Diagnostic accuracy of transabdominal ultrasonography for gallbladder polyps: systematic review

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Background: Previous research has shown variable but generally poor accuracy of transabdominal ultrasonography in the diagnosis of gallbladder polyps. We performed a systematic review of the literature with the aim of helping surgeons interpret and apply these findings in the preoperative assessment and counselling of their patients.

Methods: We searched PubMed, MEDLINE and the Cochrane database using the keywords “gallbladder,” “polyp,” “ultrasound,” “pathology” and “diagnosis” for English-language articles published after 1990 with the full-text article available through our institutional subscriptions. Polyps were defined as immobile features that on transabdominal ultrasonography appear to arise from the mucosa and that lack an acoustic shadow, and pseudopolyps were defined as features such as inflammation, hyperplasia, cholesterosis and adenomyomatosis that convey no risk of malignant transformation.

Results: The search returned 1816 articles, which were narrowed down to 14 primary sources involving 15 497 (range 23–13 703) patients who had preoperative transabdominal ultrasonography, underwent cholecystectomy and had postoperative pathology results available. Among the 1259 patients in whom a gallbladder polyp was diagnosed on ultrasonography, 188 polyps were confirmed as true polyps on pathologic examination, and 81 of these were found to be malignant. Of the 14 238 patients for whom a polyp was not seen on ultrasonography, 38 had a true polyp on pathologic examination, none of which were malignant. For true gallbladder polyps, transabdominal ultrasonography had a sensitivity of 83.1%, specificity of 96.3%, positive predictive value of 14.9% (7.0% for malignant polyps) and negative predictive value of 99.7%.

Conclusion: Transabdominal ultrasonography has a high false-positive rate (85.1%) for the diagnosis of gallbladder polyps. Further study of alternative imaging modalities and reevaluation of existing management guidelines are warranted.

Contexte: Des recherches antérieures ont montré la précision variable, mais généralement médiocre, de l’échographie transabdominale pour le diagnostic des polypes de la vésicule biliaire. Nous avons procédé à une revue systématique de la littérature scientifique afin d’aider les chirurgiens à interpréter et à appliquer ces résultats lors de l’évaluation préopératoire, et à conseiller leurs patients.


Résultats: La recherche a généré 1816 articles qui ont été ramenés à 14 sources principales regroupant 15 497 (éventail, 23–13 703) patients ayant subi une échographie transabdominale préopératoire et une cholécystectomie, et pour lesquels on disposait des résultats de l’examen anatomopathologique postopératoire. Sur les 1259 patients chez qui des polypes intravésiculaires ont été diagnostiqués à l’échographie, 188 polypes ont été jugés vrais à l’examen anatomopathologique, et 81 d’entre eux se sont révélés malins. Parmi les 14 238 patients chez lesquels...
Gallbladder cancer is a rare but serious disease. There were 500 new cases of gallbladder cancer and 265 deaths from this disease in Canada in 2015. Gallbladder polyps are malignant or potentially malignant exophytic mucosal lesions such as adenomas, adenocarcinomas or carcinomas. Pseudopolyps are features such as inflammation, hyperplasia, cholesterosis and adenomyomatosis that convey no risk of malignant transformation. On transabdominal ultrasonography, gallbladder polyps are defined as immobile features that appear to arise from the mucosa and that lack an acoustic shadow (which is typically seen with gallstones). Previous pathologic review showed that all malignant gallbladder tumours are found in polyps larger than 6 mm, that polyps 10–20 mm in size have a 43%–77% incidence of gallbladder cancer, and that polyps larger than 20 mm are “pathognomonic” for gallbladder cancer. As such, current guidelines for management of gallbladder polyps are highly focused on their size. Polyps measuring 10 mm or less should be managed with watchful waiting (with uncertainty regarding the number or frequency of visits or ultrasonography examinations required), those measuring 11–20 mm should be managed with close follow-up or cholecystectomy, and those larger than 20 mm require cholecystectomy.

