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Assessing the value of routine upper gastrointestinal contrast studies following bariatric surgery: a systematic review and meta-analysis

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Abstract

BACKGROUND: Understanding both the efficacy of upper gastrointestinal (UGI) contrast studies and the factors that impact their accuracy is necessary to optimize postoperative imaging protocols. However, a consensus as to the value of UGI performed after bariatric surgery remains elusive. The objective was to determine the sensitivity and specificity of UGI conducted routinely within 2 days after bariatric surgery for detecting anastomotic leaks.

METHODS: We conducted an electronic search of MEDLINE for all English language articles published between 2003 and 2013 concerning diagnostic imaging after bariatric surgery. Nineteen studies evaluating a total of 10,139 patients met the inclusion criteria. The methodological quality of each included study was evaluated using the Quality Assessment of Diagnostic Accuracy Studies-2 procedure.

RESULTS: UGI has an overall sensitivity of .54 and a specificity of 1.00. The standard deviation of the reported sensitivities was .36. Positive and negative predictive values were .67 and .98, respectively. Sensitivity and specificity were negatively correlated.

CONCLUSIONS: The sensitivity of UGI for detecting the presence of anastomotic leaks within 2 days of bariatric surgery is moderate overall but fluctuates substantially. The negative correlation between sensitivity and specificity could indicate that the threshold used to distinguish between positive and negative test results varies between institutions. Accordingly, clinicians may consider shifting the threshold for declaring a UGI positive; treating marginal radiological evidence of leakage as presumptively positive may be a simple way to lower specificity, increase sensitivity, and in turn maximize UGI's clinical value.

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Obesity and obesity-related illness impose a substantial, and increasing, burden on the US healthcare system. The Centers for Disease Control estimate the annual economic cost of obesity to be at least $147 billion dollars.[1] Morbid obesity, defined as a body mass index above 40, is

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especially problematic because this condition is disproportionately associated with severe co-occurring health problems. Moreover, epidemiological evidence suggests that the prevalence of morbid obesity has increased by at least 50% over the last decade, far outpacing the growth of moderate obesity.[2] This ominous shift in our population's weight distribution portends further increases in both the economic and human cost of obesity.

Although they represent reasonable first-line interventions, nonsurgical treatments have been shown to have limited efficacy in inducing and maintaining weight loss for morbidly obese patients.[3] In contrast, bariatric surgery is the only approach that has been shown to consistently bring about weight loss in morbidly obese patients, especially when the patient's condition has proven refractory to nonsurgical efforts.[4,5] Already, more than 200,000 bariatric surgeries are conducted each year in the United States,[6] and the continued surge in the prevalence of morbid obesity combined with the singular effectiveness of surgery in treating the condition suggest that bariatric surgical interventions will play an increasingly central role in our future attempts to control the societal costs of obesity.

A limited upper gastrointestinal series (UGI) is commonly used in connection with bariatric surgery to screen for the presence of postoperative complications, the most serious of which is an anastomotic leak. However, the optimal use of this imaging procedure remains a matter of debate—while many centers pre-emptively screen all patients postoperatively, the literature suggests that, as a matter of policy, a growing number of institutions conduct the UGI only when a complication is suspected.[7] Given the high volume of bariatric surgeries and severity of potential complications, it would seem both prudent and valuable to make an empirical determination of the accuracy of routine postoperative UGI. Several studies have conducted such an analysis using data from a single, or, at best, a small handful of, centers. However, to our knowledge, no meta-analysis of the data produced by these studies has been undertaken. The aim of this article, then, is to amalgamate previously reported results of the accuracy of routine postoperative UGI in assessing postoperative leaks and to calculate the overall sensitivity, specificity, and positive predictive value (PPV) and negative predictive value (NPV).

Patients and Methods

This review was conducted according to the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses.[8] The review protocol was not published in advance.

Study selection

MEDLINE (PubMed) was queried for English language, original diagnostic studies published between June 2003 and June 2013 analyzing patients who had undergone bariatric surgery. Only studies analyzing 5 or more patients were considered. The index technique was a postoperative UGI contrast study, with computed tomography (CT) or follow-up surgery used as the reference. Only studies from which it was possible to construct 2×2 tables comparing the contrast swallow results with the reference were included. The only postoperative complication considered by this analysis was anastomotic leak.

