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GASTROINTESTINAL

Diagnostic accuracy of transabdominal high-resolution US for staging gallbladder cancer and differential diagnosis of neoplastic polyps compared with EUS

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Abstract

Purpose To compare the diagnostic accuracy of transabdominal high-resolution ultrasound (HRUS) for staging gallbladder cancer and differential diagnosis of neoplastic polyps compared with endoscopic ultrasound (EUS) and pathology.

Materials and methods Among 125 patients who underwent both HRUS and EUS, we included 29 pathologically proven cancers (T1 = 7, T2 = 19, T3 = 3) including 15 polypoid cancers and 50 surgically proven polyps (neoplastic = 30, non-neoplastic = 20). We reviewed formal reports and assessed the accuracy of HRUS and EUS for diagnosing cancer as well as the differential diagnosis of neoplastic polyps. Statistical analyses were performed using chi-square tests.

Results The sensitivity, specificity, PPV, and NPV for gallbladder cancer were 82.7 %, 44.4 %, 82.7 %, and 44 % using HRUS and 86.2 %, 22.2 %, 78.1 %, and 33.3 % using EUS. HRUS and EUS correctly diagnosed the stage in 13 and 12 patients. The sensitivity, specificity, PPV, and NPV for neoplastic polyps were 80 %, 80 %, 86 %, and 73 % using HRUS and 73 %, 85 %, 88 %, and 69 % using EUS. Single polyps (8/20 vs. 21/30), larger (1.0 ± 0.28 cm vs. 1.9 ± 0.85 cm) polyps, and older age (52.5 ± 13.2 vs. 66.1 ± 10.3 years) were common in neoplastic polyps ($p < 0.05$).

Conclusion Transabdominal HRUS showed comparable accuracy for diagnosing gallbladder cancer and differentiating neoplastic polyps compared with EUS. HRUS is also easy to use during our routine ultrasound examinations.

Key Points

- *HRUS showed comparable diagnostic accuracy for GB cancer compared with EUS.*
- *HRUS and EUS showed similar diagnostic accuracy for differentiating neoplastic polyps.*
- *Single, larger polyps and older age were common in neoplastic polyps.*
- *HRUS is less invasive compared with EUS.*

Keywords High-resolution ultrasound · Endoscopic ultrasound · Gallbladder cancer · Gallbladder polyp · Diagnosis

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Introduction

Gallbladder (GB) cancer is the most common malignant tumour arising from the biliary tree [1]. It is also recognised that it has a poor prognosis. Early diagnosis and accurate staging of GB cancer are very important to improve the prognosis. Transabdominal ultrasound (US) has been considered the imaging modality of choice for the evaluation of various GB diseases. Although transabdominal US is widely used for GB evaluation, it has limitations regarding the accurate staging of GB cancer and differentiating benign from neoplastic polyps [2, 3]. Endoscopic ultrasound (EUS) has been reported to be more accurate for the evaluation of GB diseases than transabdominal US. As EUS can provide high-resolution images with the use of a high-frequency transducer, it has been reported to be able to accurately differentiate benign polyps from neoplastic polyps as well as providing accurate staging of GB cancer [4–7]. However, EUS has some shortcomings in that it is an invasive procedure, requires premedication, and can cause some complications such as bleeding and bowel perforation [3, 8, 9].

Due to recent advances in ultrasound technology, the image quality of transabdominal US has improved and more gallbladder lesions are being detected. Although technical improvement provides better resolution, a low-frequency transducer has limited image resolution. On the contrary, high-frequency transducers provide better resolution, although they penetrate less deeply. Transabdominal high-resolution ultrasound (HRUS) is a technique that uses both low- and high-frequency transducers during the GB evaluation. According to previously published reports, HRUS is useful for accurate tumour staging of GB cancer and for differentiating GB cancer from adenomyomatosis and xanthogranulomatous cholecystitis. HRUS also provides high-resolution images of gallbladder polyps [3, 9–13]. When managing GB cancer, it is very important to have preoperative differentiation between GB cancer and benign conditions such as adenomyomatosis, non-neoplastic polyp, inflammation, etc. Moreover, if GB cancer is presumed according to the preoperative imaging work-up, the accurate estimation of the T-stage is required for planning the surgical strategy [9].

