

Invited Commentary

Robotics Against the Evidence

Wouter J. Bom, MD; Marja A. Boermeester, MD, PhD

The use of robotic surgery for common operations, such as colectomy, but also for even simple procedures, such as inguinal and ventral hernia surgery, is increasing rapidly. In 2012, a trial¹ randomized patients with right-sided colonic cancer to receive robot-assisted colectomy or laparoscopically assisted colectomy. Of 70 randomized patients, hospital stay, surgical complications, resection-margin clearance, and the number of lymph nodes harvested were similar in both groups. The duration of surgery was longer in the robotic group, and overall hospital costs were also significantly higher.¹



Related article

In this issue of *JAMA Surgery*, a study by Sheetz et al² evaluates outcomes and trends in the use of robotic, laparoscopic, and open colectomy across diverse practice settings to find that robotic colectomy compared with open colectomy is associated with only a small reduction in medical complications (from 16.9% to 15.5%) and also a small increase in surgical complications (from 2.4% to 3.0%). Importantly, there are no differences whatsoever in complications between laparoscopic and robotic colectomies; yet the use of robotic colectomy increased more than 10-fold between 2010 and 2016 as a replacement of laparoscopic colectomy rather than open colectomy.

Data from Medicare Provider Analysis and Review files have been used in this study²; 191 292 patients were included in the study cohort, of whom 23 022 patients underwent robotic surgery. Because robotic surgery is new and has a learning curve, it would be expected that less complex surgeries were selected for robotic colectomy. This tendency will be only partially reflected in the assessed variables (age, sex, race, and comorbidities). To a greater extent, selection is associated with characteristics for surgical resection, such as indication, mass size, and previous surgeries, which are not present in the Medicare files. Methodologic problems inherent to using insurance and claims database analyses include selection bias as one of the major issues; treatment selection, clinical outcomes, and economic outcomes may well be influenced by factors that are not recorded in the database.³ It may be that the small difference (merely 1%) in overall complications in favor of robotic colectomy compared with open colectomy is only attributable to the fact that more technically difficult cases are selected for open surgery, and a 1% difference may actually mean that open surgery in difficult cases was a job done very well.

Other types of selection bias in the study include the selection to include fee-for-service beneficiaries only, the selection of a specific age group (those 65-99 years of age) for unknown reasons, and the exclusion of operations in hospitals that do not perform robotic colectomy. For the last reason alone, as many as 273 610 of 464 902 patients were excluded (per the eAppendix in Sheetz et al).² It does not seem a realistic reflection of practice to select only hospitals where robotic surgery is one of the treatment options and not include the data from hospitals that have excelled in laparoscopic surgery but do not practice robotics. The instrumental variable risk analysis used in the present study² is also by no means capable of adequate correction for important confounders known to cause treatment selection. Moreover, many hospitals are still in their learning curve during the study period, as reflected in data that hospitals performed a higher median annual volume of open surgery (41 [interquartile range, 21-72] cases) than laparoscopic surgery (17 [interquartile range, 7-33] cases) or robotic surgery (4 [interquartile range, 2-4] cases).

From the Minimally Invasive Versus Open Pancreatoduodenectomy (LEOPARD-2) trial,⁴ we have learned that initiating minimally invasive pancreaticoduodenectomy brought unexpected and worrisome safety concerns. Robotic colectomy and laparoscopic colectomy show competitive results in which robotics may provide the same value but at higher costs. Open surgery is still reserved for particularly difficult cases.

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Perioperative Outcomes and Trends in the Use of Robotic Colectomy for Medicare Beneficiaries From 2010 Through 2016

Kyle H. Sheetz, MD, MSc; Edward C. Norton, PhD; Justin B. Dimick, MD, MPH; Scott E. Regenbogen, MD, MPH

IMPORTANCE The use of robotic surgery for common operations like **colectomy** is **increasing** rapidly in the United States, but evidence for its effectiveness is limited and may not reflect real-world practice.

OBJECTIVE To evaluate outcomes of and trends in the use of robotic, laparoscopic, and open colectomy across diverse practice settings.

DESIGN, SETTING, AND PARTICIPANTS This **population-based study of Medicare beneficiaries undergoing elective colectomy** was conducted between January 2010 and December 2016. We used an instrumental variable analysis to account for both measured and unmeasured differences in patient characteristics between robotic, open, and laparoscopic colectomy procedures. Data were analyzed from January 21, 2019, to March 1, 2019.

EXPOSURES Receipt of robotic colectomy.

MAIN OUTCOMES AND MEASURES Incidence of postoperative medical and surgical complications and length of stay.