Transabdominal ultrasonography has been shown to be inaccurate in measuring the size of polypoid gallbladder lesions. Choi and colleagues found a mean deviation of only 0.89 mm for true polyps, but Guo and colleagues reported that transabdominal ultrasonography universally overestimates polyp size by 4.24 mm (standard deviation 0.19 mm). These variations are potentially important when one considers that the suggested management of polyps changes substantially over a 10-mm range, and they could translate into patients’ being classified into a higher risk category and being offered more ultrasonography examinations and surgical procedures than is appropriate. Guo and colleagues also found that transabdominal ultrasonography overestimates the size of cholesterosis by 5.12 mm (SD 0.21 mm), much of which may be inaccurately labelled as true polyps.

Transabdominal ultrasonography has also been shown to be a flawed modality for serial monitoring of gallbladder polyps, as longitudinal studies have demonstrated minimal to no progression in size. Kratzer and colleagues followed 2415 patients with a mean polyp size of 5.0 mm (SD 2.1 mm) and found that there was no statistically significant change in mean size at 30 months (5 mm [SD 2.8 mm]) or 84 months (4.0 mm [SD 2.3 mm]). Ito and colleagues followed 417 patients with polyps measuring less than 10 mm for a median of 17 months (range 1–81 mo) and found growth greater than 3 mm in only 6% of patients. High-risk features and malignant disease did not develop in any patient. Although these studies are small, they indicate that gallbladder polyps may not follow the standard progression of adenoma to adenocarcinoma.

Previous studies have shown poor correlation between ultrasonography diagnosis and final pathology, and an attempted meta-analysis was aborted owing to a lack of satisfactory research. This diagnostic uncertainty introduces the potential for unnecessary imaging, unnecessary surgery and all the associated risks to patients and costs to the health care system.

We performed a systemic review with the aim of helping surgeons interpret previous research and apply the findings in the preoperative assessment and counselling of their patients.

Methods

We studied transabdominal ultrasonography as it is the most widely available and most commonly used imaging modality for biliary disease. We searched MEDLINE, PubMed and the Cochrane database using the keywords “gallbladder,” “polyp,” “ultrasound,” “pathology” and “diagnosis.” The articles were screened for relevance and duplicates. We included articles for review if they contained data for patients who had had preoperative transabdominal ultrasonography and had undergone cholecystectomy, and for whom postoperative pathology results were available. The search was limited to English-language articles published after 1990 with the full-text article available through our institutional subscriptions. We used the year 1990 as a cut-off given the substantial improvement in transabdominal ultrasonography technique after that year. Articles were excluded from review if they did not focus on gallbladder polyps, if transabdominal ultrasonography was not used, if patients did not undergo cholecystectomy or if the article did not contain complete pathologic data. We also reviewed the references of screened articles.
We examined the definitions of true polyps and pseudopolyps used by the authors of each article for consistency with the standardized definitions used in this review (polyps: immobile features that on transabdominal ultrasonography appear to arise from the mucosa and that lack an acoustic shadow; pseudopolyps: features such as inflammation, hyperplasia, cholesterolosis and adenomyomatosis that convey no risk of malignant transformation). We then retrieved the data directly from the articles in concordance with the standardized definition.

RESULTS

The literature search produced 1816 results. A total of 1789 abstracts were excluded because they were off topic (e.g., ultrasonography of thyroid nodules) or were duplicates (n = 1775), or because they did not have a full-text English-language version available (n = 14). Of the 27 articles screened, 4 were excluded because they involved the incorrect imaging modality (e.g., a study of 3-dimensional ultrasonography only), and 9 were excluded because of absent or inadequate pathology data. No new articles were identified on screening of the references of the 27 full-text articles. This resulted in 14 primary articles for inclusion in our review (Fig. 1).

The sample size in the 14 studies ranged from 23 to 13,703 patients (Table 1). Among the 1,259 patients in whom a gallbladder polyp was diagnosed on preoperative transabdominal ultrasonography, 188 polyps were confirmed as true polyps on pathologic examination, and 81 of these were found to be malignant. This corresponds to 188 true-positive ultrasonography diagnoses and 1,071 false-positive ultrasonography diagnoses (Fig. 2). Among the 1,071 patients with a positive ultrasonography report and a negative pathology report, 735 pathology reports were significant for pseudopolyps, and 401 reports were significant for cholelithiasis, with some of the false-positive reports being positive for both pseudopolyps and cholelithiasis (Fig. 3). Of the 14,238 patients for whom a polyp was not seen on ultrasonography, 38 had a true polyp on pathologic examination, none of which were malignant.