To the best of our knowledge, there have only been a few studies that compared the diagnostic accuracy of transabdominal HRUS with that of EUS for staging GB cancer or neoplastic GB polyps [3, 9, 12]. Therefore, the objectives of this study are to compare the diagnostic accuracy of transabdominal HRUS for staging gallbladder cancer and the differential diagnosis of neoplastic polyps compared with those of EUS and histology.

Materials and methods

Study population

This retrospective study was approved by our institutional review board, and patient informed consent was waived. Using computerised searches of our pathology and radiology information systems between December 2010 and October 2014, we identified 125 consecutive patients who had undergone HRUS and EUS before cholecystectomy. We excluded patients with chronic cholecystitis with/without stone ($n = 59$), acute cholecystitis ($n = 1$), and metastasis ($n = 1$). Finally, 64 patients, 29 with GB cancer and 50 with a GB polyp, were included in this study. Of these 64 patients, 15 with polypoid-type GB cancer were included in both the GB cancer and polyp groups. Nine patients who had been misdiagnosed as having GB cancer on EUS and HRUS were also included and were pathologically confirmed as having chronic cholecystitis ($n = 7$), xanthogranulomatous cholecystitis ($n = 1$), or tumefactive sludge ($n = 1$). The 29 patients with GB cancer included 14 patients with non-polypoid-type GB cancer and 15 patients with polypoid-type GB cancer. There were 14 males and 15 females with a mean age 66.5 ± 12.0 years (range 44-89 years). All of these patients were histopathologically confirmed to have GB cancer. The 50 patients with GB polyps consisted of those with a non-neoplastic polyp ($n = 20$) and those with a neoplastic polyp ($n = 30$). There were 24 males and 26 females with a mean age 60.7 ± 13.3 years (range 35-83 years). These patients underwent laparoscopic cholecystectomy ($n = 59$), extended cholecystectomy ($n = 13$), or open cholecystectomy ($n = 1$). Figure 1 shows the flowchart of this study population.

HRUS examination

HRUS examination was performed using an ultrasound unit (LOGIQ 9, GE Healthcare, Milwaukee, WI, USA) by one of our three clinically experienced radiologists, each with more than 7 years of clinical experience performing HRUS. All sonography examinations were independently performed. For HRUS examination, the GB was carefully investigated using an intercostal and/or subcostal scan and a convex low-MHz transducer (4C, bandwidth 1.5-4.5 MHz, GE Healthcare, Milwaukee, WI, USA), always with real-time, spatial compound imaging techniques and speckle reduction techniques as well as with and without harmonic imaging. The settings of the low-MHz transducer were as follows: frequency, 4 MHz; dynamic range, 69; gain 27-33 %; frame rate, 30-45/s. Using a linear high-MHz transducer (7 L, bandwidth 2.5-7.0 MHz, GE Healthcare, Milwaukee, WI, USA), the GB evaluation was performed. We also used real-time, spatial compound imaging techniques and speckle reduction techniques to optimise the evaluation of the GB with the linear

