ORIGINAL ARTICLE

Contained Anastomotic Leaks After Colorectal Surgery

Are We Too Slow to Act?

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Hypothesis: Contained and free anastomotic leaks, which occur in a small percentage of patients after colorectal surgery, are different clinical entities and consequently should be managed differently.

Design: Retrospective medical record review.

Setting: Academic medical center.

Patients: Patients who underwent colectomy with primary anastomosis (N=4019) between January 1, 1992, and December 13, 2004, were eligible for participation in the study. Fifty-eight patients (1.5%) with an anastomotic leak demonstrated by communication between the collection and the gastrointestinal tract were identified. Twenty-eight of the patients had free leaks and 30 had contained leaks.

Main Outcome Measures: Time to presentation, symptoms at presentation, rates of reexploration, and in-hospital mortality.

Results: Baseline characteristics, presenting symptoms, physical examination findings, and laboratory values were similar between patients with contained and free leaks. Almost all patients with free leaks were taken directly to the operating room, whereas those with contained leaks were initially more likely to be treated nonoperatively. However, 24 of the 28 patients with contained leaks (86%) ultimately required surgical intervention. In-hospital mortality was the same in both groups (18% in the contained leak group and 17% in the free leak group).

Conclusions: In patients with contained leaks who have documented communication between the abscess cavity and the bowel, there is no difference in the rate of operative management or morbidity and mortality when compared with those with free leaks. This finding suggests that the categorization of leaks as free or contained may not be justified and argues for early operative intervention even in patients with contained leaks.

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ANASTOMOTIC BREAKDOWN after colorectal surgery is infrequent but has significant consequences, including increased risks of surgical site infection, deep vein thrombosis, pulmonary embolism, pneumonia, cerebrovascular accident, septic shock, and death.[1-4] In cancer operations, leaks increase the risk of locoregional recurrence and decrease the probability of survival.[5,6]

See Invited Critique at end of article

Conventional wisdom holds that there is a difference between the patients who present with free perforation and associated peritonitis (free leaks) and those with contained leaks. The difference is said to be defined by such features as the presence or absence of peritonitis, the presence or absence of localized findings on contrast radiographs, or the anastomotic appearance of the leak at the time of exploration.[3,7]

A distinction between free and contained anastomotic leaks makes sense to most physicians. At an intuitive level, the patient with disseminated intra-abdominal sepsis from a broken down colocolostomy simply seems different from the patient with a localized abscess next to and in communication with an anastomosis. As a result of this intuitive assumption, many surgeons treat patients with contained leaks differently from those with free leaks. Patients with contained leaks tend to be treated with percutaneous drainage, whereas the patients with free leaks tend to be treated surgically with emergent reexploration, takedown of the anastomosis and creation of an end stoma, or a proximal diversion via a loop ileostomy.[1,8] The goals of this study were to evaluate the validity of this conventional wisdom and to compare empirically the presentation, course of treatment, morbidity, and mortality in the patients with free and contained anastomotic leaks that were in communication with the gastrointestinal tract.

Table 1. Demographic Data and Indication for Operation in 58 Patients With Colonic Anastomotic Leak After Colectomy

Characteristic	Type of Leak, No. (%) of Patients: Contained (n=28)	Free (n=30)	P Value
Male	17 (61)	15 (50)	.44
Female	11 (39)	15 (50)	
Medical history			
Hypertension	14 (50)	13 (43)	.79
Previous abdominal surgery	9 (32)	14 (47)	.29
Coronary artery disease	8 (29)	7 (23)	.76
Chronic obstructive pulmonary disease	8 (29)	6 (20)	.54
Diabetes mellitus	5 (18)	0	.02
Congestive heart failure	4 (14)	4 (13)	>.99
Neoadjuvant therapy	4 (14)	0	.04
Renal insufficiency	3 (11)	1 (3)	.34
Immunosuppression	3 (11)	8 (27)	.18
Atrial fibrillation	2 (7)	4 (13)	.67
Chronic anemia	2 (7)	1 (3)	.61
Alcohol abuse or illicit drug use	2 (7)	3 (10)	>.99
Hemodialysis dependent	2 (7)	1 (3)	.60
Peripheral vascular disease	2 (7)	4 (13)	.67
Myocardial infarction	1 (4)	1 (3)	>.99
Obesity	1 (4)	1 (3)	>.99
Nongastrointestinal malignant neoplasm	0	4 (13)	.11
Indication for operation			.54
Mass	16 (57)	14 (47)	
Acute bleeding	0	1 (3)	
Irritable bowel disease	2 (7)	4 (13)	
Perforation	0	0	
Diverticular disease	5 (18)	7 (23)	
Obstruction	1 (4)	0	
Colostomy takedown	2 (7)	2 (7)	
Chronic gastrointestinal bleeding	1 (4)	0	
Volvulus	0	0	
Ischemia	0	2 (7)	
No data	1 (4)	1 (3)	

