

Anastomotic Leak Testing After Colorectal Resection

What Are the Data?

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Objective: To determine the value of anastomotic leak testing of left-sided colorectal anastomoses.

Design: Cohort analysis.

Setting: Subspecialty practice at a tertiary care facility.

Patients: Consecutive subjects were selected from a prospective colorectal database of 2627 patients treated between January 1, 2001, and December 31, 2007.

Intervention: Creation of left-sided colorectal anastomoses and air leak testing per surgeon preference.

Main Outcomes Measures: Anastomosis type, method (handsewn vs stapled), performance of air leak testing, repair method of anastomoses after air leak tests yielding positive results, and development of postoperative clinical leak.

Results: A total of 998 left-sided colorectal anastomoses were performed without proximal diversion; 90.1% were stapled and 9.9% were handsewn. Intraoperative air leaks were noted in 65 of 825 tested anastomoses (7.9%), that is, 7.8% of stapled anastomoses and 9.5% of handsewn anastomoses. A clinical leak developed in 48 patients (4.8%). Clinical leaks were noted in 7.7% of anastomoses with positive air leak test results compared with 3.8% of anastomoses with negative air leak test results and 8.1% of all untested anastomoses ($P < .03$). If air leak testing yielded positive results, suture repair alone was associated with the highest rate of postoperative clinical leak compared with diversion or re-anastomosis, 12.2% vs 0% vs 0%, respectively ($P = .19$).

Conclusions: Our data indicate a high rate of air leaks at air leak testing of left-sided colorectal anastomoses. In addition, the high rate of clinical leaks in untested anastomoses leads us to recommend air leak testing of all left-sided anastomoses, whether stapled or handsewn.

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DISRUPTION OF THE COLORECTAL anastomosis is a difficult complication that leads to significant morbidity and mortality at high cost to the patient, the health care system, and society. In addition to proper technique and patient optimization, surgeons have used a number of methods to reduce the likelihood of anastomotic leak.

See Invited Critique at end of article

One method of reducing the potential for anastomotic leak is intraoperative anastomotic testing with isotonic sodium chloride solution, povidone-iodine, or air insufflation of the anastomosis. These techniques have been proposed to alter the likelihood of anastomotic leak by selecting out porous anastomoses that may permit leakage of gastrointestinal tract contents postoperatively.

Despite the relative simplicity of intraoperative anastomotic leak testing, the data

supporting its use are not conclusive. Supporting evidence¹⁻³ demonstrates that when intraoperative interrogation of the anastomosis reveals an intact anastomosis, clinical leaks can be largely averted. However, others suggest that the results of leak testing may influence the decision to perform additional exploratory surgery in a patient in critical condition because the knowledge of a sound anastomosis at intraoperative testing provides a false sense of anastomotic integrity.⁴⁻⁶ Others have raised the question of whether intraoperative anastomotic testing produces false-positive results or weakens the anastomosis.⁷ Specifically, do high pressures generated by intraoperative testing weaken the newly formed anastomosis?

Our group has had considerable experience in testing newly constructed anastomoses to evaluate structural integrity. In the present study, we assessed our experience with anastomotic leak testing to determine the association between leak testing and the development of a clinical leak. Specifically, we sought to determine the likelihood of an anastomotic clinical leak in

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anastomoses that tested airtight vs those that demonstrated an intraoperative leak vs those that were untested in the operating room. In addition, given the variable surgical approaches to those anastomoses that fail intraoperative air leak testing, we sought to compare our results with simple repair vs takedown and repeated performance of the anastomosis vs repair and diversion.

METHODS

PATIENTS

We abstracted patient information from our prospective colorectal database dating from January 1, 2001, through December 31, 2007. This prospectively enrolled database includes all patients with gastrointestinal anastomosis formed distal to the ligament of Treitz. We specifically evaluated patients with left-sided anastomoses performed because of benign or malignant conditions. Patients were enrolled in the study if they met the following inclusion criteria: (1) anastomosis of small intestine or colon to a level below the splenic flexure, (2) laparoscopic or conventional open surgery, and (3) elective or emergency surgery. Patients were excluded if (1) they had a planned proximal diversion (either stoma marking preoperatively or indication of planned diversion in the operative notes or history and physical examination) or (2) an anastomosis could not be performed.

