Post-fundoplication contrast studies: is there room for improvement?

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Objective: Since the mid-1990s, laparoscopic fundoplication for gastro-oesophageal reflux disease has become the surgical procedure of choice. Several surgical groups perform routine post-operative contrast studies to exclude any (asymptomatic) anatomical abnormality and to expedite discharge from hospital. The purpose of this study was to determine the accuracy and interobserver reliability for surgeons and radiologists in contrast study interpretation.

Methods: 11 surgeons and 13 radiologists (all blinded to outcome) retrospectively reviewed the contrast studies of 20 patients who had undergone a laparoscopic fundoplication. Each observer reported on fundal wrap position, leak or extravasation of contrast and contrast hold-up at the gastro-oesophageal junction (on a scale of 0–4). A κ coefficient was used to evaluate interobserver reliability.

Results: Surgeons were more accurate than radiologists in identifying normal studies (specificity=91.6% vs 78.9%), whereas both groups had similar accuracy in identifying abnormal studies (sensitivity=82.3% vs 85.2%). There was higher agreement amongst surgeons than amongst radiologists when determining wrap position (κ =0.65 vs 0.54). Both groups had low agreement when classifying a wrap migration as partial or total (κ =0.33 vs 0.06). Radiologists were more likely to interpret the position of the wrap as abnormal (relative risk=1.25) while surgeons reported a greater degree of hold-up of contrast at the gastro-oesophageal junction (mean score=1.17 vs 0.86).

Conclusion: Radiologists would benefit from more information about the technical details of laparoscopic anti-reflux surgery. Standardised protocols for performing post-fundoplication contrast studies are needed.

Received 26 May 2010
Revised 14 November 2010
Accepted 2 December 2010

DOI: 10.1259/bjr/57095992

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Gastro-oesophageal reflux disease is a common problem within the community. 10–20% of the population experience symptoms of reflux or heartburn on a regular basis [1]. First-line treatment for most patients involves medical management alone, usually with proton pump inhibitors. However, a proportion of patients remain symptomatic despite maximal medical therapy and some are averse to taking medication on a long-term basis [2]. For these patients, surgical management with a laparoscopic fundoplication is an effective means of controlling symptoms [3].

A total fundoplication is a 360° wrap using the fundus of the stomach to recreate a competent lower oesophageal sphincter or valve. Whilst a total fundoplication has been shown to be very effective in controlling reflux of acid into the distal oesophagus, many patients experience increased dysphagia, bloating and flatulence after the procedure. Various forms of partial fundoplication have been developed to minimise these adverse effects, in particular a 180° anterior wrap and a 270° posterior wrap [4–6].

Early post-operative complications after laparoscopic antireflux surgery may include acute intrathoracic migration of the wrap [7–9], complete obstruction at the gastro-oesophageal junction (GOJ) [10] and perforation of the oesophagus or stomach [11]. Patients with a perforation or a complete obstruction are generally symptomatic and the decision to re-operate is made on the basis of their clinical symptoms and signs [12]. However, a recent study in our institution found that 15 out of 1894 (0.8%) patients who had undergone a laparoscopic fundoplication had an asymptomatic acute intrathoracic wrap migration and benefited from a routine early post-operative contrast study [12]. Prompt diagnosis of an asymptomatic wrap migration allows early laparoscopic re-intervention to repair the anatomical defect and prevents what would almost certainly be a more difficult revisional procedure if the diagnosis were delayed [10, 13].

Routine early contrast studies are therefore advocated in our institution for all patients undergoing laparoscopic fundoplication for gastro-oesophageal reflux disease. However, there is very little in the literature addressing the quality and accuracy of post-operative contrast swallows. One prior publication [14] found that agreement between two radiologists in differentiating partial (Type I) and total (Type II) wrap migrations was

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Table 1. Characteristics of contrast swallow studies selected for review ($n=20$)

Timing of contrast study	Early <72 h post-operatively (17); late >6 months post operatively (3)
Images	Video (11); still images (9)
Gender of patient	Male (7); female (13)
Type of fundoplication wrap	Total 360° (8); partial anterior 180° (12)
Position of wrap	Normal (11); Type I migration (4); Type II migration (5)
Leak/perforation	No leak (20)

Type I, partial wrap migration with the gastro-oesophageal junction (GOJ) below the diaphragm; Type II, total wrap migration with the GOJ at or above the level of the diaphragm.

good ($\kappa=0.84$), but no mention was made of the accuracy of diagnosis nor of the interobserver reliability within and between upper gastrointestinal surgeons and radiologists. The aim of this study was to determine the accuracy and interobserver reliability of surgeons and radiologists in interpreting post-operative contrast studies following laparoscopic fundoplication.

