A Prospective, Blinded Comparison of Laparoscopic Ultrasound with Transabdominal Ultrasound for the Detection of Gallbladder Pathology in Morbidly Obese Patients

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BACKGROUND: Transabdominal ultrasound (TAU) is the gold standard for detecting cholelithiasis. Morbid obesity can inhibit detection of gallbladder pathology due to increased subcutaneous and visceral fat. Laparoscopic ultrasound (LUS) has the potential to overcome these technical challenges. We hypothesized that LUS would have a sensitivity and specificity similar to TAU for detecting cholelithiasis and polyps in morbidly obese patients presenting for laparoscopic Roux-en-Y gastric bypass.

STUDY DESIGN: After Institutional Review Board approval, patients underwent preoperative TAU and intraoperative LUS during laparoscopic Roux-en-Y gastric bypass. Certified ultrasonographers performed all TAU's. Surgeons, blinded to TAU results, performed the LUS. Presence of cholelithiasis or polyps and common bile duct diameter was evaluated. Statistical analysis included chi-square and McNemar’s test.

RESULTS: Two hundred and fifty-three patients were prospectively enrolled during a 6-year period. Seventy-six percent were female, mean age and preoperative body mass index (calculated as kg/m²) were 43.5 years and 48, respectively. Mean time to complete the LUS was 4 minutes. Mean common bile duct diameter measured 3.7 mm via LUS and 4.0 mm via TAU. Transabdominal ultrasound and LUS identified 61 and 60 patients with cholelithiasis, respectively (p = 0.763). The sensitivity and specificity of LUS for cholelithiasis was 90.2% and 97.4%. Laparoscopic ultrasound identified polyps in 41 patients, and TAU identified polyps in 6 patients, 5 of which had polyps identified on LUS as well (p < 0.001). Sensitivity and specificity of LUS for polyps was 83.3% and 85.4%.

CONCLUSIONS: Laparoscopic ultrasound is equivalent to TAU in detecting cholelithiasis, however, LUS detected significantly more polyps. Intraoperative LUS is an appropriate alternative to TAU in patients undergoing laparoscopic Roux-en-Y gastric bypass. (J Am Coll Surg 2013;216:1057–1062. © 2013 by the American College of Surgeons)

Morbidly obese patients have a higher propensity for cholelithiasis than their leaner counterparts.1-3 Patients undergoing Roux-en-Y gastric bypass can have a 22% risk of gallstones developing at 12-month follow-up.4 In other studies, this risk has been found to be as high as 52.8%.5 This increased risk has been attributed to cholesterol supersaturation in bile, shortened nucleation time, and gallbladder hypomotility.6 The presence of gallstones...
can eventually lead to problems such as cholecystitis, symptomatic cholelithiasis, choledocholithiasis, and gallstone pancreatitis. A long history of gallstones and gallbladder polyps can also be associated with a predilection to development of gallbladder cancer.7

The impact and management of gallbladder pathology in the bariatric population remains a relevant but controversial topic with varying opinions among experts.8,9 For surgeons who perform a concomitant cholecystectomy with gastric bypass, it becomes pertinent to determine the presence of gallbladder pathology either preoperatively or intraoperatively. Diagnostic modalities that have been used include transabdominal ultrasonography, CT cholecystography, and laparoscopic ultrasound (LUS).

Historically, transabdominal ultrasound (TAU) has been known to be a limited modality in the evaluation of the morbidly obese patient.10 This is mostly because both the depth of subcutaneous tissue and the increased distance to the gallbladder can deter adequate visualization of gallbladder pathology.11,12 In this regard, we sought to investigate the role of LUS in this patient population. We hypothesized that LUS would have a sensitivity and specificity similar to TAU for detecting gallbladder pathology in morbidly obese patients.

METHODS

Our institution is a 325-bed integrated multispecialty group health system serving 19 counties over a 3-state region. There is an accredited general surgery residency program and an accredited minimally invasive bariatric surgery and advanced laparoscopy fellowship. Additionally, our institution is a Bariatric Surgery Center of Excellence, accredited by the American Society for Metabolic and Bariatric Surgery and given Level 1a designation by the American College of Surgeons. After receiving Institutional Review Board approval, patients were prospectively enrolled from February 2004 through October 2010. All patients met the National Institute of Health criteria for bariatric surgery.13 Inclusion criteria consisted of patients without a surgical history of cholecystectomy. Informed consent was obtained before enrollment. A preoperative TAU was obtained within 30 days before laparoscopic Roux-en-Y gastric bypass (LRYGB). All TAU's were performed by Registered Medical Diagnostic Sonographers on fasting patients. Images included pancreas, aorta, liver, gallbladder (supine and left lateral decubitus), common hepatic duct, common bile duct (CBD), and bilateral kidneys using an Acuson Sequoia (Siemens Medical Engineering Group) with a C5 or V4 probe, Philips IU-22 (Koninklijke Philips Electronics NV) with a C5 probe, or General Electric Logiq E9 (General Electric Company) with a C1-5 or C2-5 probe. TAU probe frequencies ranged from 2 to 5 MHz.