METHODS

STUDY POPULATION

We gathered retrospective data on 4019 patients who underwent elective colectomy with a primary anastomosis at Massachusetts General Hospital between January 1, 1992, and December 13, 2004. Identifying these patients by searching first for the *International Classification of Diseases, Ninth Revision (ICD-9)* procedure code for colectomy (45.7, 45.8, 45.93, 45.94, 48.63, and 54.21), we then identified 339 patients within this population who also had an associated *ICD-9* code for a gastrointestinal complication (997.4). We audited the medical records of these 339 patients and identified 62 patients with anastomotic leaks. One of these patients was excluded because he presented 274 days after his operation with a perforation at the anastomosis in the setting of a recurrent cancer. Three other patients were excluded because they underwent emergent colectomy and were not representative of the elective population. This left 58 patients in our study population.

The medical records of the 58 patients diagnosed as having an anastomotic leak were abstracted to capture relevant comorbidities, indications for initial colectomy, surgical details relating to the procedure, clinical and laboratory data relating to the presentation of the leak at the time of diagnosis, and information detailing the management strategy used to treat the leak. Finally, we collected data on morbidity and in-hospital mortality. We obtained approval from the Massachusetts General Hospital institutional review board before data collection.

DEFINITIONS OF LEAK

For the purposes of this study, we defined an anastomotic leak as the breakdown of a colonic anastomosis associated with an intra-abdominal collection identified either by contrast radiographs before a subsequent operation or by the surgeon at the time of a subsequent operation. We classified leaks as contained or free on the basis of the original classification by the surgeon and as verified by available clinical information by reviewing computed tomographic scans, diatrizoate meglumine (Gastrografin) enemas, abdominal radiographs, and operative reports. Clinical data were available to verify the diagnosis in all cases. In general, contained leaks were defined in terms of a localized collection, whereas free leaks were defined as those with diffuse gross contamination of the peritoneal cavity. Our study excluded patients presenting with perianastomotic collections detected by computed tomography if these collections lacked a demonstrable communication with the gastrointestinal lumen.

STATISTICAL ANALYSIS

The 28 patients who had been characterized as having contained anastomotic leaks were compared with 30 patients who had been characterized as having free leaks. Primary outcomes of our study included the need for subsequent operative exploration and in-hospital mortality; secondary outcomes included time to presentation, symptoms at presentation, and hospital course. Categorical variables were reported as percentages, and 95% confidence intervals (CIs) were calculated using standard binomial distributions for proportions. Continuous variables were reported as means or medians. The Fisher exact or χ^2 test was used to compare categorical variables. For longitudinal variables, a *t* test analysis of the means was performed. Two-tailed $P < .05$ ($\alpha = .05$) was considered statistically significant.

To prevent type II errors in accepting the null hypothesis and arguing for equivalency, the Two One-Sided Tests Procedure was performed as described elsewhere.[9] Briefly, the absolute difference between the groups (contained vs free leaks) in the percentage of the patients who achieved either primary outcome (operative intervention or in-hospital mortality) was calculated along with its $(1 - 2\alpha) \times 100$ (90%) CI. These ranges were compared against the predetermined, clinically significant, 25% absolute difference between groups. When the entire calculated range is within the ±25% boundary, then the groups can be considered statistically equivalent.

