

Routine Leak Testing in Colorectal Surgery in the Surgical Care and Outcomes Assessment Program

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Objective: To evaluate the effect of routine anastomotic leak testing (performed to screen for leaks) vs selective testing (performed to evaluate for a suspected leak in a higher-risk or technically difficult anastomosis) on outcomes in colorectal surgery because the value of provocative testing of colorectal anastomoses as a quality improvement metric has yet to be determined.

Design: Observational, prospectively designed cohort study.

Setting: Data from Washington state's Surgical Care and Outcomes Assessment Program (SCOAP).

Patients: Patients undergoing elective left-sided colon or rectal resections at 40 SCOAP hospitals from October 1, 2005, to December 31, 2009.

Interventions: Use of leak testing, distinguishing procedures that were performed at hospitals where leak testing was selective (<90% use) or routine (\geq 90% use) in a given calendar quarter.

Main Outcome Measure: Adjusted odds ratio of a composite adverse event (CAE) (unplanned postoperative intervention and/or in-hospital death) at routine testing hospitals.

Results: Among 3449 patients (mean [SD] age, 58.8 [14.8] years; 55.0% women), the CAE rate was 5.5%. Provocative leak testing increased (from 56% in the starting quarter to 76% in quarter 16) and overall rates of CAE decreased (from 7.0% in the starting quarter to 4.6% in quarter 16; both $P \leq .01$) over time. Among patients at hospitals that performed routine leak testing, we found a reduction of more than 75% in the adjusted risk of CAEs (odds ratio, 0.23; 95% CI, 0.05-0.99).

Conclusion: Routine leak testing of left-sided colorectal anastomoses appears to be associated with a reduced rate of CAEs within the SCOAP network and meets many of the criteria of a worthwhile quality improvement metric.

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ANASTOMOTIC LEAKS ACCOUNT for significant morbidity, health care utilization, and nearly one-third of all deaths following colectomy.¹⁻⁴ Leaks, on average, add 28 days to a hospitalization, with as much as a 300% increase in direct costs.^{3,5,6}

Several factors increase the risk of anastomotic leak, including poor nutrition, increased duration of the operation, and long-term corticosteroid therapy.⁷ Procedure type is relevant as well, with ascending colon resections associated with a much lower rate of leaks than left-sided colectomies (1.4% vs 5.2%),⁸ and rates vary further according to the level of anastomosis of left-sided resections.⁹ Surgeon-related factors may play a role, with wide ranges in the reported rate of leak by individual practitioners (0%-30%)^{7,9-14} depending on variables such as technique, patient selection, and perioperative practices.¹⁴

Intraoperative provocative testing of anastomoses may be one of these practice variations. It involves the instillation of air or fluid (ie, methylene blue, saline, or povidone-iodine) per rectum while maintaining intraluminal pressure by occluding the bowel proximal to the anastomosis and typically placing the anastomosis under water. A leak identified by testing is usually addressed at the time of the operation with a suture repair, revision of the anastomosis, and/or by creating a proximal diversion. Some evidence^{10,13,15} suggests that this testing of anastomoses decreases the occurrence of clinically relevant leaks. With the exception of one recent study¹³ including nearly a thousand patients, most prior reports^{10,11,16,17} evaluating the utility of leak testing have included small numbers of patients (6145). Evaluating the impact of leak testing is challenging because of individual practice variation related to when

and why surgeons use testing. Some surgeons routinely perform leak tests, using it as a screening tool for most of the anastomoses created. Other surgeons selectively use leak testing on certain types of patients or when concerned about the adequacy of an anastomosis. In this latter situation, the use of leak testing may serve as a marker of a leak and determining its value in preventing leaks would not be possible. The aim of this study was to evaluate the effect of routine anastomotic leak testing on outcomes in colorectal surgery.

METHODS

STUDY DESIGN

We evaluated all patients who underwent elective colon/rectal resection with an ileorectal or colorectal anastomosis from October 1, 2005, to December 31, 2009, in Washington state whose care was monitored across the Surgical Care and Outcomes Assessment Program (SCOAP) platform. This prospectively gathered clinical registry includes more than 55 Washington state hospitals. This study was approved by the University of Washington Human Subject Review Committee and the Washington State Department of Health.

