

ASMBS POSITION STATEMENT ON PREVENTION AND DETECTION OF GASTROINTESTINAL LEAK AFTER GASTRIC BYPASS INCLUDING THE ROLE OF IMAGING AND SURGICAL EXPLORATION

**The American Society for Metabolic and Bariatric Surgery Clinical Issues Committee
Approved by the ASMBS Executive Council, January 2009**

The following position statement is issued by the American Society for Metabolic and Bariatric Surgery in response to numerous inquiries made to the Society by patients, physicians, society members, hospitals, health insurance payers, the media, and others, regarding the complication of gastrointestinal (GI) leak after GI bariatric procedures. In this statement, available data regarding leak are summarized and suggestions made regarding reasonable approaches to prevention and post-operative detection based upon current knowledge, expert opinion, and published peer-reviewed scientific evidence available at this time. The intent of issuing such a statement is to provide objective information about the complication of leak. The statement is not intended as, and should not be construed as, stating or establishing a local, regional or national standard of care. The statement will be revised in the future as additional evidence becomes available.

Introduction. Gastrointestinal leak after gastric bypass is a known complication with a reported incidence between 1 and 5% in large case series of open and laparoscopic gastric bypass.¹⁻¹⁰ A leak can result in clinically important morbidity and mortality. Once signs and symptoms develop, prompt diagnosis and treatment of a leak may minimize the inflammatory and septic sequelae, although evidence also suggests that the immunoreactivity of the host determines the endogenous inflammatory responsiveness to a greater extent than the timing of treatment.¹¹

The purpose of this position statement is to provide an evidence-based guideline regarding prevention and detection of GI leak after gastric bypass. The utilization of imaging techniques and surgical re-exploration in the context of routine postoperative surveillance and suspected postoperative gastrointestinal leak will be reviewed.

Prevention of gastrointestinal leak.

The vast majority of GI leaks likely occur in the absence of a technical error that could have been recognized at the time of the initial procedure. Supporting this conclusion is the observation that leaks are reported to occur at some level of frequency in all reported large series of gastric bypass. Numerous intra-operative techniques have been suggested to decrease the incidence of leak including, but not limited to, over-sewing staple lines, agents that reinforce the staple lines,^{12, 13} fibrin glue or other tissue sealants,¹⁴⁻¹⁶ etc. No high quality clinical evidence exists to suggest that such interventions are able to eliminate or substantially decrease leak as a complication of

gastric bypass. Intra-operative leak assessment using endoscopy and/or distention of the anastomosis with dye, air, or other gas may be useful to detect leaks that can be repaired during the procedure, but these techniques have not been shown to decrease the risk of leak after surgery. Whereas some surgeons advocate routine placement of drains in proximity to the gastrojejunal anastomosis in order to better diagnose and/or control leakage from this site during the postoperative period,^{17, 18} others hypothesize that drains in proximity to an anastomosis are unnecessary¹⁹ and might increase the risk of a leak developing, particularly if left in place more than a few days.²⁰ In summary there is no high level evidence to support any of the above practices for the prevention or amelioration of GI leak following gastric bypass.

Post-operative leak detection

Radiologic Imaging. A hospital in which bariatric procedures are performed should have the capability for imaging by plain film, fluoroscopy, and computed tomography (CT). The size and weight capacities of current CT, fluoroscopy units, and magnetic resonance imaging (MRI) scanners will accommodate the majority of bariatric surgery patients. The weight limitations for CT and MRI scanners are provided by the manufacturer and range from 135 to 200 kg (300 to 450 lbs.).²¹ Of significance, a hospital's warranty agreement for repair of expensive CT, fluoroscopy, and MRI equipment may be voided if the equipment is damaged by patients who weigh more than the manufacturers' guidelines allow. Although CT machines that can accommodate patients of up to 350 kg body weight (800 lbs.) are commercially available, they are very expensive and therefore not purchased by most hospitals and should not be viewed as a necessity for quality patient care, at least at this time. Whereas surgeons performing bariatric surgery should be aware of the weight limitations of the radiology equipment in their facility, a subset of patients are expected to exceed the body weight limitations of certain specialized imaging equipment, such as the CT or MRI machine.

Withholding surgical treatment for obesity from the highest body weight subgroup of patients may not be sound clinical judgment as many series report acceptably low risk treatment of super-super-obese patients.²²⁻²⁶ The decision to proceed with bariatric surgery should be a clinical judgment made by the surgeon based on patient risk factors for treatment weighed against the risks of failing to provide successful weight reduction treatment to an individual patient. The capabilities of the facility, the capabilities of nearby facilities, and the patient's wishes should all be included in the surgeon's judgment regarding acceptance of a patient for surgery. A patient should not be rejected for surgical treatment based solely on the fact that the patient exceeds the weight standards or gantry limitations of the hospital's CT or MRI imaging equipment.