RESULTS

DEMOGRAPHICS

Our population of patients with contained leaks (n=28) and free leaks (n=30) were similar in age (median age, 65 and 63 years, respectively), American Society of Anesthesiologists class (median class of 3 in both cases), and medical history, with 2 exceptions: patients with contained leaks appeared to have a higher rate of diabetes mellitus and neoadjuvant therapy (**Table 1**). The populations showed no significant differences in the indica-

Table 2. Original Operation in 58 Patients With Colonic Anastomotic Leak After Colectomy[a]

Operation	Type of Leak, No. (%) of Patients: Contained (n=28)	Free (n=30)
Procedure		
Enterocolostomy	9 (32)	10 (33)
Colocolostomy	7 (25)	12 (40)
LAR	9 (32)	7 (23)
Laparoscopic enterocolostomy	0	0
Laparoscopic colocolostomy	1 (4)	1 (3)
Laparoscopic LAR	1 (4)	0
No data	1 (4)	1 (3)
Anastomosis		
End to end	18 (64)	16 (53)
End to side	4 (14)	9 (30)
Side to side	5 (18)	5 (17)
Hand sewn	7 (25)	6 (20)
Stapled	17 (61)	23 (77)
Other	3 (11)	1 (3)
No data	1 (4)	1 (3)

Abbreviation: LAR, low anterior resection.
[a] There is no statistically significant difference between the groups in the distribution of procedure (*P*=.44), anastomotic type (*P*=.38), or anastomotic method (*P*=.43).

tion for the initial operation (*P*=.54) (Table 1), the procedure performed (*P*=.44), the type of anastomosis (*P*=.38), or whether the anastomosis was hand sewn or stapled (*P*=.43) (**Table 2**).

CLINICAL FEATURES

We found that most leaks (44 [76%]) had been diagnosed radiographically with either contrast computed tomography or diatrizoate meglumine enema (*P*=.36). On average, anastomotic leaks presented on postoperative day 8 (range, 3-65 days). However, free leaks presented earlier than contained leaks (median postoperative day 6.5 [95% CI, 6-9 days] vs 9 [7-11 days]; *P*=.03). Free leaks also tended to be identified during the primary admission, whereas contained leaks presented equally during the primary admission and after discharge.

Patients in both groups presented with an average of 3 symptoms, most commonly abdominal pain (37 patients [64%]), fever (30 patients [52%]), or nausea (14 patients [24%]). Eighty percent of the patients also had nonspecific findings on their physical examination, such as low-grade fever (median temperature, 38.6°C), mild tachycardia (median heart rate, 90/min), and leukocytosis (median white blood cell count, 14.8 cells/μL [to convert to number of cells $\times 10^9$ per liter, multiply by 0.001]). Only 22% had frank peritonitis. Between the population with free and contained leaks, we found no statistically significant differences in rates of occurrence of any of these symptoms, except that more patients with a contained leak tended to report subjective fevers (68% vs 37%; *P*=.02) (**Table 3**).

Notwithstanding the generally similar presentations and symptoms, we found significant differences in the initial management of leaks, depending on their classification as free or contained. Patients with contained leaks were significantly more likely to have been treated initially with either antibiotics alone or percutaneous drainage. Those with free leaks were more likely to have undergone operative intervention (*P*=.009; **Figure 1**). Nearly all (26 of 30) patients with free leaks went to the operating room in the first 24 hours after their diagnosis compared with only 14 of the 28 patients with contained leaks (*P*=.001). Twenty-seven of the 30 patients with free leaks (90%) ultimately required proximal diversion.

A total of 14 patients underwent percutaneous drainage procedures by interventional radiology with the placement of 25 catheters. Of these patients, 4 had free leaks; these patients had an average of 2.5 drains placed, and all but 1 of them underwent subsequent operative intervention. The remaining 10 patients had contained leaks, with each patient having a mean of 1.5 drains placed; 7 of these patients underwent subsequent operative intervention. All drains were placed by the interventional radiology department with choice of technique and approach dictated by cross-sectional imaging and the clinical scenario and determined by the attending interventional radiologist.