DATA SOURCES AND CHARACTERISTICS

Data from 40 hospitals participating in SCOAP were available at the time of this study. Sociodemographic and clinical data were collected from inpatient medical records by trained abstractors at each clinical site. Operative details, including the use of leak testing, were abstracted from operative reports, and data on postoperative adverse events were obtained from hospital records using a set of standardized definitions. Annual auditing of all sites confirmed more than 98% data validity for all involved metrics.

DEFINITIONS

The data metrics and data dictionary for SCOAP are publicly available (<http://www.SCOAP.org>). For the variable *comorbid conditions*, a score modeled on the Charlson comorbidity index was calculated on the basis of associated health conditions derived from the medical record.¹⁸ Because malnutrition and low albumin levels have been shown⁷ to significantly affect anastomotic leaks, we dichotomized albumin levels to normal (≥ 3 g/dL) and low (< 3 g/dL) (to convert to grams per liter, multiply by 10).

Anastomotic leak testing was defined as the documented use of transrectal methylene blue, povidone-iodine, isotonic saline, or air with or without sigmoidoscope, as well as distention of an anastomosis generated by occluding/palpating the anastomosis. We considered this last category separately because we could not determine whether this technique was adequately provocative. A sensitivity analysis included patients whose leak testing was done by palpation.

Routine performance of an anastomotic leak test was determined in hospitals on a quarterly basis. Those with operative records that indicated performance of an intraoperative anastomotic leak test among 90% or more of the patients in a given quarter of the study period were designated *routine testing hospitals* for that quarter. Hospitals could be considered routine testing in one quarter and not in a different quarter on the basis of their use of testing. *Composite adverse event* (CAE) was defined as an in-hospital adverse event that resulted in an unplanned postoperative procedure related to an anastomotic leak

or likely to be related to a leak. Eligible unplanned postoperative procedures included a return to the operating room for the formation of a new ostomy, revision of the anastomosis, or irrigation and drainage of an intra-abdominal abscess, or a non-operative percutaneous drain placement, and/or operative drain placement associated with identification of a leak. The CAE included any of these with the addition of in-hospital deaths.

STATISTICAL ANALYSIS

The primary dependent or outcome variable in our study was the frequency of CAEs. Independent variables included patient characteristics, characteristics of the operation, and performance of an intraoperative anastomotic leak test. Patient characteristics were summarized using frequency distributions for categorical variables, and mean (SD) for continuous variables. We stratified patient characteristics by performance of intraoperative anastomotic leak testing among routine testing hospitals. Logistic regression models to evaluate the association of leak testing (among hospitals that did and those that did not routinely perform a leak test) and CAEs were developed with patient demographic and clinical characteristics and operative characteristics identified as statistically significant ($P < .05$) on univariate evaluation or those found to be important in previous studies of anastomotic leaks. We used each quarter of a hospital's performance as a unit of analysis and controlled for hospital effects in hierarchical modeling.

We evaluated temporal trends in the use of leak testing and rates of CAEs. No hospital left the cohort during the study period; however, hospitals initiated participation and data entry at a variety of times. To account for this, we used quarters of participation in SCOAP as the unit of analysis. A test for trend in leak rates and testing rates across quarters of participation was performed.

We performed several sensitivity analyses. For the designation of a hospital that routinely performed an anastomotic leak test, we used alternative cutoff points for leak testing that ranged from 80% to 95%. We explored the relationship between leak testing method (air/contrast instillation compared with palpation with colonic gas) and CAEs. We also performed a sensitivity analysis exploring the relationship of leak testing among patients with a protective diverting ostomy ($n = 543$), acknowledging that the diverting ostomy may have been performed after the leak test identified an anastomotic leak and that a diverting ostomy may decrease the rate of pelvic sepsis.^{19,20} Commercial software was used for all analyses (STATA, version 11; STATA Corp).