For the diagnosis of true gallbladder polyps by transabdominal ultrasonography, the sensitivity was 83.1%, the specificity was 96.3%, the positive predictive value was 14.9% (7.0% for malignant polyps), and the negative predictive value was 99.7% (Table 2). Stated another way, 85.1% of the patients in whom a gallbladder polyp was diagnosed on ultrasonography did not actually have a true polyp.

Data on the size of the true polyps were not consistently reported, but the available data show that true polyps (especially malignant polyps) tended to be larger than 10 mm but with a minimum SD of 4.2 mm (Table 3).

DISCUSSION

The proportions of true- and false-positive results in the included studies show generalized overestimation of the presence of true gallbladder polyps. Among the patients with a false-positive ultrasonography report,
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pathologic examination showed a pseudopolyp in 59% and cholelithiasis in 38%, both of which are known to increase the rate of false-positive results.² Generally, pseudopolyps are more likely to be found on final pathologic examination than gallstones, which indicates that the former are more difficult to distinguish from true polyps and are more likely to confound ultrasonography diagnosis.

**Table 1. Ultrasonography and pathology data from the 14 primary articles reviewed**

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of patients</th>
<th>No. of patients</th>
<th>No. of polyp</th>
<th>True polyp</th>
<th>True polyp, malignant</th>
<th>No. of patients</th>
<th>No. of patients</th>
<th>No. of polyp, pseudopolyp</th>
<th>No. of patients</th>
<th>No. of patients</th>
<th>No. of polyp, gallstones</th>
<th>True polyp</th>
<th>True polyp, malignant</th>
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<tr>
<td>Akyurek et al.¹¹</td>
<td>853</td>
<td>797</td>
<td>787</td>
<td>10</td>
<td>0</td>
<td>56</td>
<td>46</td>
<td>17</td>
<td>12</td>
<td>10</td>
<td>0</td>
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<tr>
<td>Ali Channa et al.¹²</td>
<td>28</td>
<td>0</td>
<td>—</td>
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<td>23</td>
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<td>—</td>
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<td>23</td>
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<td>Choi et al.⁵</td>
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<td>0</td>
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<td>—</td>
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<td>59</td>
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<td>8</td>
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<td>57</td>
<td>66</td>
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<td>—</td>
<td>—</td>
<td>138</td>
<td>116</td>
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<td>21</td>
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<td>Xu et al.¹⁹</td>
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<td>50</td>
<td>20</td>
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<td>9</td>
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<td>130</td>
<td>115</td>
<td>79</td>
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<td>15</td>
<td>9</td>
<td></td>
<td></td>
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<tr>
<td>All</td>
<td>15 497</td>
<td>14 238</td>
<td>14 200</td>
<td>38</td>
<td>0</td>
<td>1259</td>
<td>1071</td>
<td>735</td>
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<td>All excluding French et al.²</td>
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<td>596</td>
<td>272</td>
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</table>

**Fig. 2. Ratio of true-positive to false-positive diagnoses of gallbladder polyp on ultrasonography.**
Other imaging modalities have also been shown to be inaccurate in measuring polyps, and the modalities are not well correlated with one another. Choi and colleagues showed that there was a mean difference of 5.66 mm in measurements of polyps for cholesterolosis between ultrasonography and computed tomography and a mean difference of 2.17 mm in measurements of noncholesterol polyps. Those authors also found that a
polypoid lesion that is smaller or is not present on computed tomography, as compared to a lesion seen on ultrasonography, is more likely to be cholesterolosis than a true polyp, which was supported by Song and colleagues. Song and colleagues also found that polyps diagnosed on ultrasonography were more likely to be cholesterolosis in young patients with a high body mass index. Other modalities such as 3-dimensional ultrasonography and endoscopic ultrasonography have shown promise in the diagnosis of gallbladder polyps, but further study of their accuracy and cost–benefit ratio is required.

It is important to note that our results are heavily weighted by the extensive review conducted by French and colleagues of 13,703 patients. Their data represent 20.8% of the patients with a positive preoperative ultrasonography report in the 14 articles reviewed. Their large data set results in lower sensitivity and specificity values than those seen in the smaller study by Akyurek and colleagues, which may be a centre-specific trend but may also be closer to the true values for gallbladder polyps on ultrasonography. The data are summarized with and without the values from French and colleagues, and, although the differences are minor, they must be considered.