Despite these attempts at nonoperative treatment in the patients with contained leaks, 24 of these 28 patients (86%) ultimately required surgery, and 19 received colostomies (Figure 1). This similarity in ultimate treatment, when compared with patients with free leaks, mirrored similar out-

Table 3. Presenting Signs and Symptoms of 58 Patients With Colonic Anastomotic Leak After Colectomy

Signs and Symptoms	Type of Leak: Contained (n=28)	Free (n=30)	*P* Value
Symptoms, No. (%) of patients			
Fever	19 (68)	11 (37)	.02
Pain	17 (61)	20 (67)	.79
Nausea	8 (29)	6 (20)	.54
Tachycardia	7 (25)	3 (10)	.17
Diarrhea	6 (21)	2 (7)	.14
Emesis	6 (21)	3 (10)	.30
Distension	5 (18)	6 (20)	>.99
Anorexia	3 (11)	1 (3)	.34
Peritonitis	3 (11)	3 (10)	>.99
Sepsis	3 (11)	7 (23)	.31
Diaphoresis	2 (7)	1 (3)	.61
Hypotension	2 (7)	2 (7)	>.99
Altered mental status	1 (4)	3 (10)	.61
Chills or rigors	1 (4)	1 (3)	>.99
Gastrointestinal bleeding	1 (4)	2 (7)	>.99
Signs, median			
Maximum temperature, °C	38.64	38.25	.62
Heart rate, beats/min	100	96	.65
Systolic blood pressure, mm Hg	123	121	.62
Diastolic blood pressure, mm Hg	73	70	.20
White blood cell count, cells/μL	14.4	16.6	.19
Serum bicarbonate, mEq/L	26.0	25.4	.93
Plasma urea nitrogen, mg/dL	16	16	.79
Plasma creatinine, mg/dL	1.1	1.1	.81

SI conversion factors: To convert bicarbonate to millimoles per liter, multiply by 1; creatinine to micromoles per liter, multiply by 88.4; urea nitrogen to millimoles per liter, multiply by 0.357; and white blood cell count to number of cells $\times 10^9$ per liter, multiply by 0.001.

