

# 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.

**Méthodes :** Nous avons interrogé les réseaux PubMed, MEDLINE et la base de données Cochrane à partir des mots clés « gallbladder », « polyp », « ultrasound », « pathology » et « diagnosis » (vésicule biliaire, polype, échographie, pathologie et diagnostic) pour recenser les articles en langue anglaise publiés après 1990, pour lesquels le texte intégral était accessible par abonnement institutionnel. À l'échographie, les polypes étaient définis comme des structures fixes semblant émaner de la muqueuse et dépourvues d'ombre acoustique, et les pseudopolypes étaient définis par des caractéristiques telles que l'inflammation, l'hyperplasie, la cholestérolose et l'adénomyomatose ne comportant pas de risque de transformation maligne.

**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

aucun polype n'avait été détecté à l'échographie, 38 étaient porteurs d'un vrai polype à l'examen anatomopathologique et aucun ne s'est révélé malin. En ce qui concerne les vrais polypes intravésiculaires, l'échographie transabdominale a une sensibilité de 83,1 %, une spécificité de 96,3 %, une valeur prédictive positive de 14,9 % (7,0 % dans le cas des polypes malins) et une valeur prédictive négative de 99,7 %.

**Conclusion :** L'échographie transabdominale présente un taux de résultats faux positifs élevé (85,1 %) pour le diagnostic des polypes de la vésicule biliaire. Il faudra approfondir la recherche sur d'autres techniques d'imagerie et réévaluer les lignes directrices actuelles de prise en charge.

**G**allbladder 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.<sup>1</sup> Gallbladder polyps are malignant or potentially malignant exophytic mucosal lesions such as adenomas, adenocarcinomas or carcinomas.<sup>2</sup> Pseudopolyps are features such as inflammation, hyperplasia, cholesterosis and adenomyomatosis that convey no risk of malignant transformation.<sup>2</sup> 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).<sup>3</sup> 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.<sup>2</sup> As such, current guidelines for management of gallbladder polyps are heavily 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.<sup>2,4</sup>

Transabdominal ultrasonography has been shown to be inaccurate in measuring the size of polypoid gallbladder lesions. Choi and colleagues<sup>5</sup> found a mean deviation of only 0.89 mm for true polyps, but Guo and colleagues<sup>6</sup> reported that transabdominal ultrasonography universally overestimates polyp size by 4.24 mm (standard deviation [SD] 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<sup>6</sup> 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<sup>7</sup> 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<sup>8</sup> 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,<sup>2–4</sup> and an attempted meta-analysis was aborted owing to a lack of satisfactory research.<sup>2</sup> 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.<sup>9,10</sup> 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;<sup>3</sup> pseudopolyps: features such as inflammation, hyperplasia, cholesterolosis and adenomyomatosis that convey no risk of malignant transformation<sup>2</sup>). 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 1259 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 1071 false-positive ultrasonography diagnoses (Fig. 2). Among the 1071 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,