The search of MEDLINE was intended to find articles making reference to "bariatric surgery," "Roux-en-Y," "sleeve gastrectomy," "gastric bypass," "UGI," "upper GI series," and "contrast swallow." Queried terms were combined using both "OR" and "AND."

The title and abstract of each article were used to assess whether its inclusion in the study would be appropriate. For articles deemed appropriate based on the abstract, the full text was obtained and again assessed to determine appropriateness for inclusion. For articles deemed inappropriate, the reason for its exclusion was noted. Missed papers were identified by checking citation lists of the articles included in the study as well as the MEDLINE list of articles that cited the included papers.

The following data were extracted from each of the included studies: (1) study design (prospective/retrospective, consecutive/nonconsecutive patients); (2) demographic information describing the patient profile (sex, age, body mass index); (3) the set of operations performed (band/sleeve/bypass, laparoscopic/open); (4) type of reference standard (CT/surgery); and (5) outcome measures (complication identified by index, complication identified by reference).

Evaluation of methodological quality and bias in individual studies

The methodological quality and risk of bias were assessed using the Quality Assessment of Diagnostic Accuracy Studies-2 tool (QUADAS-2),[9] which was developed to aid in the appraisal of diagnostic studies included in a meta-analysis. The following 10 QUADAS-2 questions were analyzed for each included study: (1) Was a consecutive or random sample of patients enrolled?; (2) Was a case–control design avoided?; (3) Did the study avoid inappropriate exclusions?; (4) Were the index test results interpreted without knowledge of the results of the reference standard?; (5) Is the reference standard likely to correctly classify the target condition?; (6) Were the reference standard results interpreted without knowledge of the results of the index test?; (7) Was there an appropriate interval between the index test and reference standard?; (8) Did all patients receive a reference standard?; (9) Did all patients receive the same reference standard?; and (10) Were all patients included in the analysis? For each item, the study in question received a "yes" (adequate), "no" (inadequate), or "unclear" (usually indicating that the required

information was not reported) response. Discrepancies were resolved by consensus. Each query was evaluated separately by 2 authors and cases of disagreement were resolved by consensus.

Method of analysis

The primary outcome measure is an estimate of the overall specificity, sensitivity, PPV, and NPV of contrast swallow imaging. For each included study, a 2 × 2 contingency chart was constructed indicating the reported number of true positives (TP), false positives (FP), true negatives (TN), and false negatives (FN). Sensitivity was calculated as TP/(FN + TP), specificity as TN/(TN + FP), PPV as TP/(TP + FP), and NPV as TN/(TN + FN). All values were calculated both for each analyzed study as well as for the dataset that comprised of the aggregated study data.

Statistical heterogeneity (ie, between the individual analyzed studies) was evaluated using the I^2 statistic.[10] This statistic was developed specifically to measure statistical inconsistency in meta-analyses. Additionally, to determine whether methodological quality impacted the results, the analysis was repeated after excluding the 3 studies with the poorest methodological quality.

The potential for publication bias was assessed by constructing a funnel plot comparing the sample size and the natural logarithm (ln) of the diagnostic odds ratio (DOR) of each study. The DOR was calculated as (TP + TN)/(FP + FN). The correlation coefficient between ln(DOR) and the sample size was also assessed.

All statistical analysis was performed using Microsoft Excel (Microsoft Office 2007; Microsoft, Redmond, WA).

Results

Our initial search of MEDLINE yielded 48 articles. Two were excluded because they were duplicative and 20 more were excluded as inapplicable based on a reading of the title and abstract. The full text of the remaining 26 articles was examined. Of these, 3 were ultimately judged not to be studies of UGI diagnostic accuracy, and in 6 others, the data provided were insufficient to construct 2 × 2 contingency tables. Accordingly, these articles were excluded. Examination of the reference lists of the remaining articles and the list of other MEDLINE citations of those articles yielded 2 more appropriate studies. In total, 19 studies were included in this meta-analysis.