RESULTS

We identified 3449 patients (mean [SD] age, 58.8 [14.8] years; 45.0% male) who underwent a colectomy or rectal resection with an ileorectal or colorectal anastomosis for cancer (27.1%), diverticulitis (33.4%), or other diagnoses (39.5%) (**Table 1**). Intraoperative anastomotic leak testing was performed for 2774 patients (80.4%). Patients whose operations included anastomotic leak testing had similar clinical and demographic characteristics but were more likely to undergo a laparoscopic (vs open) procedure and low anterior resections (vs left and total colectomies) ($P < .001$). Patients undergoing operations at hospitals that routinely performed anastomotic leak tests were more likely to have a body mass index larger than 30 (calculated as weight in kilograms divided by height in meters squared) ($P = .006$) and un-

Table 1. Patient Sociodemographic and Clinical Characteristics in Hospitals That Did vs Did Not Routinely Perform an Anastomotic Leak Test

Characteristic	No. (%)			P Value
	All Patients (N = 3449)	Routine Anastomotic Leak Test (n = 1271)	No Routine Anastomotic Leak Test (n = 2178)	
Age, mean (SD)	58.8 (14.8)	58.8 (14.5)	58.8 (15.1)	.97
Female sex	1553 (45.0)	571 (44.9)	982 (45.1)	.92
Medicaid	198 (5.7)	77 (6.1)	121 (5.6)	.60
Smoker	605 (17.7)	240 (19.0)	365 (16.9)	.13
BMI >30	960 (29.3)	386 (32.2)	574 (27.6)	.01
Albumin level <3.0 g/dL ^a	185 (12.0)	65 (10.8)	119 (12.8)	.24
Diabetes mellitus	412 (12.0)	151 (11.9)	261 (12.0)	.92
Charlson comorbidity index				
0	2525 (73.2)	938 (73.8)	1587 (72.9)	.80
1	727 (21.1)	264 (20.8)	463 (21.3)	
2	154 (4.5)	56 (4.4)	98 (4.5)	
≥3	43 (1.3)	13 (1.0)	30 (1.4)	
Immunosuppressed	150 (4.4)	42 (3.3)	108 (5.0)	.02
Cancer as indication for operation	933 (27.1)	342 (26.9)	591 (27.1)	.89
Type of operation				
Left hemicolectomy	1080 (31.3)	385 (30.3)	695 (31.9)	<.001
Low anterior resection	2092 (60.7)	811 (63.8)	1281 (58.8)	
Total colectomy	277 (8.0)	75 (5.9)	202 (9.3)	
Operative approach				
Laparoscopic	1053 (30.8)	401 (31.6)	652 (30.3)	.41
Operative time, mean (SD), min	164 (93)	165 (91)	163 (94)	.46
Protective ostomy formation	544 (16.5)	181 (14.5)	363 (17.8)	.02
Leak testing performed	2774 (80.7)	1231 (97.2)	1543 (71.0)	<.001

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).

SI conversion factor: To convert to albumin to grams per liter, multiply by 10.

^aSome patients had missing albumin level data.

dergo low anterior resections ($P < .001$) but less likely to be receiving an immunosuppressant ($P = .02$) and to receive a protective ostomy ($P = .02$).

Among the entire cohort, 188 patients (5.5%) experienced a CAE in the postoperative period and 18 patients (0.5%) died. Patient characteristics associated with a CAE included tobacco use, diabetes mellitus, immunosuppressive medications, a low albumin level, and a higher Charlson comorbidity index score (**Table 2**). Operative characteristics associated with a CAE included operative time and the type of operation performed (Table 2). Patients who underwent anastomotic leak testing were equally likely to develop CAEs as were those who did not ($P = .23$).

ROUTINE ANASTOMOTIC LEAK TESTING AND CAEs

Overall, 1271 patients (36.9%) underwent an operation during a hospital quarter when leak testing was performed routinely. In our unadjusted analysis, among patients at a hospital that routinely performed an anastomotic leak test, CAE rates were not significantly different between individuals who were tested for a leak and those who were not tested (5.8% vs 11.1%, $P = .18$). In hospitals that routinely performed an anastomotic leak test, we found that leak testing was used in all patients with low albumin levels; therefore, we were unable to evaluate the effect of leak testing in this high-risk group. In

patients with albumin levels above 3 g/dL at routine testing hospitals ($n = 535$), we found a lower rate of CAEs among tested compared with untested anastomoses (5.8% vs 20.0%; $P = .02$). We adjusted for relevant patient and clinical factors (age, sex, smoking status, body mass index, albumin levels <3 g/dL, diabetes mellitus, Charlson comorbidity index, immunosuppression, type of operation, laparoscopic approach, operative time, and year of operation) and found that the use of leak testing was associated with a lower risk of CAEs in routine testing hospitals (odds ratio, 0.23; 95% CI, 0.05-0.99) (**Table 3**). As expected, in hospitals that did not routinely perform leak testing, the use of leak testing was associated with a greater odds of CAEs (odds ratio, 2.68; 95% CI, 1.14-6.26) (Table 3).