RESULTS A total of **191 292 procedures** (**23 022 robotic procedures** [12.0%], 87 639 open procedures [45.8%], and 80 631 laparoscopic colectomy procedures [42.0%]) were included. Robotic colectomy was associated with a lower adjusted rate of overall complications than open colectomy (17.6% [95% CI, 16.9%-18.2%] vs 18.6% [95% CI, 18.4%-18.7%]; relative risk [RR], 0.94 [95% CI, 0.91-0.98]). This difference was driven by lower rates of medical complications (15.5% [95% CI, 14.8%-16.2%] vs 16.9% [95% CI, 16.7%-17.1%]; RR, 0.92 [95% CI, 0.87-0.96]) because surgical complications were higher with the robotic approach (3.0% [95% CI, 2.8%-3.2%] vs 2.4% [95% CI, 2.3%-2.5%]; RR, 1.18 [95% CI, 1.04-1.35]). There were **no differences in complications between robotic and laparoscopic colectomy** (11.1% [95% CI, 10.5%-11.6%] vs 11.0% [95% CI, 10.8%-11.2%]; RR, 1.00 [95% CI, 0.95-1.05]). There was an overall shift toward greater proportional use of robotic colectomy from 0.7% (457 of 65 332 patients) in 2010 to 10.9% (8274 of 75 909 patients) in 2016. In hospitals with the highest adoption of robotic colectomy between 2010 and 2016, increasing use of robotic colectomy (0.8% [100 of 12 522 patients] to 32.8% [5416 of 16 511 patients]) was associated with a greater replacement of laparoscopic operations (43.8% [5485 of 12 522 patients] to 25.2% [4161 of 16 511 patients]) than open operations (55.4% [6937 of 12 522 patients] to 41.9% [6918 of 16 511 patients]).

CONCLUSIONS AND RELEVANCE While **robotic colectomy was associated with minimal safety benefit** over **open** colectomy and had **comparable outcomes with laparoscopic** colectomy, population-based trends suggest that it replaced a greater proportion of laparoscopic rather than open colectomy, especially in hospitals with the highest adoption of robotics.

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The United States performs more robotic surgery than all other countries combined. The use of robotics in the field of general surgery has increased 24-fold since 2010, currently making it the largest market for robotics.¹ Robotic general surgery focuses predominately on colorectal procedures, where proponents contend that the technology makes common operations, such as colectomy, safer and more efficacious.^{2,3} These safety benefits may increase further as surgeons acquire more robotic experience and learn to select patients who will benefit most from the approach.⁴ Advocates for expanding the use of robotics also assert that it increases access to minimally invasive surgery, especially among surgeons and hospitals that have historically performed most operations via the more morbid open approach.⁵

However, it remains unclear whether these theoretical benefits of robotic surgery translate into better real-world outcomes for common operations, such as colectomy. To our knowledge, prior studies have been limited to small, single-institution studies without appropriate control populations.^{6,7} These studies are further limited by comparisons between robotic colectomy and only 1 alternative surgical approach. This introduces selection bias and may lead to inaccurate estimates of treatment benefit from robotic colectomy. Practicing surgeons carefully select patients for robotic procedures, and the risk profiles for patients undergoing open or laparoscopic colectomy are known to differ in important, largely unmeasured ways.⁸ Selection may further evolve as surgeons gain more experience with certain procedural approaches. Amidst broader trends toward greater use of robotic surgery, no studies have examined whether greater use in colectomy replaces higher-risk open operations or lower-risk, already minimally invasive laparoscopic ones.

We conducted a population-based, nationwide study in the United States to evaluate perioperative outcomes and trends in the use of robotic colectomy in Medicare beneficiaries. Colectomy is common, performed in most acute care hospitals, and responsible for the largest share of major perioperative morbidity in general surgery.⁹ We used regional differences in the adoption of robotic colectomy as an instrumental variable to account for confounding from selection bias that may lead to inaccurate estimates of treatment outcome. We also evaluated temporal trends in each surgical approach (robotic, laparoscopic, and open) across hospitals that varied in their degree of adoption of robotic colectomy.

Methods

Data Source and Study Population

We used data from the 100% Medicare Provider Analysis and Review (MedPAR) files for fee-for-service beneficiaries for calendar years 2010 through 2016. We collected data on patient age, demographics, geographic location, and comorbidities. We excluded patients younger than 65 years or older than 99 years. We identified patients undergoing elective colectomy using *International Statistical Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* and *Tenth Revision, Clinical Modification (ICD-10-CM)* codes and further restricted to

Key Points

Question Is robotic colectomy safe and effective across diverse practice settings?

Findings This population-based study of Medicare beneficiaries used instrumental variable methods to account for selection bias between surgical approaches and found that robotic colectomy was associated with fewer overall complications than open surgery despite higher rates of surgical complications. There were no differences in complication rates between robotic and laparoscopic colectomy; robotic colectomy replaced a greater proportion of minimally invasive laparoscopic surgeries, rather than higher-risk open ones.

Meaning These findings suggest that surgeons and hospitals should continue to question the value of robotics for colectomy.

colectomy-specific Diagnosis Related Groups (329, 330, or 331). We used *ICD-9-CM* and *ICD-10-CM* procedure codes to identify patients undergoing open, laparoscopic, or robotic surgery (eAppendix in the Supplement). This approach has been previously used to identify robotic procedures in claims data.¹⁰ To evaluate the precision of these codes for identification of robotic surgery, we compared annual rates of robotic colectomy for all Medicare beneficiaries to those from a validated statewide clinical registry for surgical care in the state of Michigan, the Michigan Surgical Quality Collaborative.¹¹ Data in this registry were manually abstracted by trained nurses and audited for accuracy. Results from the claims data (national and Michigan-only cohorts) were similar to what was derived from the clinical registry (eAppendix in the Supplement). We linked the MedPAR files to the American Hospital Association Annual Survey to obtain additional information on hospital size, resources, and other characteristics.