Study characteristics

The total number of patients encompassed by the 19 studies included in the meta-analysis was 10,130 (84% female) and the median number of patients in each study was 227.5 (range 7 to 2,864). Two studies analyzed patients who underwent gastric band, gastric sleeve, or Roux-en-Y bypass procedures. One study was limited to only sleeves, 1 to bands, and 8 to bypasses. The analyzed studies included both laparoscopic and open operations. The studies variably used computed tomography, surgical exploration, or clinical follow-up as the reference standard. Study characteristics are listed in Table 1.

Methodological quality and risk of bias

The QUADAS-2 tool revealed the analyzed studies to be of moderate quality. Two of the studies selected patients in

Table 1 Study characteristics

	Study design	Operation	% Female	Average age	Average BMI	n
Keane[11]	Retrospective	Band				182
Brockmeyer[12]	Retrospective	All	88.3	42.9	43.1	319
Sims[13]	Retrospective	All		39	48.2	198
Goitein[14]	Prospective	Bypass	73	38	45	55
Kolakowski[15]	Prospective	Bypass	86		50.6	417
Doraiswamy[16]	Prospective	Bypass	90	42	45	516
Madan[17]	Prospective	Bypass		39	48	245
Gonzalez[18]	Prospective	Bypass	87	46	49	3,018
Hamilton[19]	Retrospective	Bypass	92	48	41	210
Carucci[20]	Retrospective	Bypass	75	45		904
Singh[21]	Retrospective	Bypass	82.6	40		242
Frezza[22]	Retrospective	Band	88	42	50	100
Serafini[23]	Prospective	Bypass	87		52	100
Carter[24]	Retrospective	Bypass	85	44	50	654
Bertucci[25]	Prospective	Bypass	88.5	44	49.7	322
Buchs[26]	Prospective	Bypass	73.7	43	44	167
Leslie[27]	Retrospective					2,099
White[28]	Retrospective					508
Bertelson[29]	Prospective	Band	92	43	45	200

Cells are blank where data were unavailable.
BMI = body mass index.

such a manner as to create a high risk of systematic bias. In all studies, the index test closely paralleled the review question. Two studies used CT as the reference standard test for a subset of patients; in these cases, the extent to which the reference standard matched the review question or avoided bias was unclear. In 3 studies, the risk of bias was created by the decision to not give all patients the reference test or to exclude certain patients from the analysis. The methodological quality of each study is listed in Table 2, and the overall quality of the included studies is described in Fig. 1.

Synthesis of data

In total, the 19 studies provided 10,130 outcomes for analysis. Of these, 91 results were TP, 9,922 TN, 34 FP, and 83 FN. These data are listed in Table 3. The overall estimates for specificity and sensitivity when each study is weighted equally are 1.00 and .54, respectively (Table 4). If the studies are weighted in proportion to sample size, the specificity and sensitivity estimates become 1.00 and .52, respectively. To avoid undefined values, each case where TN, TP, FN, or FP equaled zero was assigned a value of .01 for purposes of calculating sensitivity, specificity, PPV, and NPV. After removing the 5 studies that reported zero leaks, the estimate of overall sensitivity increased to .56. Under these conditions, the overall specificity is .99. These data are described in the table below.

Inconsistency between the studies (I^2) was calculated to be 0% for both sensitivity and specificity. The correlation coefficient between the ln of the DOR and the study sample size was .18, which suggests that there is no publication bias. The correlation coefficient between sensitivity and specificity values was −.45.

Comments

Our study is somewhat equivocal regarding the probative value of a negative UGI series result. On one hand, the overall sensitivity of postbariatric surgery UGI series was calculated to be 54%, an outcome which by itself calls into question the extent to which we may confidently rely on negative pronouncements from UGI studies. On the other hand, the negative predictive value was very nearly 100%, from which it follows that a negative UGI series result is almost certain to be correct. This apparent contradiction is driven in part by the preponderance of "true negative" results (98% overall) in our sample; under such conditions (or if TN results were virtually absent), we should not expect NPV and sensitivity values to be correlated because TN is only used in the calculation of the former, and not the latter. As a result, it is difficult to draw a strong conclusion as to the value of a negative UGI series result.