After recruiting patients, we retrospectively entered information about type and location of anastomosis, method of construction (stapled or handsewn), anastomotic leak test performance and results, and method of repair if an intraoperative air leak was discovered. We did not include information about completeness of tissue rings because this was not reliably included in the operative report. The study was approved by the Lahey Clinic Institutional Review Board

ANASTOMOTIC LEAK TESTING

Procedures were carried out by attending surgeons (R.R., P.L.R., P.W.M. and D.J.S.) with or without trainee assistance. The leak test was performed in accord with individual surgeon routine practice. All anastomotic leak tests were performed with air insufflation through a proctoscope or flexible endoscope, with the anastomosis under irrigation and with the intestine occluded proximal to the anastomosis. If an intraoperative anastomotic leak was noted at testing, the method of repair was determined from the operative notes. Rectal tube decompression was not performed in an intraoperative air leak.

CLINICAL LEAK

We used the definition of clinical leak derived from recommendations of a recent systematic review⁷ and from the Surgical Infection Study Group.⁸ A clinical leak was described as the presence of luminal contents through a drain or wound site or abscess cavity causing inflammation (ie, fever, leukocytosis, or fecal discharge). Anastomotic leaks may be detected using radiologic studies but must exhibit clinical signs of leak to be considered a clinical leak. These data were prospectively collected.

METHOD OF REPAIR

Air leaks discovered during intraoperative anastomotic leak testing were repaired at the discretion of the operating surgeon with (1) repair of the anastomosis without diversion, (2) unplanned proximal diversion, or (3) takedown of anastomosis with new anastomotic construction and no diversion.

STATISTICAL ANALYSIS

We used χ^2 tests to compare frequencies across groups using commercially available software (SAS version 9.1.3; SAS Institute, Inc, Cary, North Carolina). A power analysis was performed to determine adequate sample size for a study comparing anastomotic leak as a function of construction and revealed an effect size of 0.15. Assuming 80% power to detect significant differences at the .05 level and a 10:1 ratio of stapled anastomoses to handsewn anastomoses, we would need 3649 stapled anastomoses and 405 handsewn anastomoses. Given our sample size and clinical leak rate, our study had 42% power to detect a statistically significant difference in clinical leaks as a function of anastomotic construction.

RESULTS

From a database of 2627 colorectal procedures, 998 (38%) left-sided anastomoses were performed that met the inclusion and exclusion criteria as previously described. Of the 998 left-sided anastomoses, 899 (90.1%) were stapled with either a circular (n=811) or linear (n=88) stapler and 99 (9.9%) were handsewn. We performed a mean (SD) of 142.6 (8.9) left-sided anastomoses per year (range, 133 in 2005 to 157 in 2004). During this time, 128.4 (4.8) left-sided anastomoses were stapled (range, 122 in 2003 to 136 in 2004) and 14.1 (5.7) left-sided anastomoses were handsewn each year (5 in 2006 to 21 in 2004).

An intraoperative anastomotic leak test was performed in 825 patients (82.7%). Anastomotic leak testing was performed more commonly in stapled anastomoses (804 of 899; 89.4%) than in handsewn anastomoses (21 of 99; 21.2%). Anastomotic leak testing yielded positive results in 65 of 825 tested anastomoses (7.9%), whereas 760 of 825 anastomoses (92.1%) were airtight. Anastomotic leak testing yielded positive results in 63 of 804 stapled procedures (7.8%): 1 of 21 linear stapled anastomoses (4.8%) and 62 of 783 circular stapled anastomoses (7.9%). In addition, 2 of 21 handsewn anastomoses (9.5%) also exhibited evidence of leakage at intraoperative anastomotic testing.

CLINICAL LEAKS

A postoperative clinical anastomotic leak developed in 48 of 998 anastomoses (4.8%). Postoperative clinical leaks developed in a mean (SD) of 40 of 899 stapled anastomoses (4.4% [1.4%]), 5 of 88 linear anastomoses (5.7% [4.8%]), and 35 of 811 circular stapled anastomoses (4.3% [1.4%]). In addition, a postoperative clinical leak developed in 8 of 99 handsewn anastomoses (8.1% [5.4%]). There was no difference in the rate of anastomotic leaks between stapled (including all circular and linear) and handsewn anastomoses ($P=.13$). For all left-sided anastomoses, postoperative clinical leaks were noted in 5 of 65 patients (mean [SD], 7.7% [6.5%]) with evidence of leaking at intraoperative anastomotic testing compared with 29 of 760 airtight anastomoses (3.8% [1.4%]) and 14 of 173 untested anastomoses (8.1% [4.1%]) ($P<.03$) (**Figure, A**). Postoperative clinical leaks in circular stapled anastomoses were noted in 3 of 62 patients (mean [SD], 4.8% [5.3%]) with evidence of leaking at intraoperative anastomotic testing compared with