TEMPORAL TRENDS

Examined as a chronological function of quarters of SCOAP involvement, the rates of anastomotic leak testing increased from 56% in the starting quarter of hospital participation in SCOAP to 76% in quarter 16 (test for trend, $P < .001$) (**Figure 1**). Concomitant to the increased use of leak testing, there was a decreasing rate of CAEs from 7.0% in the starting quarter of participation to 4.6% in quarter 16 (test for trend, $P = .01$) (**Figure 2**).

In sensitivity analyses, we evaluated patients who also underwent formation of a protective ostomy. We found

Table 2. Patient, Operative, and Hospital Characteristics Associated With a CAE

Characteristic	No. (%)			P Value
	All Patients (N = 3449)	No CAE (n = 3261)	CAE (n = 188)	
Age, mean (SD)	58.8 (14.8)	58.7 (14.8)	60.4 (14.9)	.12
Male sex	1553 (45.0)	1445 (44.3)	108 (57.5)	<.001
Medicaid	198 (5.8)	189 (5.8)	9 (4.9)	.58
Smoker	605 (17.7)	562 (17.4)	43 (22.9)	.05
BMI >30	960 (29.3)	907 (29.2)	53 (29.9)	.84
Albumin level <3.0 g/dL	184 (12.0)	159 (11.1)	25 (24.0)	<.001
Diabetes mellitus	412 (12.0)	381 (11.7)	31 (16.5)	.05
Charlson comorbidity index				
0	2525 (73.2)	2407 (73.8)	118 (62.8)	<.001
1	727 (21.1)	673 (20.6)	54 (28.7)	
2	154 (4.5)	145 (4.5)	9 (4.8)	
≥3	43 (1.3)	36 (1.1)	7 (3.7)	
Immunosuppressed	150 (4.4)	131 (4.0)	19 (10.1)	<.001
Cancer as indication for operation	933 (27.1)	883 (27.1)	50 (26.6)	.89
Type of operation				
Left hemicolectomy	1080 (31.3)	1010 (31.0)	70 (37.2)	.003
Low anterior resection	2092 (60.7)	1998 (61.3)	94 (50.0)	
Total colectomy	277 (8.0)	253 (7.8)	24 (12.8)	
Operative approach				.19
Laparoscopic	1053 (30.8)	1004 (31.0)	49 (26.5)	
Operative time, mean (SD), min	164 (93)	162 (92)	195 (103)	<.001
Protective ostomy formation	544 (16.5)	496 (15.9)	48 (27.6)	<.001
Leak testing performed	2774 (80.7)	2616 (80.5)	158 (84.0)	.23
Hospitals that routinely performed anastomotic leak testing	1271 (36.9)	1196 (36.7)	75 (39.9)	.37

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CAE, composite adverse event. SI conversion factor: To convert albumin to grams per liter, multiply by 10.

Table 3. Risk Factors for a CAE Between Hospitals That Did and Did Not Routinely Perform an Anastomotic Leak Test After Ileorectal or Colorectal Anastomoses