This study was deemed exempt by the institutional review board at the University of Michigan. This study was deemed exempt from informed consent procedures because it involved the analysis of limited secondary data.

Outcomes

The primary outcome of interest was the incidence of any postoperative complication within 30 days of surgery. We used *ICD-9-CM* and *ICD-10-CM* codes to identify both medical complications (pulmonary failure, pneumonia, myocardial infarction, deep venous thrombosis/pulmonary embolism, and renal failure) and surgical complications (surgical site infection, gastrointestinal bleeding, hemorrhage, and return to the operating room during the index hospitalization). These complications represent a subset of codes with the highest sensitivity and specificity.¹² Death was not included as a complication. We also investigated hospital length of stay as a secondary outcome.

Statistical Analysis

We used generalized linear models to evaluate the association between robotic surgery and postoperative complications. For all dichotomous outcomes, we specified a binary distribution with a logit linkage. All models accounted for patient

age, sex, race, and 27 comorbidities in the Elixhauser Comorbidity Index.¹³ We further adjusted for hospital characteristics, such as teaching status, urban vs rural location, bed size, and not-for-profit status. All models accounted for clustering of outcomes within hospitals, and all estimates were made with robust standard errors.

We then performed an instrumental variable analysis to account for unmeasured differences in patient complexity or illness severity that may bias estimates of treatment effect size for robotic surgery.¹⁴ We have previously used this approach to study treatment effects for laparoscopic vs open colectomy.^{8,15,16} We hypothesized that the mean treatment effect of robotic surgery on complications would be influenced by selection bias. Surgeons may choose to perform robotic surgery for patients who are healthier or have more favorable anatomy. This would lead to biased estimates of treatment benefit relative to open surgery. In contrast, if surgeons are shifting patients from open surgery to the robotic platform (a common, although not firmly established, anecdote), this may actually increase the risk profile of patients having robotic surgery. In this example, selection bias may lead to incorrect estimates of treatment harm relative to laparoscopic surgery. The instrumental variable analysis enables testing of each of these hypotheses.

Our instrumental variable was the regional use of open colectomy (comparing open vs robotic surgery) or laparoscopic colectomy (comparing laparoscopic vs robotic surgery) in the year prior to the patient's operation. Proportions were calculated for each of the 306 hospital referral regions in the United States. Hospital referral regions represent regional health care markets and generally include at least 1 tertiary referral hospital. For open colectomy, this ranged from 7.7% to 84.4% (median, 51.6%). For laparoscopic colectomy, this ranged from 13.3% to 92.3% (median, 43.7%). Instrumental variables must be correlated with patients' receiving a specific treatment but not directly associated with the outcome itself, except through the receipt of treatment. The instrumental variables for this analysis were strongly associated with each exposure: receipt of open surgery ($F = 118$) and laparoscopic surgery ($F = 83$). (An instrument is considered strong if the F statistic is greater than 10.) Although exogeneity (ie, an instrument not being directly associated with outcomes) is generally not testable, we calculated the instrumental variable in the year prior to a patient's operation, and thus it should not have any direct association with the outcomes in question for that patient. We also show that the instrument is balanced, meaning that high and low values of the instrument are not associated with all other observable characteristics.

We used a 2-stage residual inclusion model to carry out the instrumental variable analyses. This approach has been previously applied to the study of health care treatment effects and provides more reliable estimates for nonlinear models.^{17,18} In the first stage, we modeled receipt of either open or laparoscopic surgery, accounting for the instrument and the same patient-level covariates used in the conventional risk-adjustment model. We then assessed the raw residuals from this model and included them as a covariate in the second-stage model, which estimated the mean treatment effect of ro-

botic surgery on each study outcome, adjusting for patient and hospital characteristics. The coefficients on the residuals in these models were significant for all outcomes, suggesting that the robotic surgery has a significant association with outcomes compared with laparoscopic or open surgery (eTable 1 in the Supplement). Treatment effects from the second-stage model can be interpreted within the context of the so-called marginal patient, defined as an individual who would be considered a candidate for either operation (open vs robotic or laparoscopic vs robotic) but who gets 1 type of treatment because he or she happens to live in an area where that treatment is more common.

To evaluate temporal trends in the use of robotic surgery, we stratified hospitals based on their adoption of robotic colectomy. For each hospital, we calculated the annual increase (ie, slope) in their proportional use of robotic colectomy. For reporting, we grouped hospitals into quartiles based on these values. Hospitals with low rates of robotic surgery adoption (slope, 0.6% [95% CI, 0.4%-0.8%] increase per year) represent the bottom 25%, whereas hospitals with high rates of robotic surgery adoption (slope, 9.7% [95% CI, 9.4%-10.0%] increase per year) represent the top 25%.

To address the potential for bias from hospitals with different levels of experience with robotic surgery (ie, hospitals with greater volume may be better at robotic surgery), we performed a sensitivity analysis stratifying hospitals by their annual volume of robotic colectomy. We then created 3 groups: those at less than the 25th percentile (the low-volume group; 1-4 cases annually), those in the 25th to 75th percentiles (the middle-volume group; 5-15 cases annually), and those at more than the 75th percentile (the high-volume group; 16-130 cases annually). We computed the estimated local mean treatment effects and overall outcome rates for robotic colectomy for each group.