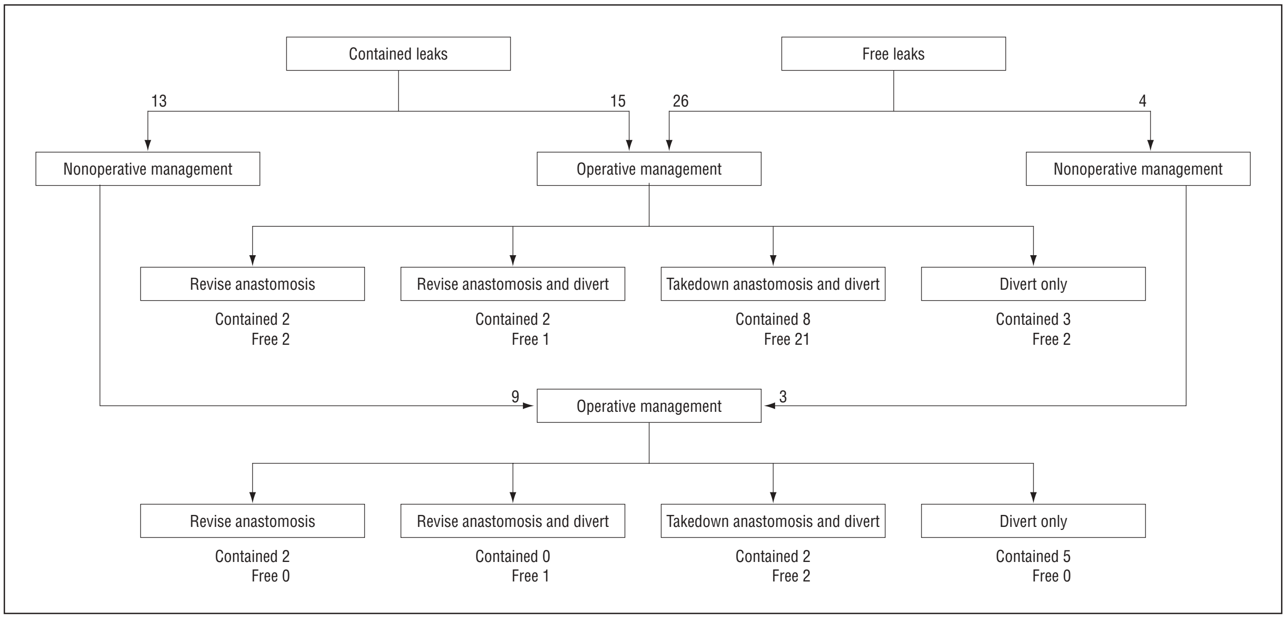

Figure 1. Treatment of 58 patients with colonic anastomotic leaks after colectomy. Fifty-three of the 58 patients ultimately underwent operative management. The leaks in the remaining 5 patients (4 with a contained leak and 1 with a free leak) were managed nonoperatively.

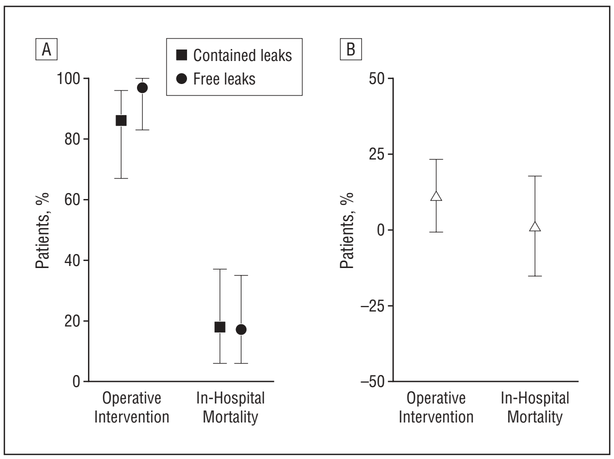

Figure 2. Primary outcomes are the same in patients with contained or free leaks. A, The percentages of patients with either a contained or free leak that required operative intervention and in-hospital mortality rates are shown with their associated 95% confidence intervals (error bars), demonstrating their equivalence. B, The Two One-Sided Tests Procedure was performed to further demonstrate this. The absolute differences between the populations were calculated and are plotted with the associated 90% confidence interval (error bars). This entire range lies within the predetermined, clinically significant difference of 25%.

comes in in-hospital mortality, which was the same between groups. In the end, no significant differences were found in either primary end point between patients with contained leaks and those with free leaks; the rate of reexploration was 14% vs 3% ($P = .10$) and the overall in-hospital mortality was 18% vs 17% ($P > .99$). Furthermore, these outcomes between the groups are statistically equivalent (**Figure 2**).

Patients with free leaks had a significantly higher rate of admission to the intensive care unit than those with contained leaks (30 of 30 [100%] vs 9 of 28 [32%]; $P < .001$) and a significantly higher rate of blood transfusions (12 patients with contained leaks vs 29 with free leaks, $P = .03$, respectively; average, 1.75 U for patients with contained leaks [95% CI, 0.7-2.8 U] vs 7.5 U for patients with free leaks [95% CI, 2.5-12.5 U]; $P = .43$), but they did not have a significantly higher rate of intubation, need for vasoactive medications, or total parental nutrition (**Table 4**). Patients with free leaks were no more likely than those with contained leaks to be readmitted for leak-related complications (4 patients [14%] vs 5 [17%]; $P > .99$). However, patients classified as having contained leaks were twice as likely to undergo successful reversal of their stoma (13 of 19 patients [68%] vs 9 of 27 patients [33%]; $P = .03$) (Table 4).