26 of 721 airtight anastomoses (3.6% [1.4%]) and 6 of 28 untested anastomoses (21.4% [15.2%]) ($P=.04$) (Figure, B). Because of the small number of linear stapled and hand-sewn anastomoses, the same analysis could not be performed with sufficient power.

REPAIR OF INTRAOPERATIVE ANASTOMOTIC LEAK TESTS

Intraoperative correction of anastomotic leaks at testing ($n=65$) included suture repair alone ($n=41$), takedown of the anastomosis and repeated anastomosis ($n=14$), and repair with proximal fecal diversion ($n=10$). Postoperative clinical leak occurred in 5 of 41 patients (12.2%) after suture repair alone, none of 14 patients after takedown of the anastomosis and repeated anastomosis, and none of 10 patients who underwent anastomotic repair with proximal fecal diversion ($P=.41$).

To assess the value of a second intraoperative leak test on postoperative clinical leak, we compared results of anastomotic leak testing in those patients with initially airtight anastomoses vs those patients who underwent suture repair of a porous anastomosis and were then re-tested. After suture repair of an intraoperative leak test, the rate of clinical leak was significantly higher than in patients with an initially airtight anastomosis (12.2% [10.0%] vs 3.8% [1.4%]; $P<.03$), respectively.

COMMENT

The crux of the discussion about anastomotic leak is focused on surgical technique. Yet, despite the clinical importance of anastomotic leak and the substantial morbidity and mortality,^{9,10} the practicing surgeon has few options to reduce the rate of anastomotic leak. In addition to establishing adequate blood supply and ensuring a tension-free anastomosis, much attention has been focused on construction techniques. Novel anastomotic buttresses¹¹ and telescoping anastomoses have been described¹² to reinforce the anastomosis; however, supporting evidence is meager, and none of these techniques are used in routine clinical practice. Given the low but appreciable rate of anastomotic complications after colorectal surgery, a simple, reliable, and reproducible method to intraoperatively predict the development of anastomotic leak would be of substantial benefit. One such method is intraoperative air leak testing, a simple and quick technique with potential value in predicting postoperative anastomotic disruption. However, the data in favor of or against anastomotic leak testing have been sparse despite its relatively high rate of adoption. It is for these reasons that we reviewed our experience with anastomotic leak testing to determine the usefulness of this technique in everyday clinical practice.

Our study has several compelling findings with important implications. First, we found no substantial difference in postoperative clinical leak when comparing stapled and handsewn anastomoses. Although our study has limited power to detect a difference in leak rates, a recent Cochrane analysis similarly described no difference in anastomotic leaks in colorectal procedures.¹³ In