Characteristic	Routine Anastomotic Leak Test		No Routine Anastomotic Leak Test	
	Unadjusted OR of CAE (95% CI)	Adjusted OR of CAE (95% CI)	Unadjusted OR of CAE (95% CI)	Adjusted OR of CAE (95% CI)
Leak test performed	0.50 (0.17-1.47)	0.23 (0.05-0.99)	1.44 (0.88-2.38)	2.68 (1.14-6.26)
Age, y	1.0 (0.99-1.02)	1.01 (0.98-1.04)	1.01 (1.00-1.02)	1.02 (0.99-1.04)
Male sex	1.97 (1.22-3.20)	3.38 (1.56-7.36)	1.49 (1.01-2.20)	0.97 (0.51-1.84)
Smoker	1.76 (1.03-2.99)	2.01 (0.94-4.33)	1.07 (0.65-1.77)	1.3 (0.58-2.91)
BMI >30	0.76 (0.45-1.31)	0.64 (0.27-1.52)	1.08 (0.70-1.66)	1.23 (0.61-2.47)
Albumin level <3 g/dL	3.24 (1.52-6.90)	4.34 (1.81-10.41)	1.89 (0.95-3.76)	2.16 (0.95-4.90)
Diabetes mellitus	1.15 (0.58-2.29)	0.98 (0.29-3.33)	1.58 (0.94-2.63)	0.8 (0.28-2.27)
Charlson comorbidity index				
1	1.35 (0.77-2.34)	1.42 (0.51-3.93)	1.45 (0.14-15.35)	1.94 (0.84-4.46)
2	0.89 (0.26-2.99)	1.59 (0.31-8.19)	1.27 (0.51-3.18)	1.16 (0.28-4.88)
≥3	5.68 (1.46-22.17)	8.49 (1.43-50.41)	3.34 (1.06-10.50)	1.45 (0.14-15.35)
Immunosuppressed	2.45 (0.91-6.56)	2.39 (0.51-11.12)	3.03 (1.63-5.67)	3.69 (1.44-9.42)
Type of operation	1.08 (0.74-1.57)	1.55 (1.01-2.37)	1.06 (0.82-1.37)	1.04 (0.69-1.59)
Laparoscopic approach	0.42 (0.23-0.79)	0.46 (0.16-1.28)	1.01 (0.65-1.57)	1.25 (0.60-2.63)
Operative time	1.14 (0.98-1.31)	1.0 (0.99-1.00)	1.19 (1.08-1.32)	1.0 (1.00-1.01)
Year of operation	0.84 (0.65-1.08)	0.9 (0.51-1.57)	0.94 (0.81-1.10)	0.87 (0.59-1.27)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CAE, composite adverse event; OR, odds ratio. SI conversion factor: To convert albumin to grams per liter, multiply by 10.

that this group appeared to have a higher rate of CAEs (8.9% vs 4.6% in the nonprotective stoma group; $P < .001$). Excluding patients who underwent formation of a protective ileostomy did not change the relationship of leak testing and CAEs.

COMMENT

Routine intraoperative leak testing in elective colorectal operations was associated with more than a 75% lower risk of unplanned postoperative intervention and/or death.

As suspected, we found that, when used selectively, leak testing is performed more often in patients for whom the surgeon has increased concern about the integrity of the anastomosis. Leak testing was used only occasionally when SCOAP was started (56% of cases), but after 5 years of benchmarking and education about leak testing, 84% of the hospitals increased their use. The SCOAP surgeons now perform such testing in nearly 90% of operations concurrent to a decrease in the rates of CAEs.

Several studies^{10,13,15,16,21,22} with relatively small numbers of patients have demonstrated the benefit of intraoperative leak testing. One randomized controlled study by Beard and colleagues¹⁷ found higher rates of clinical leaks (14% nontested vs 4% tested; $P = .04$) when testing was not performed. More recently, Ricciardi and colleagues¹³ found that clinical leaks occurred in 3.8% of anastomoses with negative air leak tests compared with 8.1% of all untested anastomoses at a single high-volume center. One of the characteristics of a quality improvement metric is that it needs to improve outcomes in the general community. We examined the impact of leak testing in a large sample of patients across a large number of varied hospital types and found that it was associated with improved outcomes.