Moreover, the precise meaning of the calculated sensitivity is unclear. For patients coded as false negative, one of the two things happened: either the patient had a leaking anastomosis at the time of the UGI series and the imaging failed to identify it or the patient developed an anastomotic leak at some point after the series was conducted. The methodologies of the available studies did not allow us to confidently make this distinction, which is unfortunate because one scenario points to a failure of the imaging modality, whereas the other suggests an easily-correctable problem with the timing of the study. In any event, it seems that the complexities and details of UGI series' value are not fully captured by the overall sensitivity calculation.

The overall specificity of the test (overall = 100%) appears more promising, although this number must be treated with some circumspection. A high level of specificity indicates that the test produces a low rate of FP, which in this case means that the UGI is unlikely to indicate that there is a complication when in fact there is not. This is potentially useful for preventing needless medical interventions, although it is unclear how commonly practitioners resort to invasive procedures solely on the basis of contrast swallow results (ie, in the absence of other indicators).

An empirical understanding of the accuracy of contrast tests is necessary but not sufficient to optimize postoperative screening protocol. First, the accuracy of this test should be compared with that of the other available options; a sensitivity of 54% may be disappointing on its face, but that figure is only meaningful when evaluated relative to the accuracy of other screening procedures or modalities. Also, while this meta-analysis sought to determine the efficacy of contrast swallow as a standalone screening tool, it is entirely possible that contrast swallow is particularly useful (or, alternatively, deleterious) when used in conjunction with other testing methods. Furthermore, data specifying the efficacy of UGI (even relative to and in conjunction with other tests) fail to truly quantify the value of the procedure; that is, whether and to what extent routine UGI reduces costs or improves patient outcomes. All these considerations may ultimately be elucidated by prospective randomized control trials quantifying outcomes and costs of different testing procedures, but should first be investigated by studies synthesizing the data revealed by this meta-analysis with information about the accuracy of alternative testing modalities and the effect of imaging protocol on costs and patient outcomes.

Limitations

The most obvious limitation of this meta-analysis is the relatively small number of studies analyzed, and the small population sizes in a number of those studies. This limitation prevented us from making more confident estimates of the various outcome measures. Additionally, we were largely unable to ascertain the effect of various study characteristics on the diagnostic accuracy of UGI series.

Table 2 Methodological quality assessment

	Keane	Brockmeyer	Sims	Goitein	Kolakowski	Doraiswamy	Dallal	Gonzalez	Hamilton	White	Bertelson	Singh	Serafini	Leslie	Frezza	Carter	Buchs	Bertucci	Carucci
Consecutive sample?	+	+	+	+	+	+	+	+	+	+	+	−	+	+	+	+	+	+	+
Avoided case control?	+	+	+	+	+	+	−	+	+	+	+	+	+	+	+	+	+	+	+
Avoid inappropriate exclusions	+	+	+	+	−	+	−	−	+	+	+	+	+	+	+	+	+	+	+
Index test performed without knowledge of reference	+	+	+	+	+	+	−	+	+	+	+	−	+	+	+	+	+	+	+
Reference likely to correctly classify condition?	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Reference conducted without knowledge of index?	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		+
Appropriate interval between index and reference?	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
All patients receive a reference?	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+-
All patients receive same reference?	+	−	−	+	+	+	−	−	−	+	+	+	+	+	+	+	+	+	−
All patients included in analysis?	+	+	+	+	+	+	−	−	+	+	+	+	+	+	−	−	+	+	+

+ = yes (adequate); − = no (inadequate); ? = unclear (information unavailable).

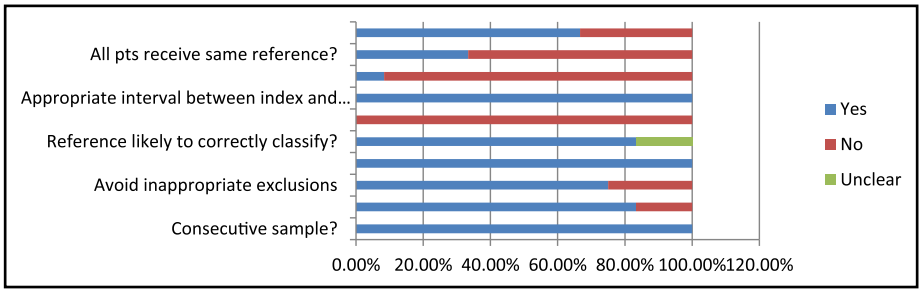


Figure 1 QUADAS-2 assessment.