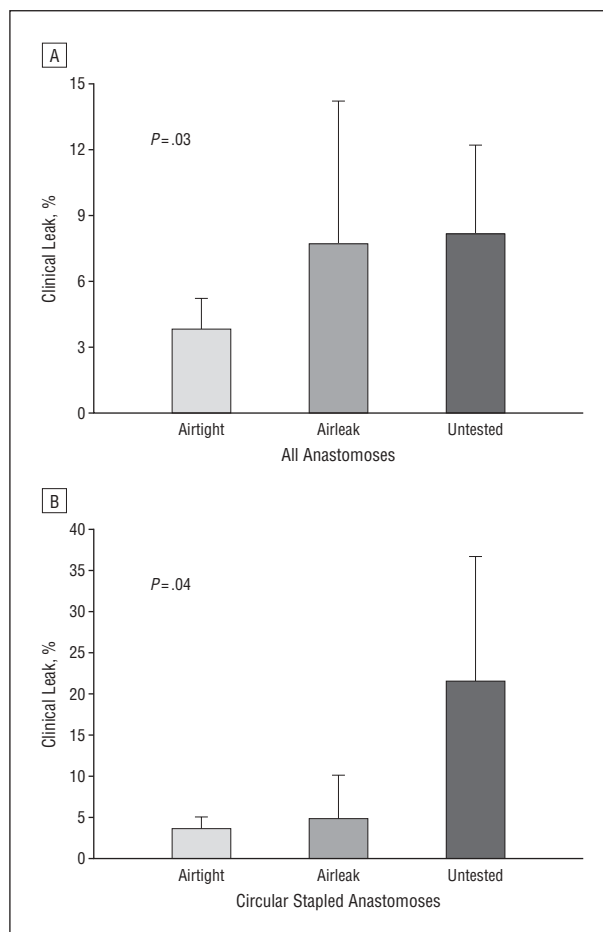


Figure. Postoperative clinical leaks in all anastomoses (A) and circular stapled anastomoses (B) that were either airtight, confirmed to have an airleak, or untested. Significance established at χ^2 testing. Bars indicate standard deviation.

their analysis of 9 studies, Lustosa et al¹³ found no difference between stapled and handsewn anastomoses insofar as mortality, overall anastomotic dehiscence, anastomotic hemorrhage, wound infection, or hospital stay.¹³ Although a systematic review of ileocolic anastomoses revealed a higher leak rate with handsewn anastomosis, this difference has not been reproduced with left-sided anastomoses.¹⁴ Our study is not sufficiently powered to compare differences in clinical leak for stapled or handsewn anastomoses; however, our data are consistent with those of previously published studies.^{15,16}

Second, we noted that surgeons refrained from intraoperative testing when the anastomosis was handsewn rather than stapled. This preference is difficult to explain inasmuch as the percentage of failed intraoperative leak tests was considerable for both handsewn and stapled anastomoses. In addition, the rate of postoperative clinical leak was similarly high whether sutures or staples were used to construct the anastomosis. We were unable to determine the benefit of leak testing for solely handsewn anastomoses as we were for stapled anastomoses. Despite our inability to perform a separate analysis for handsewn anastomoses, the high rate of intraoperative air leaks and postoperative clinical leaks in these constructions leads us to recommend intraoperative anas-

Table. Listing of Available Studies Investigating Anastomosis Leak Testing

Source	No. of Patients	Location of Anastomosis	Test Method	Test Leak, ^a %
Lazorthes and Chiotassol, ¹⁷ 1986	82	Rectum	Air	5.1
Gilbert and Trapnell, ² 1988	21	Left-sided	Saline solution	24
Davies et al, ¹ 1988	33	Rectum	Air	18.2
Beard et al, ^{3,b} 1990	145	Colorectal	Air	25
Griffith and Hardcastle, ¹⁸ 1990	60	Rectum	Air	18.3
Dixon and Holmes, ²¹ 1991	202	Rectum	Saline solution	4.2
Wheeler and Gilbert, ²⁰ 1999	102	Left-sided	Saline solution	20.6
Schmidt et al, ²² 2003	296	Rectum	Air and saline solution	18.1
Smith et al, ¹⁹ 2007	229	Colorectal	Methylene blue dye	7

^aLeaking of air or saline solution at intraoperative anastomosis testing.

^bProspective study.

tomotic leak testing in all left-sided anastomoses including those constructed with sutures.

Third, our study revealed significant benefits to anastomotic leak testing of left-sided anastomoses. Anastomotic leak testing has been proposed to reduce the development of anastomotic leak by identifying anastomoses that are not airtight or watertight. Our data show that untested anastomoses have a higher rate of postoperative clinical leak compared with anastomoses that were tested intraoperatively. Several small retrospective studies have shown similar benefits to anastomotic leak testing^{1,2,17-21}; however, these studies have included few patients^{1,2,17,18} and demonstrated high rates of intraoperative leak at testing (**Table**).^{1,2,18,20} One randomized controlled trial of intraoperative anastomotic leak testing revealed a significant benefit to anastomotic testing³ because the rate of both clinical and radiologic leaks was considerably lower in the tested group. Yet, this study included patients in whom the anastomosis was diverted and a large number of procedures (64%) performed by trainees.³ Our study has the benefit of a large sample size, creation of anastomoses by specialized colorectal surgeons, and an acceptable rate of postoperative clinical leak.

