RATIONALE FOR TESTING PRESSURES

The causes of postoperative anastomotic leaks are many, and may be multifactorial, but it is generally believed that imperfections in an anastomosis caused by deficiencies in technique play some part.⁸ It is also broadly accepted that the chance of developing a postoperative anastomotic leak is related to the mechanical strength of the freshly completed anastomosis.³⁰ The strength of an anastomosis can be assessed by distending the anastomosis with fluid (saline or solutions of methylene blue, povidone-iodine, or patent blue dye⁴⁴) and observing for leakage of fluid, or by inflating the bowel with air, immersing the anastomosis in fluid and observing the pool for bubbles. The intraoperative air leak test is most commonly used.^{33,53} Defects in an anastomosis exposed by intraoperative testing can be managed by repair, reconstruction, or diversion, or by a combination thereof, in order to minimize postoperative clinical leaks.^{16,37,43,64}

Some surgeons believe that for adequate anastomotic leak testing, the pressure distending the bowel need only exceed the extraluminal pressure (i.e., atmospheric or intraperitoneal pressure). Other surgeons feel that higher pressures may reveal additional weaknesses in the staple or suture line that could lead to postoperative leak if not repaired. Few surgeons distend the bowel to a measured pressure, which may at least partially explain why reported intraoperative leak rates vary widely; 1.5 to 24.7% according to Wu and colleagues.^{53,55} There have been calls for standardization of leak testing, including the use of a defined pressure, ^{20,31,53} but this has not yet been achieved, ⁴³ probably because the optimal pressure for air or fluid testing of colorectal anastomoses has not been rigorously determined. Several investigators, however, have endorsed a testing pressure based on their observations, experience, or investigations.

In 1988, Gilbert and Trapnell were the first to specify a pressure to which an anastomosis should be distended for intraoperative testing.⁸ They recommended a pressure of 25 cmH₂O, because all five leaks detected at operation in the 21 patients in their study were found at pressures below 25 cmH₂O. In a subsequent study of 102 patients, Wheeler and Gilbert used a maximum distending pressure of 30 cmH₂O²⁷ "on the basis of the results of a previous study," referring to Gilbert's prior work.

Rojatkar and colleagues sought to determine the "relevant pressures" for testing a colorectal anastomosis using a porcine model. After transecting the colon just above the pelvic brim, they created an anastomosis with a circular stapler. The colon was occluded proximal to the anastomosis and the pelvis filled with saline. A video was made as air was insufflated into the bowel until the anastomosis was highly distended, and intraluminal pressure was recorded and synchronized with the video. Thirty-one surgeons then gave independent evaluations of the video, indicating when they thought the appropriate maximal degree of distension for clinical leak testing had been reached (their "stopping point"). The range of pressure for the stopping points was 23.9–32.5 mmHg (32–44 cmH₂O) and the mean was 26.0 mmHg (35 cmH₂O). Based on these results and the observations of Gilbert and Trapnell⁸ and Beard et al.¹⁶, they chose 30 mmHg (40.8 cmH₂O) "as a reasonable leak pressure criteria to assess the quality of circular stapler in creating a secure anastomosis."⁵⁷

Dong and colleagues compared the intraoperative air leak test to the "methylene blue perfusion test" in 28 patients, ensuring that the pressure in the rectum reached 40 cmH₂O in both tests.⁶³

Rudnicki et al. also compared the intraoperative air leak test to the methylene blue test. They determined that the mean peak pressure applied by their three surgeons in 40 patients was $35 \text{ cmH}_2\text{O}$ (range: $15-53 \text{ cmH}_2\text{O}$) for their dye leak test and $30 \text{ cmH}_2\text{O}$ (range: $19-41 \text{ cmH}_2\text{O}$) for their air leak test. They concluded that a standardized dye leak test and air leak test with measuring a peak pressure of above 20 mmHg [27 cmH₂O] and under 30 mmHg [41 cmH₂O] "is safe and efficient to assess anastomotic integrity for colorectal anastomosis."^{67,73}

The intraluminal pressure measurements in the studies by Gilbert and Trapnell, Wheeler and Gilbert, and Rojatkar et al. were made when the extraluminal pressure was atmospheric. The studies by Dong et al. and Rudnicki et al. included laparoscopic surgeries, but there was no accounting for the elevated intraperitoneal pressure during laparoscopy, which may affect intraoperative anastomotic leakage by reducing the transmural pressure gradient.

On the basis of these studies, a transmural pressure range of 30—40 cmH₂O was selected for testing colorectal anastomoses by the manufacturer of the Colorectal Air Syringes. The indicator pin of the Colorectal Air Syringe-OP ejects when the intraluminal pressure is within this range. The indicator pin of

the Colorectal Air Syringe-LP, which is recommended for use in laparoscopic and robotic surgery, ejects when the intraluminal pressure reaches $50-60 \text{ cmH}_2\text{O}$, which corresponds to a transmural pressure range of $30-40 \text{ cmH}_2\text{O}$ when the intraperitoneal pressure is 15 mmHg ($20 \text{ cmH}_2\text{O}$).

Some surgeons have expressed concern that testing might imperil an anastomosis,^{8,11-14} even though postoperatively an anastomosis may be stressed by intraluminal pressures significantly higher than the usual testing pressures. Perianastomotic pressures as high as 122 cmH₂O have been recorded.¹⁸ High-amplitude propagated contractions, where the intraluminal colonic pressures exceed 122 cmH₂O, were recorded at a rate of about 6 per day in normal human subjects.^{10,29} Although there is no experimental evidence to validate the contention that testing has adverse consequences, one would not want to test to a pressure higher than the pressure at which a well-formed anastomosis might leak. Schwab and colleagues performed 30 anastomoses on human colon specimens within 20 minutes of removal, so that the specimens were not unduly affected by ischemia and desiccation. All anastomoses were then distended with a solution of saline and methylene blue. The mean pressure at which the anastomoses began to leak was 126 cmH₂O and the mean pressure required to burst the anastomoses was 169 cmH₂O. No anastomosis leaked below a distending pressure of 65 cmH₂O and no anastomosis ruptured below a distending pressure of 95 cmH₂O.³⁰ The transmural pressures generated by the Colorectal Air Syringes, when used as directed, do not exceed 40 cmH₂O, thereby providing a safe margin to avoid false positives and damage to the anastomosis.

In the earliest study measuring intraluminal pressure during anastomotic leak testing, Gilbert and Trapnell observed that in 1 of 21 patients "the pressure was only 1 cm because gross laxity of the anal sphincters resulted in leakage of fluid around the balloon catheter and satisfactory distension could not be achieved."⁸ Beard and colleagues, in the first of only two prospective randomized studies evaluating intraoperative leak testing, performed an air leak test by inflating the bowel with a rigid sigmoidoscope. They did not routinely measure the intraluminal pressure because "it would have unduly complicated the procedure." They did, however, measure the intrarectal pressure in five patients and found that the pressure could not be raised above 35 mmHg (48 cmH₂O) due to venting of air around the sigmoidoscope.¹⁶ The Colorectal Air Syringes occlude the anus at the anal verge and vent through a pressure regulating valve to generate and maintain a transmural pressure between 30 and 40 cmH₂O, even when anal sphincters are lax after dilation by transanal stapling under general anesthesia.

Comprehensive intraoperative evaluation of a colorectal anastomosis could include direct visual inspection, endoscopic evaluation, leak testing at a standardized pressure (or within a prescribed range), and assessments of tension and tissue perfusion. The need for a comprehensive approach is increasingly recognized, ^{58,68,69} and modalities to achieve this are available.

REFERENCES