COMMENT

To our knowledge, our population of 58 patients presenting with anastomotic leaks holds the (arguably dubious) distinction of being the largest series of symptomatic leaks reported in the literature. Nevertheless, our leak rate of 1.5% is roughly half of that reported in most other studies. Depending on the definition used and the study population, anastomotic leaks have a reported incidence of between 0.5% and 30%, with most large studies reporting a leak rate of approximately 3% to 6%.[1-4,8,10,11] This difference may in part be owing to the relatively stringent definition of anastomotic leak used in our study. There is no consensus definition of anastomotic leak, and many prior studies[12] have used a broad definition based on clinical and radiographic features. By contrast, we defined our leaks (as did a recent series from the University of Vermont[13] and the series published by Alves et al[1]) as those leaks with clear demonstrable evidence of communication between the gastrointestinal lumen and the peritoneum at the anastomosis.

We then further subdivided these leaks into either contained or free on the basis of radiographic or operative appearance. This division is consistent with the intuitive approach of many surgeons and with past studies that have asserted a difference between patients with contained and free leaks. For example, in a series of 38 anastomotic leaks

Table 4. Hospital Course and Outcome of 58 Patients With Colonic Anastomotic Leak After Colectomy

Variable	Type of Leak, No. (%) of Patients [95% CI][a] Contained (n=28)	Free (n=30)	*P* Value
In-hospital events/course			
ICU	9 (32) [15-52]	30 (100) [88-100]	<.001
Intubation	8 (29) [13-49]	13 (43) [25-63]	.28
Pressors	9 (32) [15-52]	13 (43) [25-63]	.42
TPN	10 (36) [19-56]	12 (40) [23-59]	.79
Transfusions	12 (43) [24-63]	29 (97) [83-100]	.03
Eventual proximal diversion	19 (68) [48-84]	27 (90) [73-98]	.05
Operative intervention	24 (86) [67-96]	29 (97) [83-100]	.15
Disposition or outcome			
In-hospital death	5 (18) [6-37]	5 (17) [6-35]	>.99
Admitted to rehabilitation hospital	4 (14) [4-33]	14 (47) [28-66]	.02
Leak-associated readmission	4 (14) [4-33]	5 (17) [6-35]	>.99
Stoma reversed[b]	13 (68) [43-87]	9 (33) [16-53]	.03

Abbreviations: CI, confidence interval; ICU, intensive care unit; TPN, total parenteral nutrition.
[a] The 95% CIs are calculated on the basis of the percentages and are expressed as percentages.
[b] Percentage of the patients who underwent proximal diversion.

after 219 low anterior resections, Karanjia et al[7] reported 24 free leaks (symptomatic) and 14 contained leaks (radiographic), with all mortality (3 patients [8%]) confined to the free leak group. In addition, of the patients with contained leaks, 85% had stoma closure, whereas only 54% of those with free leaks had their stomas closed, suggesting a better overall course for those with contained leaks.

In this study, by contrast, we suggest that the differences between free and contained leaks may be a result of wishful thinking more than of actual clinical outcomes. Contained leaks tended to have the same signs and symptoms as free leaks. Although they were more likely to have been subjected to attempts at nonoperative treatment, this modality failed in almost all patients with contained leaks, and these patients subsequently required surgical intervention. We also noted surprising similarities in in-hospital mortality and leak-related readmission. Thus, although the anatomy of the leak might argue for an attempt at nonoperative treatment, our series raises questions about this approach, suggesting that almost all of these patients ultimately will require surgery for definitive treatment.

Our questions about the efficacy of dissimilar treatment and delay in surgical intervention for patients with contained leaks are heightened by the unexpected finding of similar mortality in the free and contained leak populations. Patients with contained leaks were significantly less likely to require intensive care unit admission or blood transfusion and were significantly more likely to be discharged to home rather than to rehabilitation hospitals and should, perhaps, have had lower overall mortality rates. Karanjia et al[7] showed no mortality in their minor leak group and, although their definition of free and contained leaks was not commensurate with ours, it indicates that the severity of intra-abdominal disease can be correlated with overall mortality. In addition, there was a trend toward a statistically significant higher rate of stoma closure for those with contained leaks. These factors suggest that the population with contained leaks presented initially as more stable. If one posits that patients with a contained leak should have lower mortality rates than those with a free leak, then equal mortality between the 2 groups is noteworthy and may suggest that these patients were undertreated or treated too late. If this is, in fact, correct, then perhaps anastomotic leaks should be treated the same, regardless of whether they are seen as contained or free. There should be no distinction in clinical management between the two.