Methods and materials

Patient and contrast study selection

11 upper gastrointestinal surgeons and 13 general radiologists (blinded to patient outcome) retrospectively reviewed 20 contrast studies post-laparoscopic fundoplication for gastro-oesophageal reflux disease. These patients were selected from a prospective database (in operation since October 1991) of all laparoscopic fundoplications performed in both public and private hospitals in Adelaide, Australia. This database includes clinical information and details of all operations. Cases were chosen deliberately by two of the authors (MCR and DM) to provide a mix of normal/abnormal cases and a mix of partial and total fundoplications. Contrast studies also ranged from "easy to interpret" to "difficult to interpret". Cases were not chosen in a random or consecutive fashion owing to the rarity of early post-operative complications. The characteristics of the 20 contrast studies are outlined in Table 1.

Criteria for a normal contrast study

A normal contrast study, for both a total and partial fundoplication, was defined by the following criteria [15, 16]:

- a tapered narrowing of the distal oesophagus and GOJ, extending for 2–3 cm, corresponding to the wrapped segment
- wrap and fundus located below the diaphragm
- flow of contrast into the stomach
- no evidence of extravasation of contrast.

An example of each is depicted in Figures 1 and 2.

Structured report for contrast study review

Observers used a structured form to report the following findings for each swallow:

- The position of the fundoplication wrap in relation to the diaphragm [*i.e.* completely below the diaphragm; fundoplication partly herniated above the diaphragm but the GOJ remains below the diaphragm (Type I migration) (Figures 3 and 4); fundoplication completely herniated above the diaphragm with the GOJ at or above the level of the diaphragm (Type II migration) (Figure 5)] [14].
- Any leak or extravasation of contrast.

Figure 1. (a) Barium swallow, anterior–posterior projection, of a Nissen 360° fundoplication in which the fundus of the stomach is completely wrapped around the distal oesophagus and (b) barium swallow with artistic overlay.

Figure 2. (a) Barium swallow, anterior–posterior projection, of a 180° anterior fundoplication, in which the fundus of the stomach is partially wrapped anteriorly around the distal oesophagus and (b) barium swallow with artistic overlay.

- The degree of hold-up of contrast at the GOJ (ranging from 0= excellent flow of contrast into the stomach, to 4= no flow of contrast beyond the wrap into the stomach).

Observers were also asked to report their degree of confidence in reporting each of the above findings (ranging from 0= no confidence to 10= absolute confidence). The “gold standard” for the final interpretation of each contrast study was that of author DM (an experienced gastrointestinal radiologist) in conjunction with the patients’ re-operative records if relevant.

Statistical analysis

The κ coefficient was used to evaluate agreement between observers [17]. For each observer, a mean confidence score and hold-up of contrast score was

calculated across the 20 studies and independent samples *t*-test was used to compare the average scores of radiologists and surgeons. A log binomial generalised estimating equation (GEE) [18] was used to evaluate whether radiologists were more likely than surgeons to interpret the wrap position as abnormal or to judge that a leak was present. A GEE approach was chosen to adjust for correlation in the data owing to repeated measurements from the same surgeon/radiologist. Each observer’s accuracy in interpreting the studies was measured in comparison with the gold standard. Confidence intervals (CIs) were calculated using a non-linear mixed effects model with random effects for patient observer identification. To assess agreement between a randomly selected pair consisting of one surgeon and one radiologist, a κ coefficient was calculated for a total of 1000 pairs randomly selected from the sample of 11 surgeons and 13 radiologists. Calculations and statistical analysis were performed using SAS v.9.2 (SAS Institute

Figure 3. (a) Barium swallow, anterior–posterior projection, of a Type I migration of a Nissen 360° wrap, in which a portion of the fundoplication has herniated above the diaphragm but the gastro-oesophageal junction remains below the diaphragm and (b) barium swallow with artistic overlay.