All statistical analyses were performed using Stata statistical software version 14 (StataCorp). We used a 2-sided approach at the 5% significance level for all hypothesis testing.

Results

Patient and Hospital Characteristics

Characteristics for the 191 292 patients in the study cohort are included in Table 1. There were 23 022 patients who underwent robotic surgery. Patients' ages (mean [SD] age: open colectomy group, 72.4 [9.9] years; laparoscopic colectomy group, 72.9 [8.5] years; robotic colectomy group, 72.1 [8.4] years; $P < .001$), sex distribution (male participants: open colectomy group, 36 294 of 87 639 [41.4%]; laparoscopic colectomy group, 34 918 of 80 631 [43.3%]; robotic colectomy group, 10 154 of 23 022 [44.1%]; $P < .001$), and race (African American participants: open colectomy group, 7959 of 87 639 [9.2%]; laparoscopic colectomy group, 7107 of 80 631 [8.9%]; robotic colectomy group, 1832 of 23 022 [8.1%]; $P = .04$) were qualitatively similar but statistically significantly different across all surgical approaches. Patients undergoing robotic surgery were more likely to have no documented comorbidities (3054 [13.3%]) compared with both laparoscopic (10 183 [12.6%]) and

Table 1. Patient and Hospital Characteristics, 2010-2016

Characteristic	Type of Procedure, No. (%)			P Value ^a
	Open Colectomy	Laparoscopic Colectomy	Robotic Colectomy	
Patient Characteristics				
No. of patients	87 639	80 631	23 022	NA
Age, mean (SD), y	72.4 (9.9)	72.9 (8.5)	72.1 (8.4)	<.001
Male	36 294 (41.4)	34 918 (43.3)	10 154 (44.1)	<.001
White	75 467 (86.9)	69 295 (86.8)	19 891 (87.4)	.35
African American	7959 (9.2)	7107 (8.9)	1832 (8.1)	.04
Comorbidities				
Hypertension	57 788 (65.9)	53 017 (65.8)	14 920 (64.8)	.03
Fluid and electrolyte disorders	21 611 (24.7)	11 146 (13.8)	3359 (14.6)	<.001
Diabetes	18 278 (20.9)	15 927 (19.8)	4576 (19.9)	<.001
Chronic pulmonary disease	17 250 (19.7)	13 954 (17.3)	3887 (16.9)	<.001
Obesity	13 051 (14.9)	10 319 (12.8)	3027 (13.2)	<.001
Renal failure	8877 (10.1)	6155 (7.6)	1647 (7.2)	<.001
Depression	9251 (10.6)	7380 (9.2)	2085 (9.1)	<.001
Congestive heart failure	6989 (8.0)	4502 (5.6)	1139 (5.0)	<.001
Peripheral vascular disease	5456 (6.2)	3799 (4.7)	1024 (4.5)	<.001
Comorbidities, No.				
0	7604 (8.7)	10 183 (12.6)	3054 (13.3)	<.001
1	15 617 (17.8)	18 846 (23.4)	5505 (23.9)	<.001
≥2	64 418 (73.5)	51 602 (64.0)	14 463 (62.8)	<.001
Operative diagnosis				
Colon cancer	35 728 (59.5)	36 491 (66.0)	8872 (51.0)	<.001
Benign conditions	24 292 (40.5)	18 836 (34.0)	8514 (49.0)	
Hospital Characteristics				
Annual volume, procedures/y				
Mean (SD)	51.7 (42.0)	22.9 (21.2)	8.0 (7.9)	<.001
Median (interquartile range)	41 (21-72)	17 (7-33)	4 (2-10)	<.001
Size, beds				
<250	14 658 (16.9)	13 791 (17.2)	6273 (27.5)	
250-499	36 157 (41.5)	32 574 (40.7)	10 014 (43.9)	<.001
≥500	36 195 (41.6)	33 777 (42.1)	6534 (28.6)	
Educational mission				
Teaching hospital	25 883 (29.8)	22 788 (28.4)	4540 (19.9)	
Nonteaching hospital	61 127 (70.3)	57 354 (71.6)	18 281 (80.1)	<.001
Business model				
Investor owned	10 074 (11.6)	8833 (11.0)	3858 (16.9)	
Not for profit	70 170 (80.7)	65 709 (82.0)	17 374 (76.1)	<.001
Other	6766 (7.8)	5600 (7.0)	1589 (7.0)	
Geographic location				
Urban	83 078 (95.5)	77 444 (96.6)	21 917 (96.0)	
Rural	3932 (4.5)	2698 (3.4)	904 (4.0)	<.001

Abbreviation: NA, not applicable.

^a P values reflect comparisons of means (continuous variables) and proportions (categorical variables) across all 3 types of procedures.

open surgery (7604 [8.7%]; $P < .001$). The laparoscopic approach was most common for patients undergoing surgery for colon cancer (36 491 [66.0%] vs open surgery, 35 728 [59.5%] and robotic surgery, 8872 [51.0%]; $P < .001$). Hospitals performed a higher median annual volume of open surgery (41 [interquartile range, 21-72] procedures per year) than laparoscopic colectomy (17 [interquartile range, 7-33] procedures per year) or robotic surgery (4 [interquartile range, 2-4] procedures per year). Patients undergoing robotic surgery were more likely to have surgery in a hospital with fewer than 250 beds

(open colectomy group, 14 658 of 87 639 [16.9%]; laparoscopic colectomy group, 13 791 of 80 631 [17.2%]; robotic colectomy group, 6273 of 23 022 [27.5%]; $P < .001$) or a nonteaching hospital (open colectomy group, 61 127 of 87 639 [70.3%]; laparoscopic colectomy group, 57 354 of 80 631 [71.6%]; robotic colectomy group, 18 281 of 23 022 [80.1%]; $P < .001$). The instrumental variable balanced patient characteristics, and no significant differences were observed when stratifying about the median of either instrumental variable (eTable 1 in the Supplement).