Although some investigators^{10,13,15,16} have demonstrated the benefits of leak testing in preventing anastomotic leaks, this finding has been inconsistent.^{11,12} Failing to separate the routine vs selective users of leak testing, these prior negative studies of leak testing may not have accounted for critical differences in the intent of the testing and the pretest probability of a leak. To our knowledge, the present study is the first to distinguish the use of testing for screening (routine) rather than for confirmation of a suspected leak (selective). This approach parallels a study²³ conducted to evaluate the effect of performing an intraoperative cholangiogram on the rate of bile duct injury during cholecystectomy. That study distinguished between selective intraoperative cholangiogram use (done to identify a suspected injury or in patients at higher risk) and routine use in which the goal was prevention. Using a similar approach, we found that hospitals that perform routine leak testing have a lower risk of adverse events only when they use the leak testing. The strength of this analysis is that it acknowledges that there may be other factors that make the hospitals that perform routine leak testing “better,” but if leak testing is not helpful, then the adjusted risk of leaks would be equally low for both tested and nontested anastomoses at these facilities. Failing to find this, we conclude that the use of testing was a relevant factor in accomplishing better outcomes. We also found that when leak testing was used selectively (eg, in patients for whom the surgeon was concerned about the integrity of the anastomosis), it was associated with a higher risk of CAEs. Prior studies also failed to account for other patient risk characteristics, such as low albumin levels. In our study, when leak testing was performed routinely in patients at average risk, it was associated with lower rates of CAEs. Unfortunately, this was essentially not evaluable among patients at higher risk because all had leak testing performed at routine testing hospitals. Other differences in

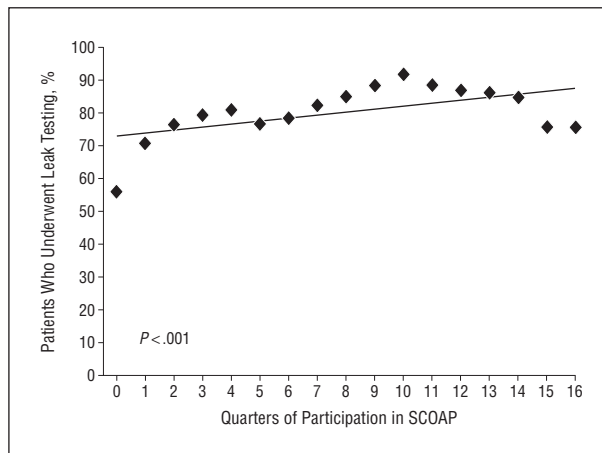


Figure 1. Trend during quarters of participation in the Surgical Care and Outcomes Assessment Program (SCOAP) in the use of anastomotic leak testing after an ileorectal or colorectal anastomosis.

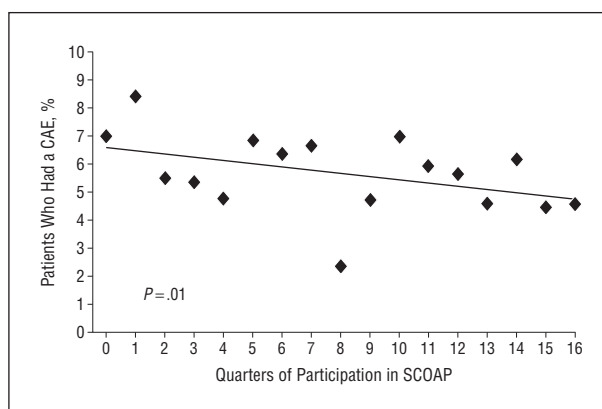


Figure 2. Trend during quarters of participation in the Surgical Care and Outcomes Assessment Program (SCOAP) in the incidence of composite adverse events (CAEs) after an ileorectal or colorectal anastomosis.

leak testing efficacy may be explained by a lack of uniform definitions of an anastomotic leak.^{24,25}

There are some appropriate criticisms of leak testing. Some leaks develop after the patient leaves the operating room. Ricciardi et al¹³ reported that 3.8% of patients without an air leak at the conclusion of the operation went on to develop a leak. Furthermore, critics claim that placing a sigmoidoscope close to a newly created anastomosis may cause barotrauma and that air leaks do not necessarily result in clinically significant leaks.^{12,26} These criticisms notwithstanding, we found that the risk of clinically significant leak and death was 77% lower when leak testing was used routinely.