The 2 surgeons (SNK and MTB) who performed the LRYGB and LUS were blinded to the results of the TAU. At the start of study enrollment, one of the surgeons (SNK) had performed approximately 93 LUSs. The second surgeon (MTB) completed our institution’s fellowship program and was involved in approximately 120 LUSs during the fellowship year. The LRYGB was performed in a retro-colic, retro-gastric fashion with a linear-stapled gastrojejunostomy. All images were obtained using the ATL 5000 (Koninklijke Philips Electronics NV) with L9 intraoperative probe at a frequency between 5 and 9 MHz. The probe was introduced through either the umbilical 12-mm port or the right upper quadrant 12-mm port. The liver was then scanned for transhepatic views of the gallbladder. The probe was placed directly on the fundus, body, and neck of the gallbladder. It was also placed on the hepatoduodenal ligament to assess the CBD diameter. Laparoscopic ultrasound images were interpreted by the surgeon, with an ultrasonographer available for assistance as needed.

The presence of cholelithiasis, sludge, gallbladder polyps, and the CBD diameter were all assessed. Cholelithiasis was defined as the presence of an intraluminal echogenic foci that cast an acoustic shadow and was gravity-dependent. Sludge was defined as low-amplitude, nonshadowing echoes that tended to layer in the most dependent portion of the gallbladder and moved slowly when the patient’s position was changed. Gallbladder polyps were defined as nonmobile, nonshadowing echogenic structures attached to the gallbladder wall.14

No concomitant cholecystectomies were performed. All patients were given a prescription for ursodiol 300 mg orally twice daily for 6 months postoperatively. Routine follow-up office visits were conducted at 3 weeks, 3 months, 6 months, 9 months, 12 months, 18 months, 24 months and annually thereafter. Patients found to have gallbladder polyps were offered annual ultrasound scans.

Results of the 2 studies were analyzed using chi-square and 2 ¥ 2 contingency tables. McNemar’s test was used to analyze the difference in sensitivities between the paired studies. The k coefficient was computed to determine statistical nonrandom concordance between the 2 techniques. This was considered poor if the coefficient
was between 0 and 0.40, fair to good if the coefficient was between 0.41 and 0.80, and excellent for a coefficient between 0.81 and 1.0. Statistical analysis was performed using the SAS software (SAS Institute).

**RESULTS**

There were 253 patients who met inclusion criteria and were enrolled in the study, 192 (76%) were female and 61 (24%) were male. Mean age was 43.5 years. Mean preoperative body mass index (calculated as kg/m²) was 48. Mean time to complete the LUS was 4 minutes. Mean CBD measurements were similar between LUS and TAU (Table 1). No gallbladder pathology was detected in 62% and 58% of patients on TAU and LUS, respectively (Fig. 1). There were no complications from performing the LUS.

Laparoscopic ultrasound detected cholelithiasis alone in 60 patients (23.7%) and TAU detected cholelithiasis in 61 patients (24.1%). Fifty-five patients (21.8%) had a concordant finding of cholelithiasis alone on both modalities. When TAU was assumed to be the gold standard test, the sensitivity and specificity of LUS for detecting cholelithiasis were 97.4% and 90.2%, respectively (Table 2). The nonrandom concordance between LUS and TAU on determining cholelithiasis were 97.4% and 90.2%, respectively (Table 2). The nonrandom concordance between LUS and TAU was considered excellent, with a \( \kappa \) coefficient of 0.882 (McNemar’s test, \( p = 0.76 \)).

Laparoscopic ultrasound detected polyps in 41 patients (16.2%), and only 6 patients (2.37%) were found to have polyps on TAU (Table 3). Five of these six patients also had polyps detected via LUS. When TAU served as the gold standard test, the sensitivity and specificity of LUS for detecting gallbladder polyps were 85.4% and 83.3%, respectively (Table 2). The nonrandom concordance between the tests for detecting gallbladder polyps was considered poor with a \( \kappa \) coefficient of 0.179 (McNemar’s test, \( p < 0.0001 \)).