Complications Following Open, Laparoscopic, and Robotic Colectomy

In the conventional risk-adjustment analysis, robotic colectomy was associated with fewer complications than open surgery (13.8% [95% CI, 13.1%-14.5%] vs 18.1% [95% CI, 17.9%-18.5%]; RR, 0.75 [95% CI, 0.72-0.79]) (Table 2; Figure 1A). The mean treatment effect was attenuated in the instrumental variable analysis, where robotic colectomy was associated with fewer complications than open colectomy overall (17.6% [95% CI, 16.9%-18.2%] vs 18.6% [95% CI, 18.4%-18.7%]; RR, 0.94 [95% CI, 0.91-0.98]) (Table 2; Figure 1A). In the instrumental variable analysis, the incidence of medical complications (pulmonary failure, pneumonia, myocardial infarction, deep venous thrombosis/pulmonary embolism, and renal failure) was lower with the robotic approach (15.5% [95% CI, 14.8%-16.2%] vs 16.9% [95% CI, 16.7%-17.1%]; RR, 0.92 [95% CI, 0.87-0.96]), but the rate of surgical complications (surgical site infection, gastrointestinal bleeding, hemorrhage, and return to the operating room during the index hospitalization) was higher (3.0% [95% CI, 2.8%-3.2%] vs 2.4% [95% CI, 2.3%-2.5%]; RR, 1.18 [95% CI, 1.04-1.35]).

In the conventional risk-adjustment analysis, robotic colectomy was associated with higher incidence of complications than laparoscopic surgery (10.9% [95% CI, 10.5%-11.3%] vs 10.2% [95% CI, 9.9%-10.4%]; RR, 1.07 [95% CI, 1.02-1.12]) (Table 2; Figure 1B). In contrast, there were no differences in complications between robotic and laparoscopic colectomy in the instrumental variable analysis (11.1% [95% CI, 10.5%-11.6%] vs 11.0% [95% CI, 10.8%-11.2%]; RR, 1.00 [95% CI, 0.95-1.05]) (Table 2; Figure 1B). Results were similar in a sensitivity analysis stratified by hospital volume of robotic surgery, anatomic (left vs right) resection type, diagnosis, and severity of complication (eTables 2, 3, 4, and 5 in the Supplement).

In the conventional risk-adjustment analysis, hospital length of stay was shorter for robotic surgery compared with open surgery (5.8 vs 7.3 days; mean difference, -1.54 [95% CI, -1.64 to -1.43]) (eTable 2 in the Supplement). The effect of robotic surgery was attenuated in the instrumental variable analysis (6.3 vs 7.4 days; mean difference, -1.18 [95% CI, -1.2 to -1.09]). There were no differences in length of stay between robotic and laparoscopic surgery in either conventional (5.2 vs 5.2 days; mean difference, -0.01 [95% CI, -0.11 to 0.08]) or instrumental variable analyses (5.2 vs 5.4 days; mean difference, -0.09 [95% CI, -0.22 to 0.04]).

Trends in the Use of Robotic Surgery

There was an overall trend toward greater proportional use of robotic colectomy from 0.7% (in 457 of 65 332 patients) in 2010 to 10.9% (in 8274 of 75 909 patients) in 2016 (Figure 2A). In hospitals not performing robotic colectomy, the use of laparoscopic colectomy increased from 40.7% (in 22 904 of 56 276 patients) in 2010 to 45.9% (in 11 979 of 26 099 patients) in 2016, and the rate of open colectomy declined accordingly from 59.3% (in 33 371 of 56 276 patients) to 55.1% (in 14 381 of 26 099 patients) (Figure 2B). In the quartile of hospitals with highest robotic surgery adoption rates, however, increasing use of robotic colectomy (0.8% [100 of 12 522 patients] to 32.8% [5416 of 16 511 patients]) was associated with a greater proportional

Table 2. Perioperative Complications After Elective Colectomy, Stratified by Operative Approach