There are limitations to this study. Although we found no significant differences in patient and clinical characteristics between tested and nontested patients at routine testing hospitals, it may be that nontested patients were at higher risk for leaks because of other nonmeasured metrics. Another untestable assumption that we made is that, at selective hospitals, leak testing is performed in patients suspected of having leaks or being at higher risk for leaks. We found evidence that leak testing in hospitals where it is not routine was performed in patients at higher risk (eg, those receiving immunosup-

pressants), but we cannot rule out that leak testing in those centers caused some leaks. We did not have information on surgeons' reactions to detecting a leak, and this limits the ability to differentiate the efficacy of different methods to manage leaks identified during intraoperative leak testing. Furthermore, the threshold of 90% leak testing as a definition of routine testing was arbitrary. We performed a sensitivity analysis looking at different cut-off points (80%, 90%, and 95%) and, although we found the same general effect, this cutoff point had face validity among SCOAP surgeons and a better balance of cases between groups. Hospital-level rates of leak testing assume that all surgeons at that hospital have a similar use of leak testing. Most hospitals in the SCOAP have 1 or 2 surgeons doing most of the colorectal resections, and separate physician-level analysis was not performed secondary to low numbers of procedures. We adjusted for hospital sites in our hierarchical modeling but could not adjust for other factors, including training and infrastructure issues, that may relate to CAEs. There are also operational limitations with this study. There was no standard method of leak testing by surgeons across all hospitals; therefore, we could not assess the comparative value of one type of leak testing over another, including a method of testing where the anastomosis is occluded on either side by the surgeon's hands and bowel gas is manipulated in the distended anastomotic segment and the bowel is submerged. We performed a sensitivity analysis in which this type of testing was excluded and found no changes in our point estimates. The term *leak* is not used in SCOAP; instead, a more conservative approach is applied to describing adverse clinical events that lead to intervention or death. This strategy was used because only clinically relevant leaks have an effect on patients' therapy vs radiographically identified leaks that are asymptomatic, and it is difficult to distinguish the relationship of abscesses to anastomotic microperforation using this approach. We also included patients who received a protective diverting ostomy. Patients in both the tested and untested groups with protective stomas had a higher rate of CAEs, suggesting that the stoma creation followed a positive leak test result or was created in patients at high risk for leak. Our sensitivity analysis excluding these patients did not change our point estimates. Last, SCOAP hospitals were recruited over time and were engaged in separate serial quality improvement activities concerning colorectal surgery. To distinguish whether improvements in the CAE rate were the result of changes in leak testing or other variables that changed, we adjusted for time in our analysis. We also used each quarter of a hospital's performance as a unit of analysis.

In conclusion, we found that routine leak testing was associated with a 77% adjusted risk reduction in CAEs after elective colorectal resections. Although leak testing is a complex metric to evaluate using observational data, there was a clear subgroup of average-risk, routinely tested patients for whom it showed clear benefit. Given the low risk of leak testing, we believe the burden of proof for future studies might better be to demonstrate that routine leak testing does not improve outcomes. These data suggest that, by including actionable process-of-care metrics such as leak testing in quality im-

provement initiatives, surgeon-led performance benchmarking activities can have a direct effect on the quality of surgical care. Performance benchmarking and educational activities aimed at increasing routine leak testing appear to improve outcomes and should be considered in broader campaigns aimed at quality improvement.

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REFERENCES

1. Petersen S, Freitag M, Hellmich G, Ludwig K. Anastomotic leakage: impact on local recurrence and survival in surgery of colorectal cancer. *Int J Colorectal Dis.* 1998;13(4):160-163.
2. Alves A, Panis Y, Trancart D, Regimbeau JM, Pocard M, Valleur P. Factors associated with clinically significant anastomotic leakage after large bowel resection: multivariate analysis of 707 patients. *World J Surg.* 2002;26(4):499-502.
3. Bellows CF, Webber LS, Albo D, Awad S, Berger DH. Early predictors of anastomotic leaks after colectomy. *Tech Coloproctol.* 2009;13(1):41-47.
4. Khan AA, Wheeler JM, Cunningham C, George B, Kettlewell M, Mortensen NJ. The management and outcome of anastomotic leaks in colorectal surgery. *Colorectal Dis.* 2008;10(6):587-592.
5. Rios J, Murillo C, Carrasco G, Humet C. Increase in costs attributable to surgical infection after appendectomy and colectomy. *Gac Sanit.* 2003;17(3):218-225.
6. Swenson BR, Hollenbeak CS, Koltun WA. Hospital costs and risk factors associated with complications of the ileal pouch anal anastomosis. *Surgery.* 2002;132(4):767-774.
7. Suding P, Jensen E, Abramson MA, Itani K, Wilson SE. Definitive risk factors for anastomotic leaks in elective open colorectal resection. *Arch Surg.* 2008;143(9):907-912.
8. Veyrie N, Ata T, Muscari F, et al; French Associations for Surgical Research. Anastomotic leakage after elective right versus left colectomy for cancer: prevalence and independent risk factors. *J Am Coll Surg.* 2007;205(6):785-793.
9. Platell C, Barwood N, Dorfmann G, Makin G. The incidence of anastomotic leaks in patients undergoing colorectal surgery. *Colorectal Dis.* 2007;9(1):71-79.
10. Davies AH, Bartolo DC, Richards AE, Johnson CD, McC Mortensen NJ. Intra-