There are reasons to believe that early surgical intervention will improve mortality rates in those diagnosed as having contained leaks. Alves et al[1] showed that the mortality rate was 0% (of 11) for patients operated on again before postoperative day 5 and 22% (5 of 23) for those operated on after postoperative day 5. Importantly, in our study, the median day of presentation was postoperative day 6.5 for free leaks and postoperative day 9 for contained leaks. The fact that patients with contained leaks tended to present and to have their conditions diagnosed later may help explain why there were no differences in mortality rates between those with contained and free leaks. Had these leaks been detected the average of 2.5 days earlier that free leaks were, it is possible that there would have been lower mortality rates in the contained leak group. The lower mortality rate associated with earlier definitive intervention in other studies further strengthens the argument that delays associated with nonoperative treatment may further exacerbate the mortality of those with contained leaks.

A word of caution is in order. Our study, as previously noted, used a narrow and relatively rigorous definition of leak. Many patients whom their surgeons would classify as having a contained leak (ie, a fluid collection around the anastomosis with purulent material obtained via percutaneous drainage) did not satisfy our criteria because they either lacked radiographic evidence of communication between the gastrointestinal lumen and abscess cavity or were not tested for one. In this broader group of patients, it may still be appropriate to assume a benign course, with no need for further operative intervention. Because of this, patients whose conditions do not improve rather rapidly after percutaneous drainage should have a catheter injection to assess whether there is communication with the anastomosis. However, within our narrow definition of leak, our data argue for aggressive treatment, with no distinction between leaks classified as contained and those classified as free.

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INVITED CRITIQUE

What constitutes a leak after colonic anastomoses and how often should it occur? These questions are answered in the article by Damrauer et al on this topic. Damrauer et al first offer a precise definition of a leak: leaks are "communications between the gastrointestinal lumen and the peritoneum at the anastomosis." This definition is important to distinguish between fluid collections associated with leaks from abscesses that may form from bacterial contamination of the peritoneal cavity that is not associated with a leak. Failure to make this distinction has caused a wide variance in reported colonic anastomotic leak rates, ranging from 0.5% to 30%. True leaks are relatively uncommon. In this series of 4019 patients undergoing colon operations at a single institution between 1992 and 2004, the leak rate was 1.5%.

This number is important. It provides us with a benchmark at which to evaluate surgical performance. Leaks are technical complications. Theoretically, they can be avoided, but, in practice, they are inevitable, occurring at a rate of approximately 1.5%. When do we decide that an individual surgeon's leak rate is too high? Using the cited definition of leaks and considering the natural variation that occurs in complication rates, one could easily justify doubling the leak rate of 1.5% observed by Damrauer et al. Surgeons experiencing leak rates that exceed 3.0% should probably undergo peer review. Should this review threshold be risk adjusted? No; risk adjustment makes little sense for technical complications. Risk adjustment may be helpful for stratifying medical complications, such as pneumonia or postoperative myocardial infarction, based on a patient's overall medical condition and how it may contribute to these sometimes unavoidable complications. Thus, one important outcome from the series of Damrauer et al is the establishment of a clearly articulated definition for colonic anastomotic leaks and their expected rates from which we can benchmark surgeon performance.

The other important conclusion reached from this article is how we should manage these leaks. In contrast to abscesses that are adequately treated by percutaneous drainage, leaks require subsequent operation. Damrauer and colleagues found that 7 of 10 patients with a demonstrated leak as defined by having a "communication between the intestinal lumen and the peritoneum" who were treated by percutaneous drainage procedures ultimately required surgery. In fact, 86% of all patients with leaks required subsequent operation. This subsequent operation rate represents a powerful indictment of conservative approaches for treating leaks. In most cases, nonoperative treatment approaches fail. The authors encourage us to use a strategy of early operation when these leaks are identified to avoid delay in the inevitable and encourage a more rapid recovery from these serious complications. If failure of conservative measures is duplicated in other case series, we may wish to consider early additional operation the standard of care for treating postoperative colonic anastomotic leaks.

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