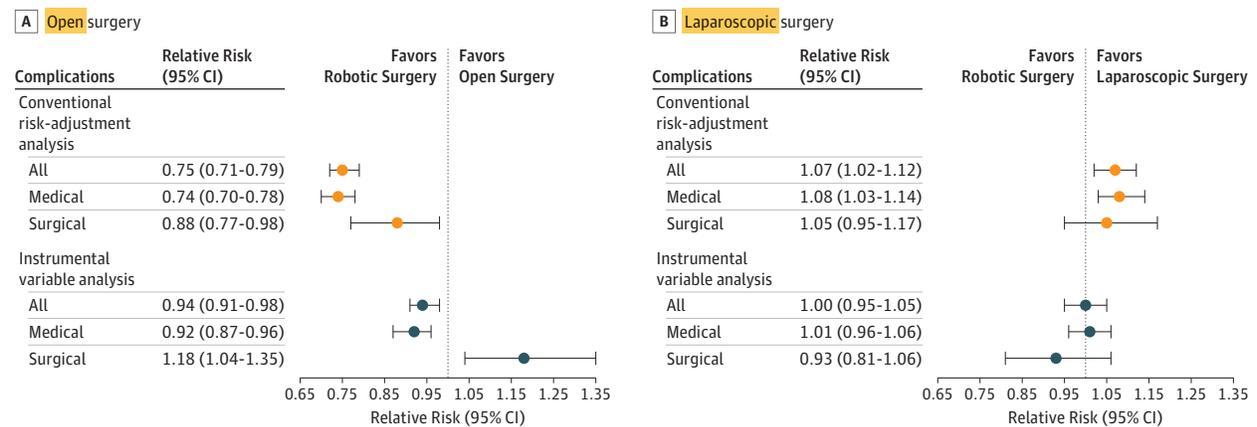
Outcomes	Colectomy, Risk-Adjusted Rates, % (95% CI)	
	Open or Laparoscopic	Robotic
Open Procedures		
All complications		
Conventional risk-adjustment analysis	18.1 (17.9-18.5)	13.8 (13.1-14.5)
Instrumental variable analysis	18.6 (18.4-18.7)	17.6 (16.9-18.2)
Medical complications		
Conventional risk-adjustment analysis	17.2 (16.9-17.4)	12.7 (12.0-13.4)
Instrumental variable analysis	16.9 (16.7-17.1)	15.5 (14.8-16.2)
Surgical complications		
Conventional risk-adjustment analysis	2.5 (2.4-2.6)	2.2 (1.9-2.4)
Instrumental variable analysis	2.4 (2.3-2.5)	3.0 (2.8-3.2)
Laparoscopic Procedures		
All complications		
Conventional risk-adjustment analysis	10.2 (9.9-10.4)	10.9 (10.5-11.3)
Instrumental variable analysis	11.0 (10.8-11.2)	11.1 (10.5-11.6)
Medical complications		
Conventional risk-adjustment analysis	8.9 (8.7-9.2)	9.7 (9.3-10.1)
Instrumental variable analysis	9.9 (9.7-10.1)	10.0 (9.5-10.4)
Surgical complications		
Conventional risk-adjustment analysis	2.1 (1.9-2.2)	2.2 (2.0-2.4)
Instrumental variable analysis	2.1 (1.9-2.2)	1.9 (1.7-2.1)

decrease in the use of laparoscopic colectomy (43.8% [5485 of 12 522 patients] to 25.2% [4161 of 16 511 patients]) than of open operations (55.4% [6937 of 12 522 patients] to 41.9% [6918 of 16 511 patients]) (Figure 2C and D).

Discussion

In this population-based study, robotic colectomy was associated with a lower risk of complications than open colectomy. This difference was driven by fewer medical complications in patients undergoing robotic colectomy, in that surgical complications were more common with the robotic approach. There was no difference in complication rates or hospital length of stay between robotic and laparoscopic colectomy. These findings suggest that the benefits of robotic compared with open surgery may be derived from the minimally invasive approach rather than the robotic technology itself. As overall use of robotic surgery increased, hospitals with the highest rate of adoption of robotic surgery replaced a greater proportion of minimally invasive laparoscopic operations rather than open operations. These findings challenge the belief that robotics will increase access to minimally invasive colon surgery. Recognizing the substantial added cost of robotic surgery¹⁹ (25% higher and up to \$3000 more expensive

Figure 1. Forest Plots Indicating the Relative Risk of Complications Associated With Robotic Colectomy Compared With Open or Laparoscopic Surgery



Results from the conventional risk-adjustment analysis are displayed first, followed by results from the instrumental variable analysis. The relative risk estimates from the instrumental variable analysis represent the local mean

treatment effect of robotic surgery in patients who would be considered candidates for either surgical approach.

than laparoscopic colectomy), these findings also question the relative benefits of robotic colectomy, in that outcomes are only modestly better than open surgery, and robotic procedures primarily replaced laparoscopic operations with equivalent outcomes.

In the context of rapidly increasing use, the clinical effectiveness of robotic surgery has been the subject of considerable debate.²⁰ In general surgery and with respect to the surgical treatment of colorectal diseases in particular, the robotic platform has been promoted as a tool to overcome the anatomic challenges of minimally invasive pelvic surgery, particularly total mesorectal excision for rectal cancer.²¹ Yet even in this context, the Robotic Versus Laparoscopic Resection for Rectal Cancer (ROLARR) Trial (NCT01736072), which randomized patients to either laparoscopic or robotic pelvic dissection for rectal cancer, did not find any significant differences in conversions to open procedures, complications, or oncologic resection quality.²² Beyond colorectal surgery, the Laparoscopic Versus Open Distal Pancreatectomy for Symptomatic Benign, Premalignant and Malignant Disease (LEOPARD) and Minimally Invasive Versus Open Pancreatoduodenectomy (LEOPARD-2) trials (NTR5188 and NTR5689) have raised broader concerns about the safety of adopting newer and more technically complex operative approaches. For example, results from the LEOPARD-2 trial suggest that laparoscopic pancreaticoduodenectomy may be associated with higher complication-associated deaths than traditional open surgery.