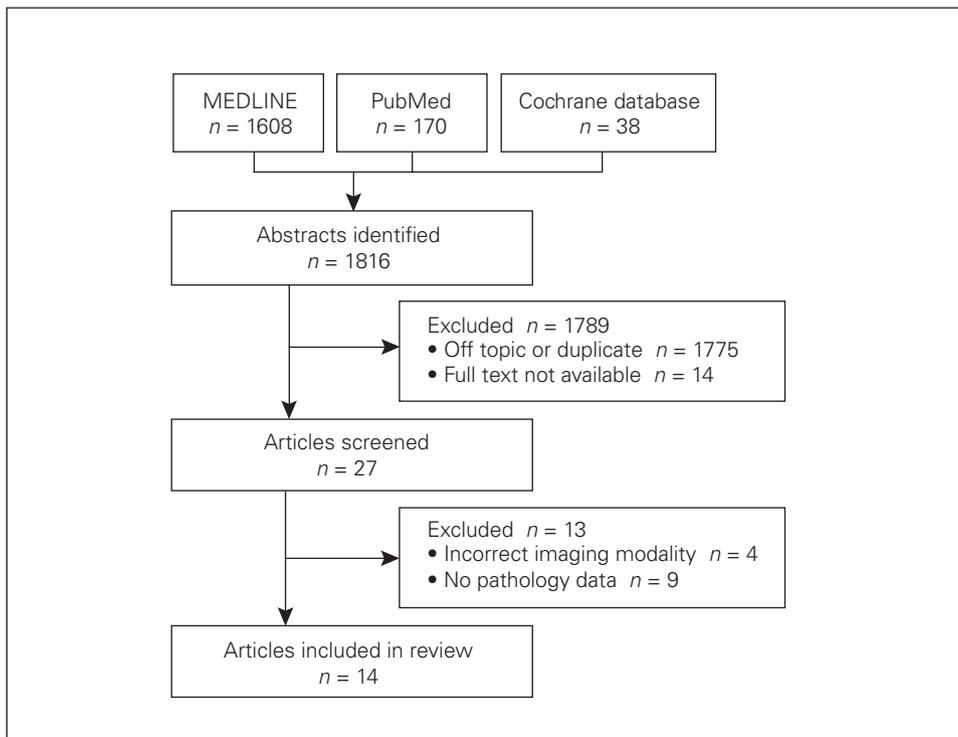
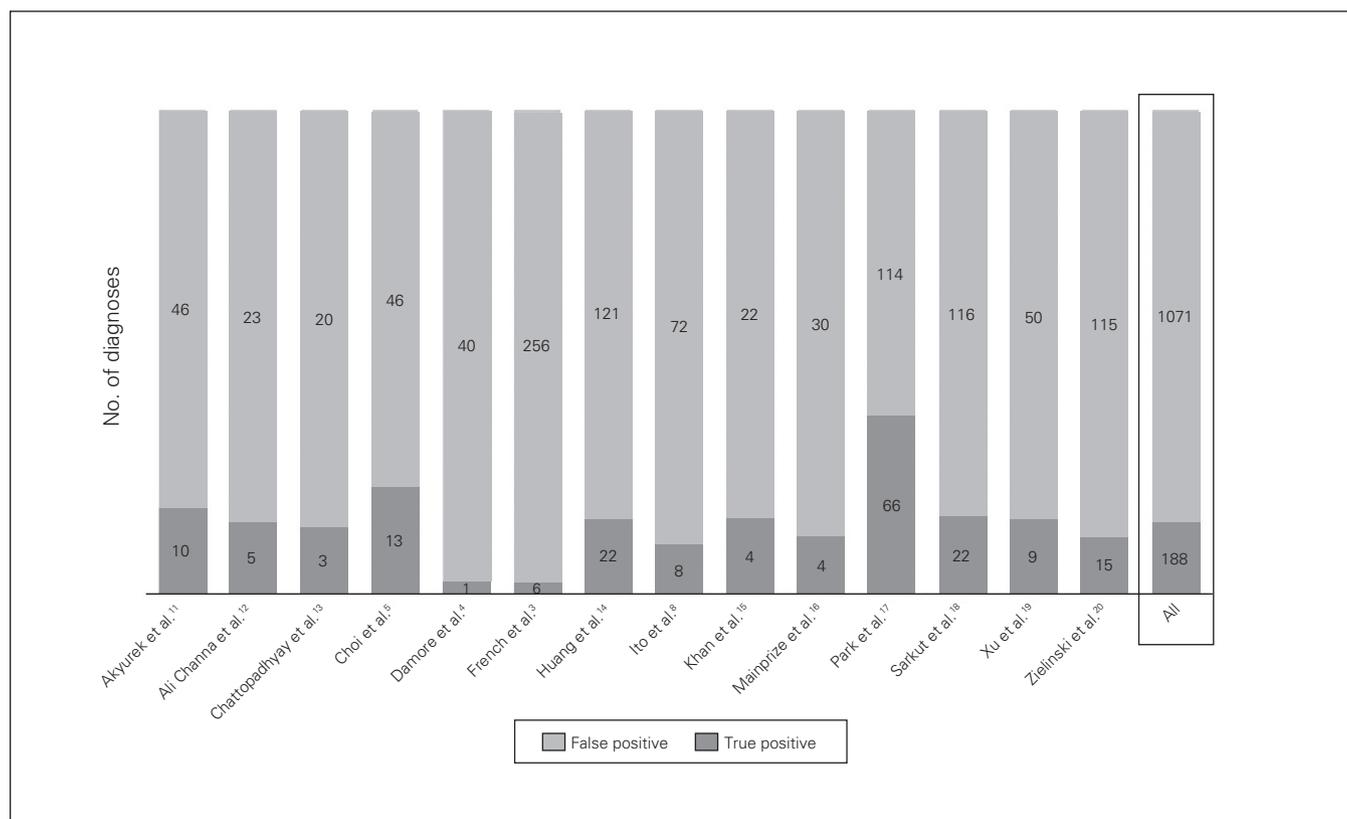


Fig. 1. Flow diagram showing article selection.