The presence of any gallbladder pathology (cholelithiasis, polyps, or sludge) was detected in 105 patients (41.5%) by LUS. Only 70 patients (27.7%) were found to have any gallbladder pathology on TAU (Table 4). Again, when TAU was assumed to be the gold standard test, the sensitivity and specificity of LUS for detecting any gallbladder pathology were 76.5% and 88.6%, respectively (Table 4). The nonrandom concordance between TAU and LUS for detecting gallbladder pathology was considered fair to good with a \( \kappa \) coefficient of 0.563. Ten patients (3.9%) eventually underwent cholecystectomy at a mean interval of 811 days after LRYGB (Table 1), and pathology reports were available for 9 of these patients. Three patients had cholelithiasis identified on both TAU and LUS, which was corroborated by the pathology report after cholecystectomy. Four patients had a normal TAU and LUS, but cholelithiasis subsequently developed, and 2 patients had normal findings at TAU and LUS and were found to have chronic cholecystitis at cholecystectomy.

**DISCUSSION**

Transabdominal ultrasonography is considered the imaging procedure of choice for the diagnosis of cholelithiasis and most gallbladder pathology in the general population. However, its role in the evaluation of the morbidly obese patient has been met with some criticism. Klingensmith and Eckhout found a 75% sensitivity of ultrasonography to detect cholelithiasis in morbidly obese patients. They noted that this sensitivity was lower than what was obtained in studies of nonobese patients. They attributed this to the detrimental effect of extreme obesity on image quality. Herbst and colleagues stated their preference for intraoperative ultrasonography because it eliminated the technical difficulties posed by excessive fat in the morbidly obese. They believed that it was a safe procedure with an acceptably low false-positive rate of 1.8%.

Intraoperative ultrasound was first introduced in the early 1960s. At this early phase, the use of A-mode or static B-mode ultrasound limited its widespread use, due to difficulty in image interpretation. However, in the late 1970s, interest in intraoperative ultrasound was rekindled after the introduction of real-time B-mode ultrasound. Subsequently, with the widespread acceptance of laparoscopic surgery in the 1990s, LUS technology was developed. It found its first use in the evaluation of CBD during laparoscopic cholecystectomy.

In our study, we sought to investigate the applicability of LUS in the evaluation of gallbladder pathology in the morbidly obese. To date, this is the largest study comparing both modalities in the absence of a gold standard test (ie, pathological evaluation). Using our statistical analysis, we were able to deduce that LUS and TAU were comparable tests in the evaluation of cholelithiasis alone. However, there was a statistically noticeable discordance in their abilities to detect gallbladder polyps, with LUS detecting far more polyps than TAU.
might be a result of the improved resolution obtained from the elimination of the distance required for imaging a nonshadowing structure in morbidly obese patients.

There are varying reports in the literature about the accuracy of TAU in the diagnosis of gallbladder polyps. Damore and colleagues\(^1\) found that TAU was inaccurate in making a diagnosis of gallbladder polyps in 95% of patients in their series. Akyurek and colleagues\(^2\) found it to be inaccurate in 82% of patients. They were also able to determine that the sensitivity of TAU was better in diagnosing polyps $>1$ cm vs $<1$ cm (80% vs 20%). At the other end of the spectrum, Yang and colleagues\(^3\) were able to show that TAU had a sensitivity of 94% for detecting gallbladder polyps. Another imaging modality that is gaining increasing popularity in the diagnosis of gallbladder polyps is endoscopic ultrasound (EUS). The gallbladder lies in close proximity to the gastric antrum and duodenal bulb. An EUS probe can be placed at this site to provide high-resolution images of the gallbladder.\(^4\) One study was able to show that EUS was superior to TAU in distinguishing gallbladder polyps. Endoscopic ultrasound had an accuracy of 97% compared with 76% obtained with TAU.\(^5\) In a similar manner, we propose that LUS would be a superior study to TAU for the diagnosis of gallbladder polyps in the morbidly obese, because of the shortened imaging distance.

At our center, a cholecystectomy is performed concomitantly during LRYGB only if the patient has symptomatic gallstone disease. However, we do not routinely obtain preoperative TAU. We have adopted a practice of placing our patients on a 6-month course of ursodiol 300 mg twice daily. With this we have been able to achieve a cholecystectomy rate of about 4%, as shown in this study. Villegas and colleagues\(^6\) reported a cholecystectomy rate of 7.3% in patients treated with ursodiol after gastric bypass. In another study, Caruana and colleagues\(^7\) reported that only 8% of their patients who had undergone an open gastric bypass required a subsequent cholecystectomy. This patient population received no ursodiol therapy. Evidently, the trend of almost routine prophylactic cholecystectomy that existed in the open gastric bypass era has given way to a more selective option based mostly on the presence of symptomatic cholelithiasis.\(^8\)