Figure 4. (a) Barium swallow, anterior-posterior projection, of a Type I migration of a 180° anterior wrap, in which a portion of the fundoplication has herniated above the diaphragm but the gastro-oesophageal junction remains below the diaphragm and (b) barium swallow with artistic overlay.

Inc., Cary, NC) and Stata v.10.1 (Stata Corporation, College Station, TX). A p -value <0.05 was considered significant.

Results

Nine patients had an intrathoracic wrap migration, whilst none of the patients had an oesophageal or gastric perforation. Of these nine patients, five had the diagnosis confirmed at re-operation or during post-operative upper endoscopy.

The accuracy in interpreting the position of the fundoplication wrap was similar between surgeons and radiologists (Table 2). However, both groups were less accurate in differentiating the appearance of a Type I or Type II wrap migration. Surgeons were more accurate than radiologists in correctly identifying a normal wrap position (*i.e.* below the diaphragm). Radiologists were

25% more likely to interpret the position of the wrap as abnormal, with a relative risk of 1.25 (95% CI=0.98–1.59, $p=0.08$), but the difference between the two groups was not statistically significant. The confidence in reporting wrap position was not significantly different between surgeons and radiologists (8.4 *vs* 8.1, $p=0.46$).

When evaluating interobserver reliability in interpreting the wrap position, there was good agreement between the 11 surgeons and moderate agreement between the 13 radiologists (Table 3). The calculated agreement for a random pair of assessors, consisting of one surgeon and one radiologist, was determined to be moderate (0.51κ, Table 3). Where the position of the wrap had been interpreted as abnormal, the agreement in differentiating this as a Type I or Type II migration was fair for surgeons and poor for radiologists (almost no better than chance alone).

Radiologists correctly identified that there were no oesophageal or gastric perforations in this series 97% of

Figure 5. (a) Barium swallow of a Type II migration of a Nissen 360° wrap in which the entire fundoplication including gastro-oesophageal junction has herniated above the diaphragm and (b) barium swallow with artistic overlay.

Table 2. Interpretation of the position of the wrap on post-operative contrast studies following laparoscopic fundoplication

Observers	Sensitivity (95% CI), accuracy in identifying abnormal study	Specificity (95% CI), accuracy in identifying normal study	Type I vs Type II, accuracy in identifying the type of wrap migration
Surgeons	82.3% (72.9–89.1%)	91.6% (84.7–95.7%)	69.7%
Radiologists	85.0% (77.1–90.9%)	78.9% (71.1–85.1%)	61.2%

CI, confidence interval; Type I, partial wrap migration with the gastro-oesophageal junction (GOJ) below the diaphragm; Type II, total wrap migration with the GOJ at or above the level of the diaphragm.

the time (95% CI=91.9–97.9%). Surgeons were close behind, correctly identifying the absence of a leak 96% of the time (95% CI=93.8–98.6%). There was no difference between radiologists and surgeons in the probability of judging that a leak was present, with a relative risk of 0.74 ($p=0.55$). There was also no difference between surgeons and radiologists in confidence level for this finding (8.7 *vs* 9.1, $p=0.36$).

Surgeons reported a mean degree of hold-up of contrast score of 1.17 compared with radiologists, who reported a mean score of 0.86 ($p=0.06$). Again, there was no difference in the confidence of reporting hold-up of contrast between the two groups (8.1 *vs* 8.3, $p=0.60$).

Discussion

The use of routine post-operative contrast studies after fundoplication is controversial amongst upper gastrointestinal surgeons [10, 13, 19] and in our centre we have shown that 0.8% of patients who are clinically asymptomatic will benefit from this investigation [12]. In these patients, a partial or complete herniation of the wrap and/or fundus will be seen (from inadequate crural closure, a shortened oesophagus and/or severe retching or coughing [20]), and the aim of an early re-operation is to correct the problem before it becomes clinically evident. However, this strategy relies heavily on the accuracy of the contrast study interpretation.