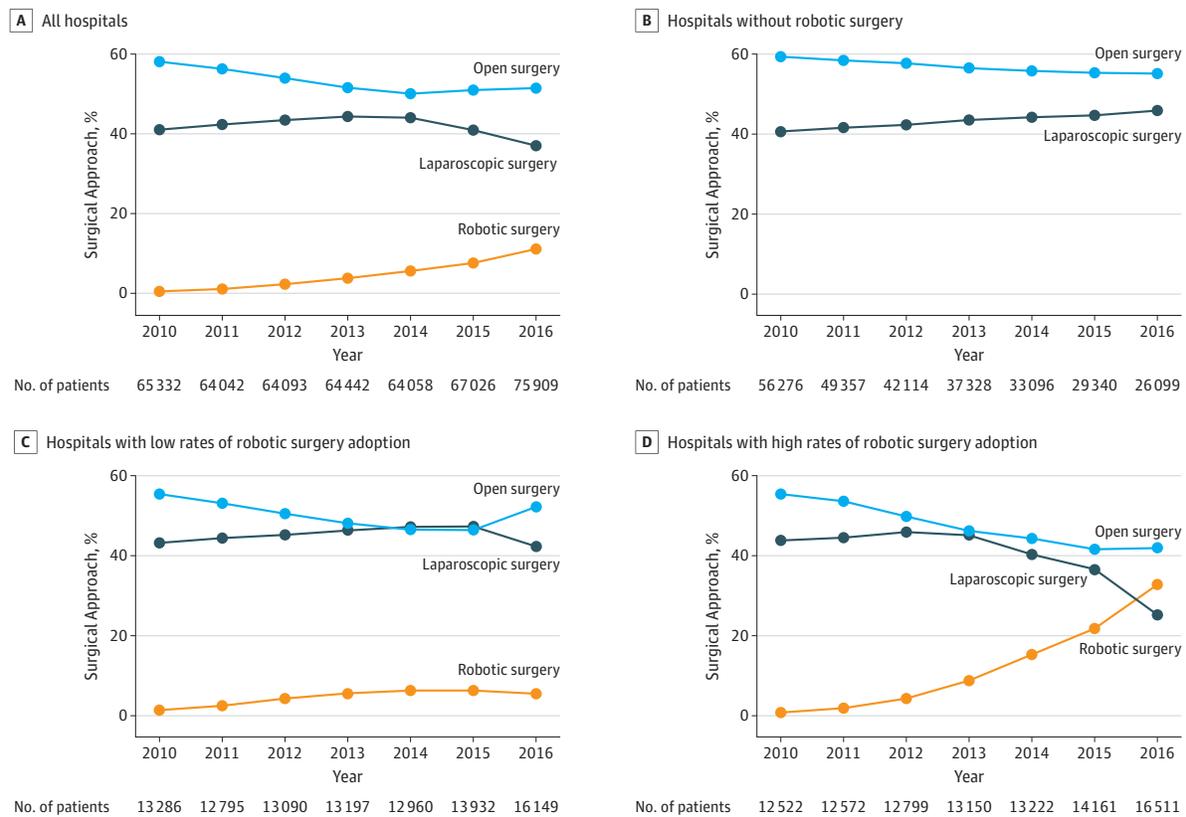
The expansion of robotic surgery to more common operations such as colectomy has even fewer theoretical benefits; for example, intra-abdominal procedures may pose less anatomical barriers to minimally invasive resection. Furthermore, laparoscopic colectomy is already routine and common in surgical practice nationwide.²³⁻²⁵ Most of the literature promoting the adoption of robotic colectomy has been limited to single-centered analyses or studies without appropriate control groups.²⁵⁻²⁷ For example, a recent study²⁷ detail-

ing a single institution's experience with robotic inguinal hernia repair notes that the robotic approach is safe, effective, and has a manageable learning curve. Yet this study²⁷ does not compare patients undergoing robotic repairs with a control population and makes conclusions around learning curves using an individual surgeon's experience. Those performing the studies may also have an influence on the purported benefits of the technology. Many were performed by robotic surgery enthusiasts, some of whom consult for or have conflicts of interest with companies that manufacture robotic surgical systems.²⁸ Evidence suggests that these professional relationships are associated with a higher likelihood of studies reporting benefits of robotic surgery (eg, fewer complications).²⁹

Our study expands on the existing understanding of robotic colectomy in several ways. First, we used national data representative of diverse practice settings for colectomy across the United States, rather than single-center experiences. Second, we evaluated robotic colectomy against both open and laparoscopic approaches to reflect the decision-making of surgeons in practice, who may decide between 2 or even 3 surgical approaches for a given patient. Third, we used econometric techniques (instrumental variable analysis) to account for both measured and unmeasured differences in patient characteristics that may lead to inaccurate estimates of treatment effect because of selection bias. Finally, we evaluated temporal trends in the use of robotic surgery to highlight how its adoption is associated with contemporary practice patterns that, prior to its diffusion, were already shifting toward greater use of the laparoscopic approach.