Despite one prospective trial that confirmed the benefit of anastomotic leak testing, others have argued that the disadvantages of anastomotic leak testing outweigh the benefits. In a letter to the editor, surgeons from Tunbridge Wells, United Kingdom, raised the potential for reduced anastomotic integrity after routine intraoperative anastomotic testing. In addition, they argue that the testing for anastomotic leak may be misleading and delay appropriate care and sound judgment.⁴ Still others argue that the rate of leak is unaffected by leak testing. In one large retrospective study, 18.1% of all tested anastomoses showed lack of anastomotic integrity; however, immediate correction of these inadequacies did not change the rate of anastomotic leaks compared with untested anastomoses.²² Conversely, our data indicate a much higher rate of postoperative clinical leak when intraoperative leak testing was not performed. Overall, our data indicate that untested anastomoses have twice the rate of postoperative clinical leaks compared with those that were tested.

Once an intraoperative air leak is demonstrated at testing, attempts to correct the leak are varied and range from simple suture closure of the defect to dismantling and reconstructing the anastomosis to repairing the defect or diverting the anastomosis. Evidence-based data to drive

decision making in the scenario of intraoperative air leak is lacking at this time. Griffith and Hardcastle¹⁸ recommended intraoperative repair of stapled anastomotic defects using interrupted sutures as a safe alternative to a covering colostomy or ileostomy. We similarly noted that most porous anastomoses were repaired with suturing of the defect; however, the ensuing leak rate of 12.2% is substantial and significantly larger than the clinical leak rate (3.8%) for anastomoses with initially negative intraoperative leak test results. Thus, suture repair alone in the setting of a positive air leak results in a postoperative clinical leak rate that is significantly higher than with an initially airtight anastomosis although the method of leak testing is identical in each scenario. Although a small sample size prevents us from making firm conclusions about repair, our data indicate that patients treated with diversion or dismantling and reconstruction of the anastomosis have negligible leak rates. Larger prospective studies are needed to clarify this; however, at this time, we are hesitant to suture repair an anastomosis that is not airtight at the initial air leak test.

Our study has many strengths and limitations. The data were prospectively collected (including the development of clinical leak), thereby enabling us to include all consecutively performed procedures during the study period. In addition, our data include a large number of patients who underwent treatment for a variety of conditions; therefore, the findings should be applicable to most surgeons. Despite these advantages, there are limitations related to the retrospective nature of the medical records review (specifically, technical details). It is possible that a surgeon did not clearly describe an intraoperative leak at leak testing when the surgeon's reason for performing or deferring a test were not clearly indicated in the operative report. In addition, we have not included information about patient diagnosis, use of preoperative radiotherapy, and urgency of the procedure, which have been associated with the development of clinical leak. Our study is underpowered to evaluate differences in clinical leaks as a function of diagnosis or use of radiotherapy. However, of the untested circular stapled anastomoses, the likelihood of preoperative radiotherapy or a cancer diagnosis was similar to that in the tested group. The only obvious difference was that more than 75% of all untested circular stapled anastomoses were performed by 1 surgeon, who indicated that the data for testing were previously sparse. Despite these limitations, our data confirm the results of 1 pro-

spective trial and confirm the usefulness of anastomotic testing in a large cohort of patients.

In conclusion, our study of a large number of left-sided colorectal anastomoses indicates a substantial benefit for anastomotic leak testing. We maintain that an airtight anastomosis at intraoperative testing is a reliable indicator of anastomotic integrity. While an airtight anastomosis does not guarantee postoperative anastomotic integrity, the likelihood of a clinical leak is markedly reduced if the initial leak test yields negative findings compared with a leak test with positive findings or no leak test. Further data are needed to detail best practice for intraoperative anastomotic interrogation and to determine an optimal method to rectify an unsatisfactory intraoperative air leak test. At present, we favor intraoperative anastomotic leak testing of all left-sided anastomoses constructed in the setting of no fecal diversion including handsewn and stapled anastomoses.

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INVITED CRITIQUE

An anastomotic leak following restoration of intestinal continuity is one of the most dreaded complications following gastrointestinal tract surgery. Disruption of the colorectal anastomosis is a difficult complication that leads to significant morbidity and, at times, death. Since the inception of intestinal anastomoses, surgeons have looked for various methods to try

and predict its occurrence prior to the patient's leaving the operating room. Several techniques have evolved to comfort the surgeon that his or her anastomosis is secure from disruption, but mostly center on integrating the anastomosis with an isotonic sodium chloride solution, 10% povidone-iodine, or air insufflation. Although most surgeons today will rely on the instillation