Surgeons were more accurate than radiologists in identifying normal studies (92% *vs* 79%) whereas both groups had a similar sensitivity in accurately identifying abnormal studies (82% *vs* 85%). It is important to note that all surgeons who participated in this study were specialist upper gastrointestinal surgeons who perform laparoscopic fundoplications on a regular basis. The radiologists in the study were general radiologists who report contrast studies with variable frequency. It is therefore not surprising that surgeons had greater accuracy in identifying normal post-operative anatomy and were less likely to mistake normal features (*e.g.* peristalsis or contrast within the wrap) as abnormal.

Several other points are worthy of discussion. Assessment of hold-up of contrast in the early post-operative period may be difficult owing to oedema at the GOJ and oesophageal ileus from surgical manipulation [21]. Patients are therefore kept on a specific diet (avoiding foods that may cause a bolus obstruction) for up to 6 weeks [10, 22, 23]. As such, hold-up of contrast is to be expected and, as far as the surgeon is concerned, any flow of contrast beyond the junction is usually sufficient in the early post-operative period.

There was low accuracy and poor agreement in differentiating Type I and Type II wrap migrations for both groups, although there were only nine such cases included in our study. Whether or not this differentiation is important in a practical sense is beyond the scope of this manuscript. However, the low accuracy may have been due to the quality of the study itself. To illustrate this problem, Figure 6 demonstrates two images taken from two separate studies performed on the same patient on the same day following a total laparoscopic fundoplication. Figure 6a is unusual in its appearance and different observers interpreted this study as normal, diagnostic of a post-operative leak and/or diagnostic of a wrap migration. A repeat study was performed with the patient in the erect, prone oblique and supine positions. Figure 6b, taken in the supine position, clearly demonstrates a Type II wrap migration with the GOJ, wrap and herniated stomach lying well above the diaphragm.

This study has several limitations. First, and perhaps most important, we do not have an objective gold standard for the final results of most of the contrast studies. Only five out of nine abnormal study results were confirmed by intra-operative findings, the remaining four patients chose not to undergo a revisional procedure for various reasons. However, in day-to-day practice, the opinion of a specialist gastrointestinal radiologist would probably be sought if the interpretation of a contrast study were unclear to a general radiologist. Thus, in the absence of a “better” gold standard, we feel this is a useful comparison to make. Second, this is a retrospective study but, given the low frequency of post-operative complications, a prospective study would be difficult (and lengthy) to perform. Third, there were many

Table 3. Interobserver reliability between surgeons and radiologists for position of the fundoplication wrap on post-operative contrast studies

Observers	Kappa (strength of agreement) (95% CI), normal <i>vs</i> abnormal wrap position	Kappa (strength of agreement) (95% CI), Type I <i>vs</i> Type II wrap migration
Surgeons	0.65 (good) (0.59–0.71)	0.33 (fair) (0.21–0.45)
Radiologists	0.54 (moderate) (0.49–0.59)	0.06 (poor) (0–0.15)
Surgeons and radiologists	0.51 (moderate) (0.15–0.87)	N/A

CI, confidence interval; Type I, partial wrap migration with the gastro-oesophageal junction (GOJ) below the diaphragm; Type II, total wrap migration with the GOJ at or above the level of the diaphragm.

Figure 6. (a) Poor quality barium swallow in a patient who had undergone a 360° Nissen fundoplication the day before and (b) repeat barium swallow in the same patient in the supine position, demonstrating a Type II wrap migration.

more abnormalities in the study group than one would expect in real life. Surgeons and radiologists participating in the study were probably more alert to the possibility of an abnormal study, and this may have influenced our results. Finally, 20 contrast studies is a relatively small sample size. It took each observer approximately 1 h to participate in the study and we felt an increased time commitment (with an increase in the number of studies) would limit the number of surgeons and radiologists willing to participate in our study.

Despite these limitations, our study provides insight into the current accuracy and reliability of post-fundoplication contrast study interpretation. Because contrast study results may affect patient management (*i.e.* whether to undergo a re-operation), improving and standardising reports are important. We have identified three areas in which improvements in interpretation can occur and from which a standardised protocol could be formulated (Table 4).