Routine post-operative radiologic assessment for leak.

Routine postoperative upper GI contrast studies are performed by many surgeons to detect leaks, but there is growing evidence to support selective, rather than routine,

contrast studies after gastric bypass.²⁷⁻²⁹ Based on current evidence, the decision to perform routine versus selective upper GI contrast studies should be left to the discretion of the surgeon based on their experience, on factors related to the system of care in place, and on other characteristics of the patient and the population being treated.

Radiologic evaluation versus exploration for suspected leak.

Upper GI contrast examination is utilized by many surgeons to evaluate the gastrojejunostomy in patients with suspected leak after gastric bypass. Numerous factors may influence the accuracy of such testing including patient-related factors (ability to stand, balance, move about, the ability to swallow, and size of the patient) and factors related to the system of care in place (experience of the radiologist with bariatric patients and procedures, capabilities of the facility). Sensitivity of upper GI contrast examination varies among reports between 22 to 75%.^{2,29,30}

Computerized tomography of the abdomen after gastric bypass can detect leaks, abscesses, and bowel obstruction. In addition CT of the lung has become a mainstay of evaluation for pulmonary embolism.^{31,32} There are inherent limitations of CT imaging in the obese patient and patient weight has a profound effect on the magnitude of enhancement by intravenous contrast material both in the vascular system and in parenchymal organs such as the liver.³³ Additionally, patient positioning and the inability to ingest adequate oral contrast are important limitations in this population. The experience of the radiologist in interpreting post-operative gastric bypass anatomy also plays an important role. These limitations may lead to false negative results and CT has not consistently demonstrated a high level of sensitivity in detecting early post-operative leaks in this patient population. When upper GI and CT are combined, up to one-third of patients will have both studies interpreted as normal despite the presence of a leak.²

Laparoscopic or open re-exploration is an appropriate diagnostic option, regardless of the feasibility of obtaining a post-operative imaging test, when gastrointestinal leak is suspected. Re-exploration is characterized by a higher sensitivity, specificity, and accuracy than any other postoperative test to assess for leak and should be considered to be the definitive assessment for the possibility of leak. Although invasive, several studies demonstrate that re-exploration is a safe intervention when compared to the consequences of peritonitis, excessive inflammatory response, sepsis, organ failure, and mortality which may develop when diagnosis and treatment of a leak are delayed.^{2,34,35} Thus, re-exploration should be considered in patients with suspected leak and it is important to note that reliance on false negative imaging studies may delay operative intervention, particularly when there is a leak at sites other than the gastrojejunostomy, e.g. the gastric remnant or the jejunio-jejunostomy.³⁶

Summary. Gastrointestinal leak after gastric bypass surgery is an infrequent complication but one that can be expected to occur at some point in every bariatric surgeon's experience. Early detection and treatment of gastrointestinal leak after gastric bypass may play a role in reducing morbidity and mortality. Upper GI contrast studies can be used routinely or selectively to detect leaks. CT may be useful to detect post-operative leaks in some patients, but important limitations exist in its accuracy, in part due to issues inherent in the bariatric patient population, that may make CT imaging impractical or impossible. Surgical re-exploration is an acceptable strategy to diagnose and treat patients who are highly-suspected of having a post-operative leak after gastric bypass. A surgical re-exploration that reveals no explanation for a post-operative patient's worrisome clinical findings or deterioration after gastric bypass should be considered an appropriate and indicated intervention and not a complication.

Gastrointestinal Leak Position Statement and Standard of Care

This Position Statement is not intended to provide inflexible rules or requirements of practice and is not intended, nor should it be used, to state or establish a local, regional, or national legal standard of care. Ultimately, there are various appropriate treatment modalities for each patient, and the surgeon must use their judgment in selecting from among the different feasible treatment options.

The American Society for Metabolic and Bariatric Surgery cautions against the use of this position statement in litigation in which the clinical decisions of a physician are called into question. The ultimate judgment regarding appropriateness of any specific procedure or course of action must be made by the physician in light of all the circumstances presented. Thus, an approach that differs from the position statement, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious physician may responsibly adopt a course of action different from that set forth in the position statement when, in the reasonable judgment of the physician, such course of action is indicated by the condition of the patient, limitations on available resources or advances in knowledge or technology. All that should be expected is that the physician will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient, in order to deliver effective and safe medical care. The sole purpose of this position statement is to assist practitioners in achieving this objective.

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