### Table 2. Cholelithiasis on Transabdominal Ultrasound vs Laparoscopic Ultrasound

<table>
<thead>
<tr>
<th>TAU, n</th>
<th>Cholelithiasis</th>
<th>No cholelithiasis</th>
<th>Total, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUS</td>
<td>55</td>
<td>5</td>
<td>60</td>
</tr>
<tr>
<td>No cholelithiasis</td>
<td>6</td>
<td>187</td>
<td>193</td>
</tr>
<tr>
<td>Total</td>
<td>61</td>
<td>192</td>
<td>253</td>
</tr>
</tbody>
</table>

Sensitivity = 90.2%, specificity = 97.4%, K coefficient = 0.882.

LUS, laparoscopic ultrasound; TAU, transabdominal ultrasound.

### Table 3. Gallbladder Polyp Findings on Transabdominal Ultrasound vs Laparoscopic Ultrasound

<table>
<thead>
<tr>
<th>TAU, n</th>
<th>Polyps</th>
<th>No polyps</th>
<th>Total, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUS</td>
<td>5</td>
<td>36</td>
<td>41</td>
</tr>
<tr>
<td>No polyps</td>
<td>1</td>
<td>211</td>
<td>212</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>247</td>
<td>253</td>
</tr>
</tbody>
</table>

Sensitivity = 83.3%, Specificity = 85.4%, Kappa coefficient = 0.179.

LUS, laparoscopic ultrasound; TAU, transabdominal ultrasound.
For surgeons who routinely image the gallbladder before gastric bypass, we would recommend the use of LUS. It has been estimated that about 25 to 30 cases might be required to achieve proficiency in the performance and interpretation of LUS. The surgeons involved in our series had performed >90 LUSs before study enrollment, so the effect of a potential learning curve or other surgeon-dependent factors remains largely unknown. In the hands of a well-trained surgeon, LUS is a quick and safe technique to execute. Mean time required to perform this procedure in our study was 4 minutes. Scott and colleagues24 reported an LUS time of approximately 3 minutes. In addition, LUS has been found to assist in delineating CBD anatomy and therefore reducing the incidence of CBD injury encountered during a laparoscopic cholecystectomy.25 It is also a reasonable alternative to intraoperative cholangiography for the detection of occult choledocholithiasis.26

### CONCLUSIONS

Laparoscopic ultrasound is a reasonable alternative to TAU for detection of gallbladder pathology in the morbidly obese patient. Our study is limited by the fact that we do not have a reference gold standard test with which to compare both tests. However, to obtain a definitive knowledge of the presence of specific gallbladder pathology, we would have had to subject our patients to a concomitant cholecystectomy. In light of this, we subjected both modalities to adequate statistical analysis comparing them. Our analysis showed that LUS is equivalent to TAU in the detection of gallstones, but more sensitive in the detection of gallbladder polyps. Laparoscopic ultrasound has been shown to be safe, quick, and easy to use. It also offers the additional advantage of evaluating CBD anatomy intraoperatively. Although a comprehensive cost analysis was outside the scope of this study, given the equivalent sensitivity and specificity of LUS to TAU, the cost effectiveness of each modality is the next logical area for future research, particularly in an environment of increased transparency in health care resource use. Laparoscopic ultrasound could convey a benefit for patient satisfaction because it can save patients a separate office visit. Laparoscopic ultrasound can also detect intraoperative pathology in a patient with abdominal symptoms and a negative TAU.

### Author Contributions

Study conception and design: Kothari, Baker, Mathiason Acquisition of data: Kallies Analysis and interpretation of data: Kothari, Obinwanne, Baker, Mathiason, Kallies Drafting of manuscript: Kothari, Obinwanne, Mathiason, Kallies Critical revision: Kothari, Obinwanne, Baker, Mathiason, Kallies

### REFERENCES


### Table 4. Gallbladder Pathology Findings on Transabdominal Ultrasound vs Laparoscopic Ultrasound

<table>
<thead>
<tr>
<th>TAU, n</th>
<th>Stones/sludge/polyp</th>
<th>Normal</th>
<th>Total, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stones/sludge/polyp</td>
<td>62</td>
<td>43</td>
<td>105</td>
</tr>
<tr>
<td>Normal</td>
<td>8</td>
<td>140</td>
<td>148</td>
</tr>
<tr>
<td>Total</td>
<td>70</td>
<td>183</td>
<td>253</td>
</tr>
</tbody>
</table>

Sensitivity = 88.6%, Specificity = 76.5%, Kappa coefficient = 0.563. LUS, laparoscopic ultrasound; TAU, transabdominal ultrasound.