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

Study	No. of patients	Negative ultrasonography report				Positive ultrasonography report					
		No. of patients	No polyp	True polyp	True polyp, malignant	No. of patients	No polyp	No polyp, pseudopolyp	No polyp, gallstones	True polyp	True polyp, malignant
Akyurek et al. <sup>11</sup>	853	797	787	10	0	56	46	17	12	10	0
Ali Channa et al. <sup>12</sup>	28	0	—	—	—	28	23	15	8	5	1
Chattopadhyay et al. <sup>13</sup>	23	0	—	—	—	23	20	8	12	3	2
Choi et al. <sup>5</sup>	59	0	—	—	—	59	46	46	5	13	3
Damore et al. <sup>4</sup>	41	0	—	—	—	41	40	27	15	1	0
French et al. <sup>3</sup>	13 703	13 441	13 413	28	0	262	256	139	129	6	3
Huang et al. <sup>14</sup>	143	0	—	—	—	143	121	121	23	22	6
Ito et al. <sup>8</sup>	80	0	—	—	—	80	72	54	9	8	1
Khan et al. <sup>15</sup>	26	0	—	—	—	26	22	21	12	4	1
Mainprize et al. <sup>16</sup>	34	0	—	—	—	34	30	29	22	4	2
Park et al. <sup>17</sup>	180	0	—	—	—	180	114	82	57	66	25
Sarkut et al. <sup>18</sup>	138	0	—	—	—	138	116	77	39	22	21
Xu et al. <sup>19</sup>	59	0	—	—	—	59	50	20	30	9	7
Zielinski et al. <sup>20</sup>	130	0	—	—	—	130	115	79	28	15	9
All	15 497	14 238	14 200	38	0	1259	1071	735	401	188	81
All excluding French et al. <sup>3</sup>	1794	797	787	10	0	997	815	596	272	182	78



**Fig. 2.** Ratio of true-positive to false-positive diagnoses of gallbladder polyp on ultrasonography.

pathologic examination showed a pseudopolyp in 59% and cholelithiasis in 38%, both of which are known to increase the rate of false-positive results.<sup>2</sup> 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.

