFFECT OF CASE VOLUME ON LAC OUTCOMES

Studies have demonstrated that hospitals and surgeons performing more colectomies have better short- and long-term outcomes.³¹⁻³⁴ A subset analysis of the 29 hospitals participating in the Colon Cancer Laparoscopic or Open Resection (COLOR) trial found that the 3 highest-volume hospitals had better short-term outcomes, specifically for inadvertent events, operative time, conversion rate, number of lymph nodes harvested, complication rates, readmission rates, time to first bowel movement, and length of stay.³⁵ No prior studies have examined the effect of hospital LAC case volume on outcomes in the general population. We found that there were minimal differences in short-term outcomes across volume strata, except for lymph node evaluation rates. Highest-volume LAC centers examined a median of 12 nodes compared with 8 nodes at lowest-volume centers. There were no differences in recurrence rates or long-term survival by hospital LAC volume.

COMPARISON WITH CLINICAL TRIALS

Thus far, the COST trial is the only multi-institutional prospective randomized clinical trial focusing on laparoscopic colon surgery that has reported short- and long-term results comparing LAC and OC.^{8,10,11,27,28} Compared with the COST study, margin-positive resection rates, lymph node counts, perioperative mortality, and long-term survival rates were considerably worse in the general population (**Table 5**). Recurrence rates are often underreported in cancer registries owing to the dif-

Table 5. Comparison of Laparoscopic-Assisted Colectomies in the NCDB Population and the COST Prospective Randomized Controlled Trial

Characteristic	%	
	NCDB (n=11 038)	COST Trial (n=435)
Age, median, y	72	70
Cancer stage		
0/I	37	40
II	34	31
III	29	26
IV	0	2
Positive resection margins	3	0 ^a
Lymph nodes examined, median	10	12
Perioperative mortality	2.4	0.5
Recurrence rate (local and distant)	17.6	19.4
3-y Overall survival	74.9	86
5-y Overall survival	64.1	76.4

Abbreviations: COST, Clinical Outcomes of Surgical Therapy; NCDB, National Cancer Data Base.

^aThe COST study reported an inadequate margin (<5 cm from tumor) in 5% of patients undergoing laparoscopic colectomy, but no patients were reported as having involved margins.

ficulty of following patients long-term for outcomes other than death; thus, the actual frequency of recurrences may be higher in the general population compared with the COST trial in which patients were followed closely.

There are multiple factors that may contribute to the better outcomes after LAC observed in the COST trial. First, the 66 surgeons in the COST trial were required to submit a videotape for review of their LAC technique, and they had to have performed at least 20 LACs, an infrequent occurrence in the early 1990s. These surgeons had a higher level of expertise than those in the general population, in which the highest-volume quintile of hospitals performed 9 or more LACs per year. Second, prospective randomized clinical trials impose strict selection criteria.⁸ Third, we recently demonstrated that patients treated at low-volume, community hospitals were significantly older and had more severe comorbidities than patients treated at high-volume centers (K.Y.B., unpublished data, October 2007). As most patients undergoing LAC in the NCDB population were treated at community hospitals, there are likely differences in case mix between the 1223 hospitals in the general population and the 48 COST trial hospitals, which could further explain the more favorable results after LAC in the COST cohort.

STUDY LIMITATIONS

First, specific details are unavailable regarding whether the procedure was converted from the laparoscopic to the open approach, how much of the procedure was performed laparoscopically, whether a hand port was used, and how the vascular ligation and anastomoses were performed. However, the surgical approach is classified in the NCDB according to how most of the resection was performed, and conversions from LAC to OC should be coded as an OC.²¹ In addition, data are not available regarding trocar site recurrences. Second, the NCDB did

not start collecting data regarding comorbidities until 2003. We could not adjust for specific comorbidities in our analysis; however, we did adjust for age, race, and socioeconomic factors that may serve as a limited proxy for comorbidities. Finally, retrospectively comparing the results of surgical procedures may be confounded by indication, as patients could have been selected for LAC or OC based on the clinical situation and patient risk factors, particularly in the early years of LAC. The gold standard for treatment decisions should be evidence from clinical trials, but the results from population-based studies can serve to generate hypotheses for future trials. Despite these limitations, the NCDB offers a unique opportunity to monitor the incorporation and outcomes of novel surgical techniques in the general population.

CONCLUSIONS

As use of LAC expands, particularly among nonspecialists, hospitals and surgeons should track their outcomes using cancer registries and compare their results with those of other institutions. Although the results may be attributable to nonrandom assignment of treatment, LAC could be the procedure of choice in select patients. Larger cooperative trials may be warranted to determine whether LAC is superior in certain patient subsets.

Accepted for Publication: April 7, 2008.

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Author Contributions: Dr Bilimoria 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:* Bilimoria, Bentrem, and Ko. *Acquisition of data:* Bilimoria, Stewart, and Ko. *Analysis and interpretation of data:* Bilimoria, Bentrem, Nelson, Stryker, Stewart, Soper, Russell, and Ko. *Drafting of the manuscript:* Bilimoria and Bentrem. *Critical revision of the manuscript for important intellectual content:* Bilimoria, Bentrem, Nelson, Stryker, Stewart, Soper, Russell, and Ko. *Statistical analysis:* Bilimoria, Bentrem, Stewart, and Ko. *Obtained funding:* Russell and Ko. *Administrative, technical, and material support:* Stewart and Ko. *Study supervision:* Bentrem, Nelson, Stryker, Soper, Russell, and Ko. **Financial Disclosure:** None reported.