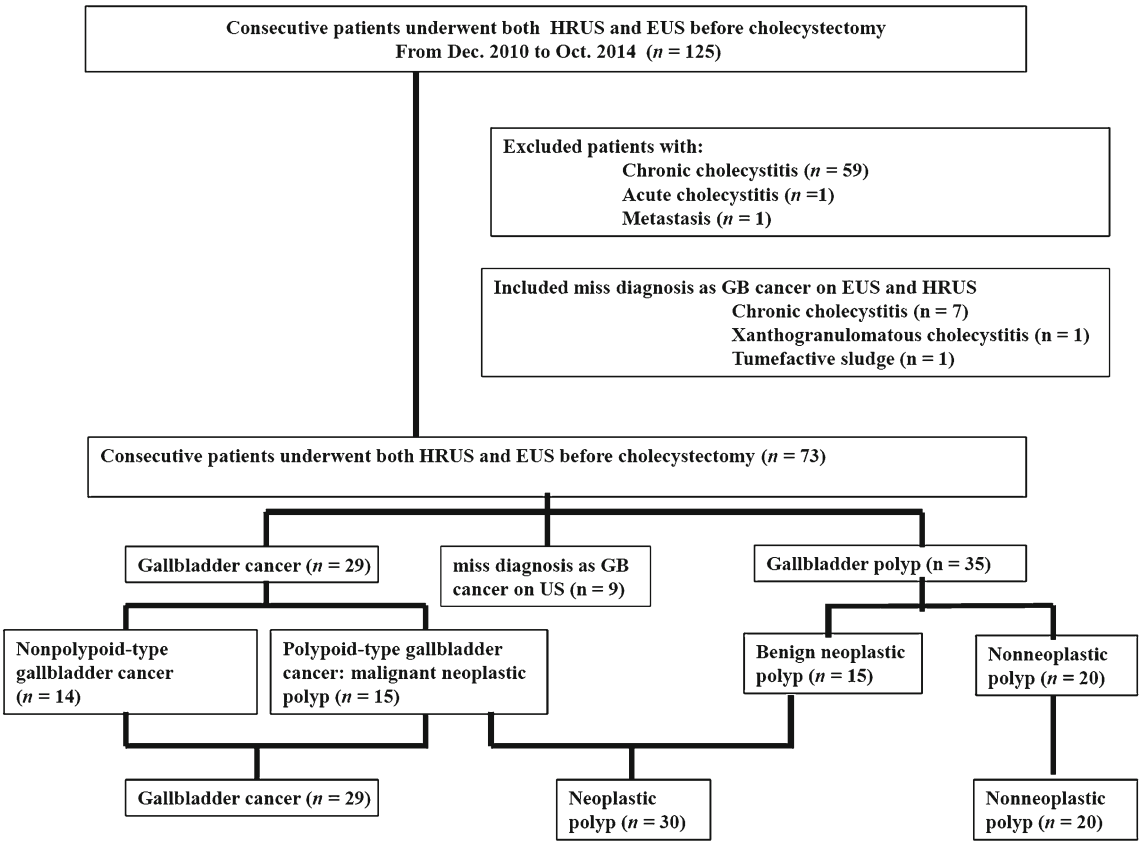

Fig. 1 Flow chart shows process of patient selection. *HRUS* = high resolution ultrasound, *EUS* = endoscopic ultrasound

probe, with or without harmonic imaging because of the issue of penetration and spatial resolution. Settings of the high-MHz transducers were as follows: frequency, 6-7 MHz; dynamic range, 66-72; gain 27-30 %; frame rate, 14/s. We also performed colour Doppler US using the convex and linear transducers.

EUS examination

EUS examination was performed by a clinically experienced gastroenterologist with more than 10 years of EUS experience to evaluate the entire GB using a radial echoendoscope (GF-UE 240, Olympus Co., Tokyo, Japan; SSD-alpha 10 Ultrasound System, Aloka Co., Ltd., Tokyo, Japan) with a 7.5-12-MHz rotating transducer (GF-UM2, -UM3, -UM20, Olympus Co., Tokyo, Japan). Under conscious sedation using 3-5 mg of midazolam, patients underwent EUS with local pharyngeal anaesthesia of a 2 % lidocaine spray and when in the left lateral decubitus position. The endoscope was introduced through the stomach and further down into the duodenal bulb or the second portion of the duodenum. The entire GB was then assessed. The results were recorded according to the structured reporting format at the end of EUS examination.

Image analysis

Two board-certified radiologists (JH Kim and JS Lee) with 7 years and 1 year of clinical experience in HRUS retrospectively analysed the HRUS. HRUS analyses were based on the formal reports focussing on the presence of GB cancer and the stage of the GB cancer. We also analysed the possibility of a neoplastic polyp, the size of the polyp, and the multiplicity (single or multiple) of polyps based on the formal reports. When there was an unclear description on the formal reports, we made the final decision by consensus of two radiologists. All of the images were reviewed on a PACS workstation (M-view, Marotech, Seoul, Korea). Retrospective review of each EUS examination was also done focussing on the presence of GB cancer, the stage of the GB cancer, the possibility of a neoplastic polyp, the size of the polyp, and the multiplicity (single or multiple) of polyps, based on the formal reports, by a certified abdominal radiologist (JS Lee, 5 years of clinical experience). When there was an unclear description on the formal reports, we made the final decision by consensus of two radiologists (JH Kim and JK Han). We analysed the image findings of the largest one if there were multiple polyps. We used the T stage of GB cancer provided by the American Joint Committee on Cancer (AJCC), 7th edition. The US definitions of the T stage are as follows: T1a is a focal wall-thickening or polypoid lesion with intact inner hypoechoic layers; T1b is a focal