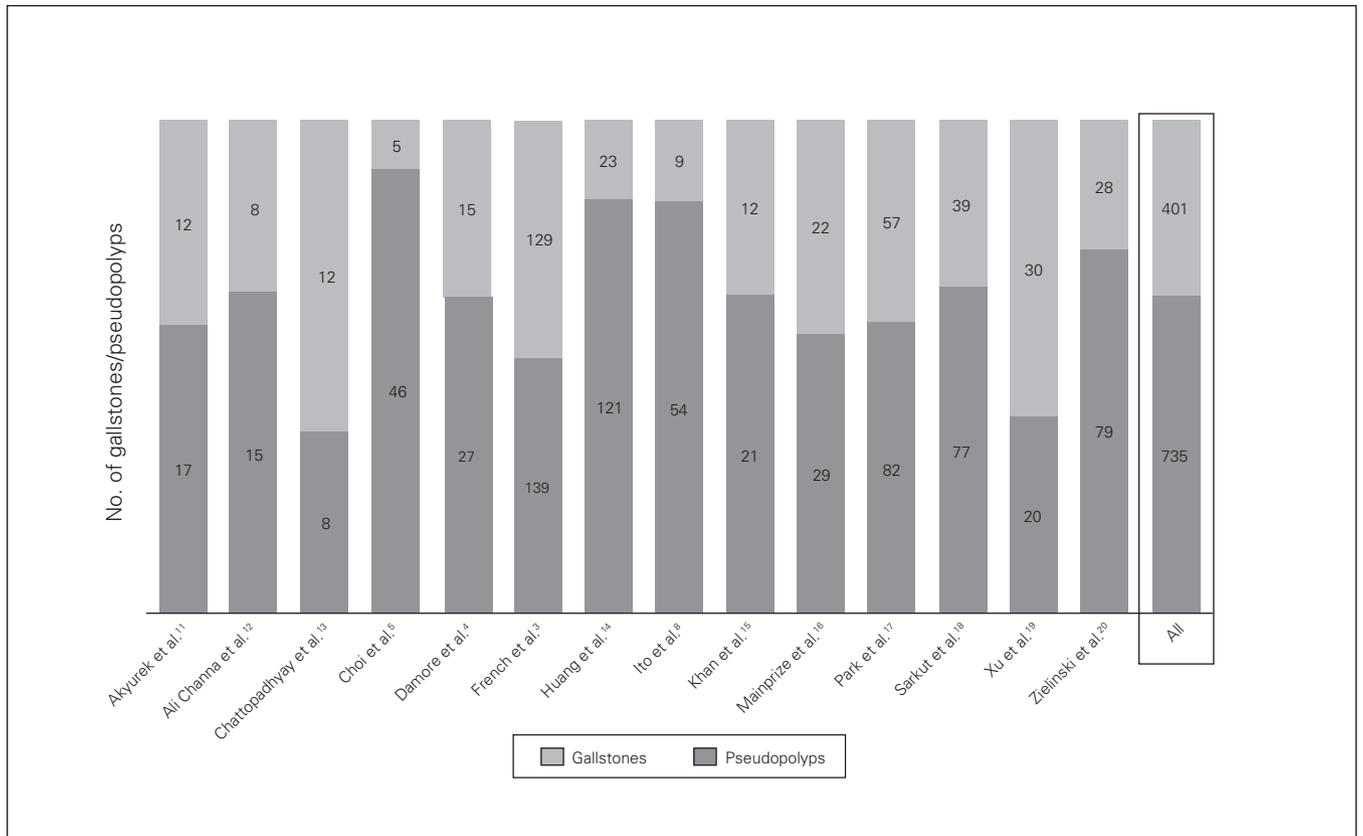


Fig. 3. Ratio of gallstones to pseudopolyps on ultrasonography with false-positive diagnosis.

Study	Sensitivity	Specificity	Positive predictive value		Negative predictive value
			True polyp	Malignant polyp	
Akyurek et al. <sup>11</sup>	0.500	0.945	0.179	0.000	0.988
Ali Channa et al. <sup>12</sup>	—	—	0.179	0.042	—
Chattopadhyay et al. <sup>13</sup>	—	—	0.130	0.091	—
Choi et al. <sup>5</sup>	—	—	0.220	0.061	—
Damore et al. <sup>4</sup>	—	—	0.024	0.000	—
French et al. <sup>3</sup>	0.176	0.981	0.023	0.012	0.998
Huang et al. <sup>14</sup>	—	—	0.154	0.047	—
Ito et al. <sup>9</sup>	—	—	0.100	0.014	—
Khan et al. <sup>15</sup>	—	—	0.154	0.043	—
Mainprize et al. <sup>16</sup>	—	—	0.118	0.063	—
Park et al. <sup>17</sup>	—	—	0.367	0.180	—
Sarkut et al. <sup>18</sup>	—	—	0.159	0.153	—
Xu et al. <sup>19</sup>	—	—	0.153	0.123	—
Zielinski et al. <sup>20</sup>	—	—	0.115	0.073	—
All	0.831	0.963	0.149	0.070	0.997
All excluding French et al. <sup>3</sup>	0.948	0.945	0.183	0.087	0.988

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<sup>5</sup> showed that there was a mean difference of

5.66 mm in measurements of polyps for cholesterosis between ultrasonography and computed tomography and a mean difference of 2.17 mm in measurements of noncholesterol polyps. Those authors also found that a

**Table 3. Size of true polyps on final pathologic report**

Study	Size, mm; no of cases			Minimum size, mm	Maximum size, mm	Median size, mm	Mean size $\pm$ SD, mm	Comment
	< 5	5–10	> 10					
Ali Channa et al. <sup>12</sup>	0	27	1	—	15	—	—	Incomplete data
Chattopadhyay et al. <sup>13</sup>	0	0	3	12	20	18	16.7 $\pm$ 4.2	Benign and malignant polyps
Damore et al. <sup>4</sup>	0	1	0	—	6	—	—	Incomplete data
Khan et al. <sup>15</sup>	0	0	4	—	—	—	—	Incomplete data
Mainprize et al. <sup>16</sup>	0	0	2	—	—	—	—	Incomplete data
Park et al. <sup>17</sup>	0	1	24	8	30	15	15.2 $\pm$ 5.6	Malignant polyps only
Xu et al. <sup>19</sup>	—	—	—	3	12	—	—	Incomplete data
Zielinski et al. <sup>20</sup>	2 (< 6)	3 (6–9)	8 ( $\geq$ 10)	4	53	18	18.5 $\pm$ 15.4	Benign and malignant polyps
Akyurek et al. <sup>11</sup>	1 (< 6)	1 (6–10)	8	—	—	—	—	Incomplete data
Sarkut et al. <sup>18</sup>	0	1	21	—	—	—	—	Incomplete data
Huang et al. <sup>14</sup>	—	Benign	—	—	—	—	10.8 $\pm$ 4.7	Incomplete data
	—	Malignant	—	—	—	—	13.5 $\pm$ 4.2	Incomplete data

SD = standard deviation.