(1) Requesting the study

The surgeon should give the radiologist the following information: the type of fundal wrap performed (*i.e.* total or partial), the timing of the operation relative to the study and the presence of any intra-operative complications. In order to direct attention to the most relevant aspects of an early post-operative study, the reasons for the study should be detailed in the request. These include (1) confirming the position of the wrap below the diaphragm;

(2) ensuring flow of contrast into the stomach; and (3) ensuring absence of an oesophageal or gastric perforation.

(2) Quality of the study

We noted a great range in the quality of the contrast studies selected for this study and suggest the following standards should be met. Initial use of a water-soluble contrast agent is recommended to rule out a leak. There is a small theoretical risk that extravasation of barium into the mediastinum can cause a granulomatous reaction with mediastinitis or mediastinal fibrosis [24]. If no leak is detected then barium should be used [15]. It is denser and allows for better coating of the oesophageal and gastric mucosa and it is also more sensitive for detecting subtle perforations [22, 25]. We recommend that a minimum of 50 ml of contrast should be administered for early post-operative studies when a degree of hold-up of contrast is to be expected (a greater volume would generally be used when the study is not performed in the immediate post-operative period [16]).

Patient positioning is by far the most important factor in improving the quality of the study. Standard views generally include the erect anterior–posterior and erect oblique views. However, the most useful views for assessing the location of the wrap include the prone oblique and supine anterior–posterior views. For the prone oblique view, the patient is positioned prone with slight

Table 4. Recommendations to improve accuracy and interobserver reliability in interpreting post-fundoplication contrast studies

Requesting the study	Provide clinical information Specify the type of wrap (360°, 270°, 180°) Detail the reasons for the study
Quality of the study	Use a water-soluble contrast agent initially, then, if no leak, convert to barium Use at least 50 ml of contrast Include prone oblique and supine views Limit radiation exposure to the region of interest at the gastro-oesophageal junction
Interpretation of the study	Standardised criteria for reporting Education about normal and abnormal post-operative appearances of various fundal wraps

elevation of one side of their body. This coats the fundus of the stomach, and sometimes even the wrap itself, with contrast [16]. Although this position may be uncomfortable in the immediate post-operative period, most patients are able to comply. The supine anterior-posterior view is important as it may allow better visualisation of the fundal wrap and stomach in relation to the diaphragm.

For the purposes of illustration, single images with artistic overlays have been provided, but interpretation of the location of the hiatus should be based on real-time evaluation (with the patient breathing and swallowing). It is important to note that the top of the dome of the diaphragm is not the location of the diaphragmatic hiatus, which is usually lower.

Limiting radiation exposure should be a consideration in every radiological examination performed. In early post-operative contrast studies, the examination should focus on the region of interest only (*i.e.* the GOJ). The radiologist need not evaluate the oropharyngeal swallow nor assess for aspiration of contrast as these are beyond the scope of questions being asked during the early post-operative period.

(3) Interpretation of the study

Based on our results, there is a need for surgeons to discuss with their radiology colleagues about the types of funduplications they perform (*i.e.* partial *vs* total) and explain the normal post-operative anatomical appearances of each type of wrap. Understandably the radiology literature contains scant information about the technical details of laparoscopic fundoplication, especially partial fundoplication [15, 16, 26, 27]. We chose to include Figures 1–5 to demonstrate the normal and abnormal appearances of both a partial and total laparoscopic fundoplication.

Conclusion

There is a need for improvement in both the accuracy and interobserver reliability in interpreting post-operative contrast studies after laparoscopic fundoplication. Our results should be validated in a well-designed prospective study. Improving the quality of the study, with particular attention to patient positioning and the type and volume of contrast agent used, will lead to better sensitivity and specificity in interpretation. Providing more information to the radiologist regarding the type of wrap performed and any problems encountered intra-operatively will also improve the accuracy of contrast study interpretation. Standardised protocols for post-fundoplication contrast studies are necessary.

Acknowledgments

The authors would like to thank Thomas Sullivan (Data Management & Analysis Centre, Discipline of Public Health) for performing the statistical analysis. We also appreciate the work of Carolyn Lally, Janet Pinno, Lorelle Smith and Nicky Ascott in maintaining the laparoscopic fundoplication database. Finally, we would like to thank the remaining 8 upper gastrointestinal surgeons and 13 consultant radiologists who volunteered their time to participate in this study.

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