A more subtle, but equally important, concern is the difficulty associated with properly identifying false negatives. In many of the papers analyzed in this study, patients with a negative contrast test who were not specifically noted to be FN were assumed to be TN. This assumption is justified to some extent by clinical realities: we can fairly assume that patients who are properly classified as false negative will often present with complications to the institution where the surgery was performed. That said, this approach excludes patients who either (1) presented to a different institution with a complication, (2) presented to same institution with a complication but were logged in such a manner as to avoid detection by the study, or (c) developed a medium- or long-term complication. Absence of evidence (of postoperative complications) is not necessarily evidence of absence. Regardless of the specific reason causing these patients to be improperly categorized, the effect is to artificially decrease the number of FN (with a corresponding increase in the proportion of TN). This limitation was acknowledged in our evaluation of methodological quality; however, it remains likely that this meta-analysis overestimates both the sensitivity and the negative predictive value of UGI, and those figures should thus be treated with the appropriate caution.

Also, a number of the studies were conducted at institutions that are more likely to conduct contrast swallow testing when there are separate indications of complications. This methodological deficiency was noted in the QUADAS-2 analysis, but we still must point out that employing UGI in this fashion is likely to inappropriately depress the rate of FP, whether because of observer bias or because complications that engender a heightened index of suspicion are more likely to be apparent on UGI. In any event, the effect of limiting the false positive rate in this manner is to overestimate PPV and specificity.

Table 3 Study results and meta-analysis

	TP	TN	FP	FN	Specificity	Sensitivity	PPV	NPV
Keane	32	146	0	5	1.00	.86	1.00	.97
Brockmeyer	0	309	0	10	1.00	.00	.5	.97
Sims	6	143	1	10	.99	.38	.86	.93
Goitein	0	55	0	0	1.00	.5	.5	1.00
Kolakowski	27	386	4	0	.99	1.00	.87	1.00
Doraiswamy	16	488	9	3	.98	.84	.64	.99
Madan	6	234	3	2	.99	.75	.67	.99
Gonzalez	17	2,628	0	39	1.00	.30	1.00	.99
Hamilton	2	201	0	7	1.00	.22	1.00	.97
Carucci	38	1,202	0	12	1.00	.76	1.00	.99
Singh	3	231	8	0	1.00	1.00	.27	1.00
Frezza	0	97	0	0	1.00	.5	.5	1.00
Serafini	2	92	1	1	.99	.67	.67	.99
Carter	3	625	4	2	.99	.6	.43	1.00
Smith	0	194	0	0	1.00	.5	.5	1.00
Bertucci	0	322	0	0	1.00	.5	.5	1.00
Buchs	0	167	0	0	1.00	.5	.5	1.00
Leslie	7	2,085	6	1	1.00	.88	.54	1.00
Bertelson	0	199	0	1	1.00	.01	.5	1.00
Meta-analysis	155	8,588	17	122	1.00	.56	.90	.99

TP, TN, FP, and FN values of zero were changed to .01 for calculation purposes.

FN = false negatives; FP = false positives; NPV = negative predictive value; PPV = positive predictive value; TN = true negatives; TP = true positives.

Table 4 Overall Results

	Sensitivity (standard error)	Specificity (standard error)	PPV (standard error)	NPV (standard error)
Overall	.54 (.32)	1.00 (<.01)	.67 (.23)	.98 (.03)
Weighted	.52 (.31)	1.00 (<.01)	.73 (.29)	.99 (.01)
Excluding studies with 0 leaks	.56 (.36)	.99 (.01)	.67 (.29)	.99 (.01)

Conclusions

Contrast swallow imaging is a highly specific and moderately sensitive screen for anastomotic leaks occurring after bariatric surgery. This procedure may continue to be used as a screen for postoperative leaks; however, it is imperative for that we combine these data with information regarding patient outcomes and the accuracy of other testing procedures to optimize postoperative complication screening protocols.

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