While additional research is necessary, these conclusions may be generalizable to other specialties, such as urology and gynecology, where the use of robotic surgery expands to an increasingly broad range of procedures despite unclear clinical benefits.^{10,30-33} For example, there is emerging evidence from the gynecology literature suggesting that the adoption of minimally invasive radical hysterectomy was associated with a decline in overall survival for cervical cancer.³⁴

Figure 2. Population-Based Trends in Surgical Approach for All Medicare Beneficiaries Undergoing Elective Colectomy (2010-2016)



A, Sample size reflects all US hospitals; starting values were 58.1% (37 952 of 65 332 patients) for open surgery, 41.1% (26 847 of 65 332 patients) for laparoscopic surgery, and 0.7% (457 of 65 332 patients) for robotic surgery, and ending values were 51.5% (39 093 of 75 909 patients) for open surgery, 37.1% (28 162 of 75 909 patients) for laparoscopic surgery, and 10.9% (8274 of 75 909 patients) for robotic surgery. B, Starting values were 59.3% (33 371 of 56 276 patients) for open surgery and 40.7% (22 904 of 56 276 patients) for laparoscopic surgery; ending values were 55.1% (14 381 of 26 099 patients) for open surgery and 45.9% (11 979 of 26 099 patients) for laparoscopic surgery. C and D, Temporal trends for hospitals with the lowest and highest rates of adoption of robotic surgery. Robotic adoption rates were derived for each

hospital from the slope with respect to time and hospitals' proportional use of robotic colectomy. C, Starting values were 55.4% (7360 of 13 286 patients) for open surgery, 43.2% (5739 of 13 286 patients) for laparoscopic surgery, and 1.4% (186 of 13 286 patients) for robotic surgery, and ending values were 52.2% (8430 of 16 149 patients) for open surgery, 42.3% (6831 of 16 149 patients) for laparoscopic surgery, and 5.5% (888 of 16 149 patients) for robotic surgery. D, Starting values were 55.4% (6937 of 12 522 patients) for open surgery, 43.8% (5485 of 12 522 patients) for laparoscopic surgery, and 0.8% (100 of 12 522 patients) for robotic surgery, and ending values were 41.9% (6918 of 16 511 patients) for open surgery, 25.2% (4161 of 16 511 patients) for laparoscopic surgery, and 32.8% (5416 of 16 511 patients) for robotic surgery.

What is far less controversial is the incremental cost. There is broad consensus that robotic surgery incurs considerably greater equipment and maintenance costs than other techniques.³⁵⁻³⁷ Continued expansion of robotic surgery in these contexts is problematic for several reasons. For example, the use of laparoscopic surgery for common operations like colectomy, hernia repair, or hysterectomy is already high and continues to grow. Replacing minimally invasive laparoscopic techniques with a more expensive technology for which there is no consistent clinical benefit is an example of low-value care. This has the potential to affect a large number of patients and incur substantial costs; these 3 operations alone are performed more than 1 million times per year in the United States. In addition, it may be irrevocable; if robotic approaches replace laparoscopic surgery, the less costly technique may quickly fall out of common practice, as the field may be observing in the hospitals with most rapid adoption of robotic colectomy.

Limitations

This study should be interpreted within the context of several limitations. Because we use fee-for-service Medicare data, these results may not be generalizable to Medicare Advantage or other younger patients with commercial insurance. However, colon surgery is more common in populations older than 65 years, and there are no unique clinical or anatomic factors that would distinguish operative decision-making in Medicare patients compared with members of the general population. Claims data also does not capture actual surgeon decision-making; however, we use the instrumental variable analysis to address clinical differences that would influence treatment choice. Some may also be concerned that the sensitivity analyses capture annual rather than longitudinal experience and therefore may not adequately acknowledge the learning curve for robotic-assisted surgery. This would limit our ability to capture truly better results for robotic surgery. However, most hospitals included in the analysis contributed multiple years of cases, reflecting a longitudinal experience.

rience performing robotic-assisted colectomy. Some may also be concerned that our instrumental variable is a surrogate for hospital or surgeon quality. Patients living in areas where more robotic-assisted surgery is performed (in more technologically advanced hospitals) may receive better care. However, the instrument itself is not directly associated with postoperative outcomes. It is also possible that the instrumental variable approach does not fully account for important technical aspects of the operation that may influence outcomes (eg, tumor size), which could bias our results in either direction based on surgeons' choices around the robotic approach. While the instrumental variable estimates reflect only the so-called marginal patient (ie, one considered a candidate for either treatment), these estimates reflect the real decisions that practicing surgeons may be making when choosing robotic surgery. Finally, we did not address other important outcomes such as costs, long-term cancer survival, or conversion to open surgery.⁵ That said, the current dialogue motivating greater use of robotic surgery centers foremost on surgical safety and clinical resource use (eg, length of stay). In ad-

dition, most prior studies on open conversions are far less common than the complications we use in this analysis.

Conclusions

After accounting for selection bias between different operative approaches, this population-based study found that **robotic colectomy was associated with minimal safety benefit over open colectomy and had outcomes comparable with laparoscopic colectomy.** Despite the **lack of demonstrably better outcomes**, the use of robotic surgery for **colon resections increased** substantially throughout the study period. Hospitals with the highest adoption of robotic colectomy **replaced laparoscopic** operations far **more** than they expanded candidacy for minimally invasive surgery. **These findings suggest that surgeons and hospitals should continue to question the value of robotics for colectomy.**

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