Funding/Support: Dr Bilimoria is supported by the American College of Surgeons Clinical Scholars in Residence program.

Previous Presentations: This paper was presented at the 2008 Annual Meeting of the Pacific Coast Surgical Association; February 16, 2008; San Diego, California; and is published after peer review and revision. The discussions that follow this article are based on the originally submitted manuscript and not the revised manuscript.

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DISCUSSION

Michael J. Stamos, MD, Orange, California: This a very important study due to its large size and because it gives us a snapshot of clinical care in the United States during the time period 1998 to 2002. It is quite interesting to note that this was during the era when there was essentially a moratorium on laparoscopic colectomy for curative cancer outside of clinical trials. Obviously, this was not a mandated moratorium, but it certainly may explain the low rates of utilization of this technique and the relative slow advance, at least during this time period. It also may help explain the lower lymph node harvest rate. I notice that you had a higher number of stage I patients in the laparoscopic arm compared with the open arm. Some of these patients may have been going to operation for polyps that turned out to be early cancers. Although many papers have been published showing the importance of treating a polyp like a cancer when you operate on it, in fact that does not always happen, and it may or may not explain some of the lower lymph node harvest rates. So I would be curious if you have any data to suggest that that may or may not be true.

On a similar note, does this database allow any kind of evaluation of gross data of utilization during the periods from 2002 until now? Do you have any preliminary data to suggest that the 5.2% rate has gone up since that time and where it has gone to?

It is also interesting to note that your highest quintile group of hospitals performed only 9 cases per year. That is not per surgeon; that is per hospital! In fact, these 34 hospitals, with this relatively modest annual volume, accounted for 20% of the total volume in the United States despite the fact that they made up only a little under 3% of the overall number of hospitals reporting to the NCDB. I think this is important to keep in mind, as what we define as a high-volume hospital is obviously a very relative term.

You also noted that patients undergoing laparoscopic colectomy at lowest volume hospitals were 2-fold less likely to have more than 12 nodes resected and examined compared with patients at the highest-volume centers. Did you look at these lowest-volume hospitals and highest-volume hospitals to see whether they were also low and high volume for open colectomy; in other words, were they just low-volume hospitals period, or were they just low volume for laparoscopic compared with open? Further, did you look at the lymph node harvest numbers for their open cases? In other words, what I am trying to say is, is this a pathologist issue or is this a surgeon issue?

The reason I ask that question is that your lymph node harvest rate did not seem to correlate with your observed patient outcome or survival. Others have found similar results so this may just be the confounding nature of lymph node evaluation or the small differences absolutely between the 2 groups.

Perhaps the most important and controversial finding in this study is the improved outcome or cancer-related survival in the laparoscopic cases compared with the open cases. Again, as you pointed out, the COST trial did not show this

and neither did the COLOR trial nor the CLASICC [Conventional vs Laparoscopic Surgery in Colorectal Cancer] trial. Antonio Lacey's single-institution trial out of Barcelona, published in 2002, did show improved cancer-related survival, although it was largely confined to stage III patients in contrast to yours where it is mostly stage I and stage II patients. There was also a recent meta-analysis combining the COLOR, the COST, and the CLASICC trials that found no difference in cancer-related outcomes. It is certainly possible that the reason your study found a better outcome was because of its large size compared with these randomized trials, and it may be that these other trials were just simply underpowered and it was not their end point. The other possibility of course is patient selection, as you pointed out, or surgeon selection; that is, maybe the most experienced and most qualified surgeons are doing the cases laparoscopically and perhaps they are "cherry picking" the most favorable cases. I would appreciate your thoughts and comments. In particular I would like your opinion as to how we could really answer this question definitively, how big of a study that would take.

Dr Russell: I think before I try to answer some of Dr Stamos' questions, I would like to point out the power of these databases. I think it is really important as surgeons that we have some ability to collect and control data. I think that ACS NSQIP [American College of Surgeons National Surgical Quality Improvement Program] provides good data for examining short-term outcomes, and the NCDB is good for assessing long-term oncologic outcomes.

With respect to some of Dr Stamos' questions, obviously the utilization rate of laparoscopic colectomy is still low, probably

a reflection of the moratorium that you mentioned and the complexity of the procedure. Recent studies have shown that, even in 2006, utilization of laparoscopic colectomy remains in the 6% to 8% range. Cancer registries in the United States stopped collecting the laparoscopic vs open field in 2003, so we are going to try to change this so detailed data can be collected regarding the surgical approach. The volume thresholds were defined a priori based on quintiles with equal numbers of patients in each category. This allows for good discrimination between the groups while providing enough statistical power to make reasonable inferences.

If the operation is being performed, it is being performed for a reason. It should be a standard cancer operation each time. An appropriate number of lymph nodes should be resected and examined any time a colectomy is done for cancer. The low node counts are somewhat concerning, and they are related to the hospital case volume. This volume–node count association was seen for both open and laparoscopic cases. We think that lymph node examination needs to continue to be improved. The low node count may be related to the pathologists' interest and diligence. But, nevertheless, this will become more often used, and I think payment may be linked to the count.

There are certainly selection factors influencing the results. Our analysis showed that a more favorable population in terms of patient and tumor characteristics was undergoing laparoscopic colectomy. We attempted to adjust for these, but this may be incomplete.

Financial Disclosure: None reported.