**Recommendations**

Despite the finding that transabdominal ultrasonography is a limited modality for the diagnosis and monitoring of gallbladder polyps, its limitations must be weighed against the severity of gallbladder cancer. Therefore, we recommend that patients with polyps smaller than 10 mm be educated as to the limitations of ultrasonography and the low likelihood of current or future malignant disease (Fig. 4). They can be offered elective cholecystectomy. If patients with polyps smaller than 10 mm decline cholecystectomy, they should be followed with transabdominal ultrasonography at 6 and 12 months to check for rapid polyp growth and other high-risk features. Patients with polyps 10–20 mm in size should be offered cholecystectomy, and, if surgery is contraindicated, they should be followed with transabdominal ultrasonography at 6 and 12 months. Patients with polyps greater than 20 mm should proceed to cholecystectomy with the same threshold for surgical contraindications as other oncologic procedures. Patients with polyps of any size should be offered cholecystectomy if they have any of the following high-risk features: rapid growth of 3 mm or more in a 6-month period, sessile polyps, solitary polyps, thickened gallbladder wall, cholelithiasis, biliary colic, atypical right upper quadrant pain, history of cholelithiasis, coma or primary sclerosing cholangitis or age more than 50 years.

**Limitations**

The data in this review are biased by the fact that most patients who undergo ultrasonography have abdominal problems, that most patients who undergo cholecystectomy have symptomatic disease, and that 20.8% of the positive ultrasonography results in the review came from 1 study. Our review is further limited by the lack of large studies, specifically of randomized and blinded studies, and by the relative homogeneity of the included studies. In addition, a meaningful likelihood ratio for the presence of true polyps based on an ultrasonography diagnosis cannot be calculated given that the true incidence of gallbladder polyps is not known, incidence data gathered by ultrasonography reviews are inherently flawed, and incidence data gathered by pathologic review are biased because the patients required cholecystectomy.

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Table 3. Size of true polyps on final pathologic report

<table>
<thead>
<tr>
<th>Study</th>
<th>Size, mm; no of cases</th>
<th>Minimum size, mm</th>
<th>Maximum size, mm</th>
<th>Median size, mm</th>
<th>Mean size ± SD, mm</th>
<th>Comment</th>
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<td>&gt; 10</td>
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<td>27</td>
<td>1</td>
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<td>0</td>
<td>3</td>
<td>12</td>
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<tr>
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<td>1</td>
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<td>—</td>
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<tr>
<td>Khan et al.</td>
<td>0</td>
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<td>—</td>
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<tr>
<td>Mainprize et al.</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>—</td>
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<tr>
<td>Park et al.</td>
<td>0</td>
<td>1</td>
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<td>8</td>
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<td>Xu et al.</td>
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<td>3</td>
<td>12</td>
<td>—</td>
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<tr>
<td>Zielinski et al.</td>
<td>2</td>
<td>(&lt; 6)</td>
<td>3</td>
<td>8</td>
<td>53</td>
<td>18</td>
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<tr>
<td>Akyurek et al.</td>
<td>1</td>
<td>(&lt; 6)</td>
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<td>8</td>
<td>—</td>
<td>—</td>
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<tr>
<td>Sarkut et al.</td>
<td>0</td>
<td>1</td>
<td>21</td>
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<td>Huang et al.</td>
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</table>
| SD = standard deviation.
CONCLUSION

In this systematic review involving 1259 patients who had positive findings on preoperative transabdominal ultrasonography and then underwent cholecystectomy, ultrasonography had a sensitivity of 83.1% for true gallbladder polyps, a specificity of 96.3%, a positive predictive value of 14.9% (7.0% for malignant true polyps) and a negative predictive value of 99.7%. Further studies are needed to clarify the optimal use and cost–benefit ratio of transabdominal ultrasonography in the diagnosis of gallbladder polyps.

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Competing interests: None declared.

Contributors: E. Martin and E. Debru designed the study. E. Martin acquired and analyzed the data, which R. Gill also analyzed. E. Martin wrote the article, which all authors reviewed and approved for publication.

References


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