- operative air testing: an audit on rectal anastomosis. *Ann R Coll Surg Engl.* 1988; 70(6):345-347.
11. Wheeler JM, Gilbert JM. Controlled intraoperative water testing of left-sided colorectal anastomoses: are ileostomies avoidable? *Ann R Coll Surg Engl.* 1999; 81(2):105-108.
 12. Schmidt O, Merkel S, Hohenberger W. Anastomotic leakage after low rectal stapler anastomosis: significance of intraoperative anastomotic testing. *Eur J Surg Oncol.* 2003;29(3):239-243.
 13. Ricciardi R, Roberts PL, Marcello PW, Hall JF, Read TE, Schoetz DJ. Anastomotic leak testing after colorectal resection: what are the data? *Arch Surg.* 2009; 144(5):407-412.
 14. Fielding LP, Stewart-Brown S, Blesovsky L, Kearney G. Anastomotic integrity after operations for large-bowel cancer: a multicentre study. *Br Med J.* 1980; 281(6237):411-414.
 15. Gilbert JM, Trapnell JE. Intraoperative testing of the integrity of left-sided colorectal anastomoses: a technique of value to the surgeon in training. *Ann R Coll Surg Engl.* 1988;70(3):158-160.
 16. Metcalfe MS, Hemingway D. Testing for anastomotic integrity after reversal of loop ileostomy. *Ann R Coll Surg Engl.* 2000;82(5):344-345.
 17. Beard JD, Nicholson ML, Sayers RD, Lloyd D, Everson NW. Intraoperative air testing of colorectal anastomoses: a prospective, randomized trial. *Br J Surg.* 1990;77(10):1095-1097.
 18. Deyo RA, Cherkin DC, Ciol MA. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. *J Clin Epidemiol.* 1992;45(6):613-619.
 19. Matthiessen P, Hallböök O, Rutegård J, Simert G, Sjö Dahl R. Defunctioning stoma reduces symptomatic anastomotic leakage after low anterior resection of the rectum for cancer: a randomized multicenter trial. *Ann Surg.* 2007;246(2):207-214.
 20. Hüser N, Michalski CW, Erkan M, et al. Systematic review and meta-analysis of the role of defunctioning stoma in low rectal cancer surgery. *Ann Surg.* 2008; 248(1):52-60.
 21. Akyol AM, McGregor JR, Galloway DJ, George WD. Early postoperative contrast radiology in the assessment of colorectal anastomotic integrity. *Int J Colorectal Dis.* 1992;7(3):141-143.
 22. Griffith CD, Hardcastle JD. Intraoperative testing of anastomotic integrity after stapled anterior resection for cancer. *J R Coll Surg Edinb.* 1990;35(2):106-108.
 23. Flum DR, Dellinger EP, Cheadle A, Chan L, Koepsell T. Intraoperative cholangiography and risk of common bile duct injury during cholecystectomy. *JAMA.* 2003;289(13):1639-1644.
 24. Bruce J, Krukowski ZH, Al-Khairy G, Russell EM, Park KG. Systematic review of the definition and measurement of anastomotic leak after gastrointestinal surgery. *Br J Surg.* 2001;88(9):1157-1168.
 25. Peel AL, Taylor EW; Surgical Infection Study Group. Proposed definitions for the audit of postoperative infection: a discussion paper. *Ann R Coll Surg Engl.* 1991; 73(6):385-388.
 26. Smith S, McGeehin W, Kozol RA, Giles D. The efficacy of intraoperative methylene blue enemas to assess the integrity of a colonic anastomosis. *BMC Surg.* 2007;7:15. doi:10.1186/1471-2482-7-15.