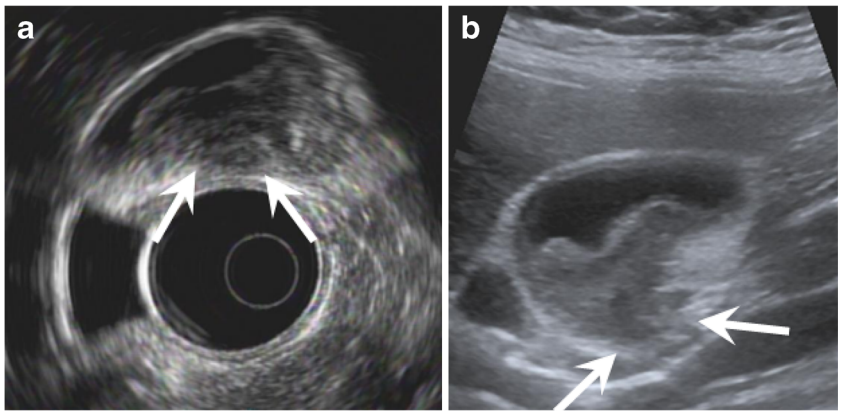

Fig. 2 T2 stage gallbladder cancer in a 48-year-old female. **A**. EUS image demonstrates asymmetrical wall thickening of the gallbladder involving an outer hyperechoic layer (*arrow*). T staging by EUS was T2. **B**. HRUS image shows wall thickening of the gallbladder with irregularity of the outer hyperechoic layer by tumour involvement (*arrows*). HRUS diagnosis was T2 stage

wall-thickening or polypoid lesion with an inner hypoechoic layer; T2 is a focal wall-thickening or polypoid lesion with an outer hyperechoic layer of the gallbladder wall; T3 is a group in which a mass or tumour disrupts the outer hyperechoic layer of the GB wall and/or extends to the liver [3, 6].

Statistical analysis

The imaging diagnoses of GB cancer and assessment of the T stage using both modalities were compared with the histopathologic findings. For diagnosis of GB cancer and neoplastic GB polyps, the sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV) of the EUS and HRUS were estimated. The degree of the T stage accuracy of EUS and HRUS compared with those of the pathologic diagnosis was considered using weighted κ statistics and was interpreted as follows: poor, less than 0.20; fair, 0.20–0.39; moderate, 0.40-0.59; good, 0.60-0.79; excellent, 0.80 or greater. Comparison of the diagnostic accuracy of the T stage was assessed using the chi-square and McNemar tests. The chi-square test was used to assess the association of each sonography finding and the histopathologic diagnosis of neoplastic or non-neoplastic polyps. All statistical analyses were performed using commercially available statistical software (SPSS, version 14.0, and MedCalc, version 6.15). A *P* value of less than 0.05 was considered to indicate a statistically significant difference.

Results

Among the 29 patients with GB cancer, 2 had carcinoma in situ (stage 0), 5 had T1 stage, 19 had T2 stage, and 3 had T3 stage. The tumours were located at the fundus ($n = 11$), body ($n = 11$), neck ($n = 4$), and in the entire gallbladder ($n = 3$). In all of the patients with a non-neoplastic polyp ($n = 20$), they were confirmed as cholesterol polyps. In the 30 patients with neoplastic polyps, these included the polypoid type of GB cancer ($n = 15$), tubular adenoma ($n = 10$), tubulopapillary adenoma ($n = 4$), and intracystic papillary ($n = 1$). The polyps were located at the fundus ($n = 15$), body ($n = 31$), and neck ($n = 4$).