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.<sup>21</sup> Song and colleagues<sup>21</sup> 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<sup>3</sup> 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,<sup>11</sup> 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,<sup>3</sup> 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, choledocholithiasis, biliary colic, atypical right upper quadrant pain, history of choledochal cyst, comorbid primary sclerosing cholangitis or age more than 50 years.<sup>2,22,23</sup>

### 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.<sup>3</sup> 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.

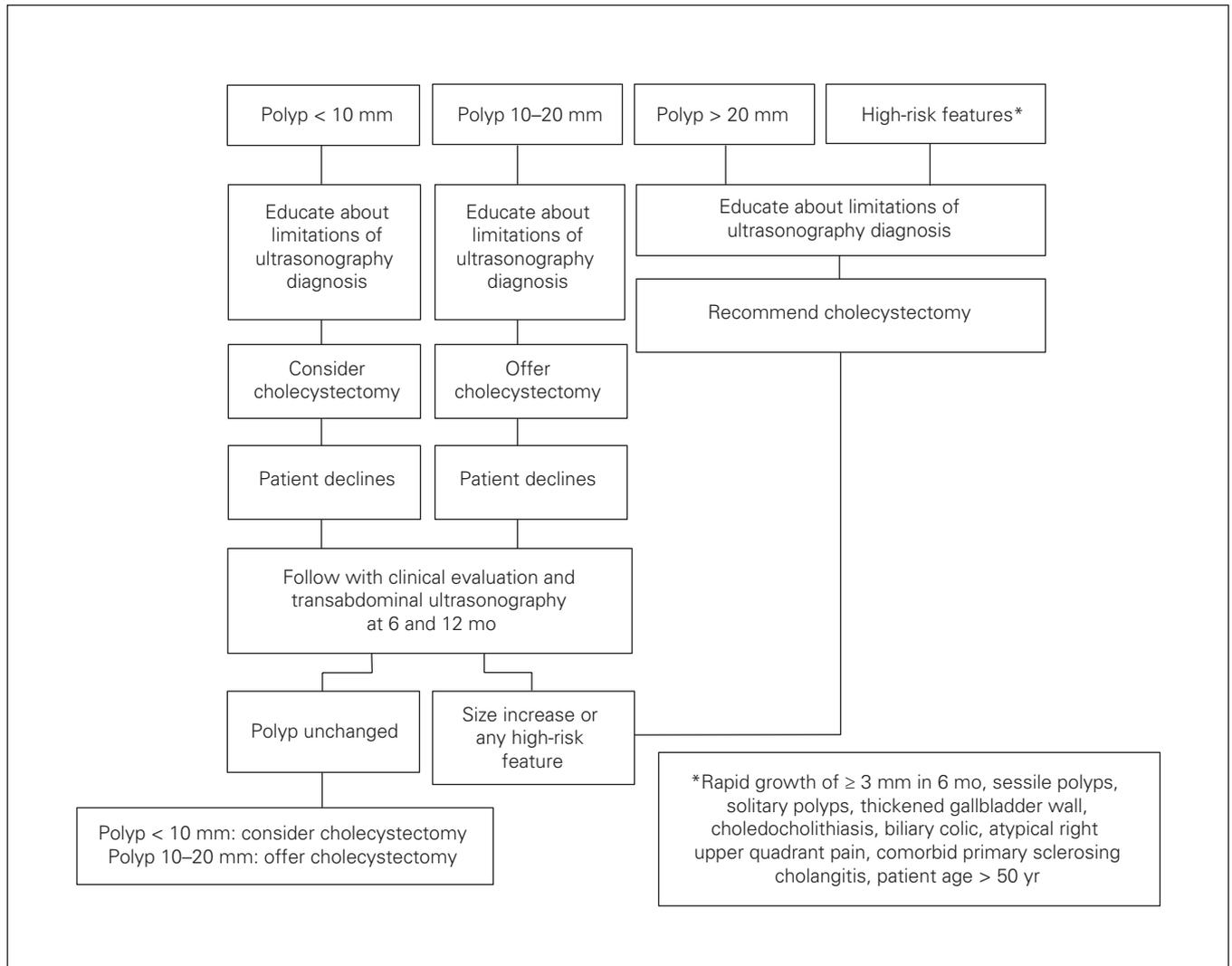


Fig. 4. Suggested management of gallbladder polyps detected on transabdominal ultrasonography.

**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.

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