The diagnostic accuracy and positive predictive value for GB cancer were 71 % and 78.1 % with EUS and 73.6 % and 82.7 % with HRUS. HRUS showed a slightly higher diagnostic accuracy and positive predictive value than EUS, although without a significant difference (Fig. 2). Table 1 summarises the diagnostic accuracy of HRUS and EUS for detecting GB cancer. Regarding the staging accuracy, compared with the histopathologic results, EUS and HRUS correctly estimated 41.4 % ($n = 12/29$) and 44.8 % ($n = 13/29$) of the cases with GB cancer, although with poor agreement ($k = 0.11$ on EUS and 0.106 on HRUS, respectively). The overstaging rate of EUS and HRUS were the same at 17 % (5/29) and the downstaging rates were 41.4 % (12/29) on EUS and 37.9 % (11/29) on HRUS, respectively. Overstaging of Tis to T1 or T2 was noted in two cases for both modalities and downstaging of T2 to T1 was common with EUS ($n = 7$) (Fig. 3) and HRUS ($n = 5$). Table 2 summarises the staging accuracy of EUS and HRUS compared with the pathologic diagnosis.

The diagnostic accuracy for neoplastic polyps was 78 % on EUS and 80 % on HRUS. The sensitivity, specificity, positive predictive value, and negative predictive value for neoplastic polyps were 80 %, 80 %, 86 %, and 73 % on HRUS and 73 %, 85 %, 88 %, and 69 % on EUS. HRUS showed a higher sensitivity, diagnostic accuracy, and negative predictive value than EUS, and EUS showed a higher specificity and positive

Table 1 Sensitivity, specificity, accuracy, positive predictive value, and negative predictive value of EUS and HRUS for the diagnosis of gallbladder cancer

	Sensitivity	Specificity	Accuracy	Positive predictive value	Negative predictive value
EUS	86.2 %	22.2 %	71 %	78.1 %	33.3 %
HRUS	82.7 %	44.4 %	73.6 %	82.7 %	44 %

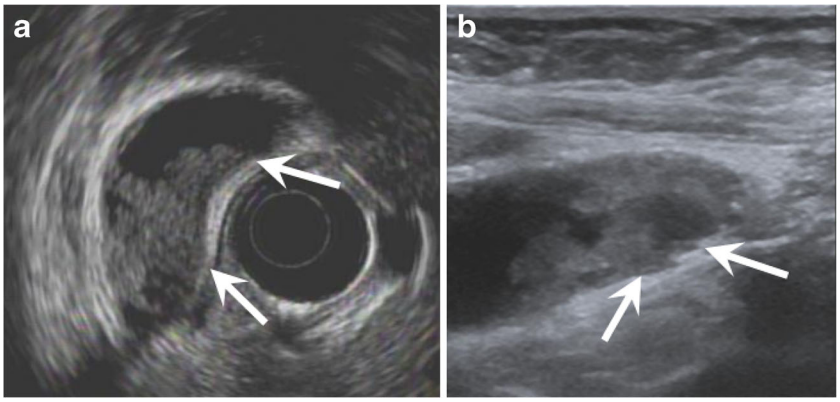

Fig. 3 T2 stage polypoid gallbladder cancer in a 44-year-old female. **A**. EUS image shows a broad-based polypoid mass in the fundus and body of the gallbladder with a preserving outer hyperechoic layer (*arrow*). T-staging by EUS was T1 stage. **B**. HRUS image demonstrates a polypoid mass of the gallbladder with irregularity of the outer hyperechoic layer (*arrows*). HRUS diagnosis was T2 stage. It was pathologically proven as T2 stage gallbladder cancer

predictive value than HRUS. Table 3 summarises the diagnostic accuracy of EUS and HRUS for neoplastic GB polyps. Single (8/20 vs. 21/30, $p = 0.035$) and larger (1.0 ± 0.28 cm vs. 1.9 ± 0.85 cm, $p = 0.000$) polyps were more common in neoplastic polyps than in non-neoplastic polyps (Fig. 4). The neoplastic polyp patient group was significantly older than the non-neoplastic patient group (52.5 + 13.2 vs. 66.1 + 10.3, $p =$ 0.000). However, there was no difference between sexes ($p =$ 0.419). Table 4 summarises each of the parameters for neoplastic and non-neoplastic polyps.

Discussion

According to our study, the diagnostic accuracy and positive predictive value for GB cancer was 71 % and 78.1 % in EUS and 73.6 % and 82.7 % in HRUS. HRUS showed a slightly higher diagnostic accuracy and positive predictive value than EUS. In addition, the diagnostic accuracy for neoplastic polyps was 78 % on EUS and 80 % on HRUS. Transabdominal HRUS showed comparable accuracy for the diagnosis of gallbladder cancer and for differentiating neoplastic polyps compared with EUS. HRUS is also easy to use following our routine ultrasound examination. Single (8/20 vs. 21/30, $p = 0.035$) and larger (1.0 ± 0.28 cm vs. 1.9 ± 0.85 cm, $p = 0.000$) polyps were more common in neoplastic polyps than in non-neoplastic polyps. The neoplastic polyp patient group was significantly older than the non-neoplastic patient group (52.5 + 13.2 vs. 66.1 + 10.3, $p = 0.0000$).

EUS is considered superior to conventional US for GB imaging as its high frequency (7.5-12 MHz) can provide high-resolution images of small lesions [3, 14]. Sugiyama et al. evaluated the usefulness of EUS for differentiating GB polypoid lesions compared with that of transabdominal US. Their study reported that EUS and transabdominal US correctly differentiated polypoid lesions in 97 % (63/65) and 71 % (46/65) of the cases with GB polypoid lesions, respectively [14]. However, as EUS is based on endoscopy, it can also cause some inconvenience related to the endoscopic procedure, such as gag reflux, the risk of bowel perforation, and requiring a relatively long time [3, 8, 9]. In addition, the outcome of EUS heavily depends on the endoscopist's skill. Recently, advances in US techniques, especially related to compounding imaging, harmonics, and speckle reduction imaging, have led to improved US resolution [10, 11, 15, 16]. As HRUS uses alternatively low- and high-frequency transducers, it can also provide high-resolution images in more patient-comfortable situations than EUS. According to previously published studies, HRUS delineates the layers of the GB wall in a manner similar to EUS. Also, the usefulness of HRUS in the accurate T staging of GB cancer [3, 9, 12], differentiating neoplastic

Table 2 T stage accuracy of EUS and HRUS compared with pathologic diagnosis

		Pathologic T stage				
	T-stage	0	1	2	3	Total
EUS	0	**0**	1	1	0	2
	1	2	**4**	7	0	13
	2	0	0	**8**	3	11
	3	0	0	3	**0**	3
	Total	2	5	19	3	29
HRUS	0	**0**	1	3	1	5
	1	1	**2**	5	0	8
	2	1	2	**10**	1	14
	3	0	0	1	**1**	2
	Total	2	5	19	3	29

Note: Data along a diagonal line that would reflect perfect accuracy are in bold

Table 3 Sensitivity, specificity, accuracy, positive predictive value, and negative predictive value of EUS and HRUS for the diagnosis of neoplastic gallbladder polyps

	Sensitivity	Specificity	Accuracy	Positive predictive value	Negative predictive value
EUS	73 %	85 %	78 %	88 %	69 %
HRUS	80 %	80 %	80 %	86 %	73 %

polyps from adenomyomatosis [10, 11] and xanthogranulomatous [13] ones, and distinguishing neoplastic from non-neoplastic polyps [3, 9] has been proven.

In our previous study evaluating the differential diagnostic and staging accuracies of CT, EUS, and HRUS for GB polypoid lesions, Jang et al. found that HRUS showed better diagnostic accuracy for evaluating GB cancer than EUS or CT. The sensitivity, specificity, PPV, and NPV were as follows: sensitivity, 89.6 %, 86.2 %, 72.4 %; specificity, 86.9 %, 86.9 %, 91.3 %; PPV, 63.4 %, 62.5 %, 67.7 %; NPV, 97.1 %, 96.1 %, 92.9 % (the values of HRUS, EUS, and CT, respectively). In our study, the diagnostic accuracy of HRUS for evaluating GB cancer was comparable with that of EUS. The sensitivity was similar (82.7 % vs. 86.2 %), although the specificity, PPV, and NPV of HRUS (44.4 %, 82.7 %, and 44 %, respectively) were higher than those of EUS (22.2 %, 78.1 %, and 33.3 %, respectively). These results were in agreement with those of a previous study performed at our hospital [9]. However, regarding the stage accuracy, compared with the histopathologic results, EUS and HRUS correctly estimated 41.4 % ($n = 12/29$) and 44.8 % ($n = 13/29$), respectively, with poor agreement (k value = 0.11 in EUS and 0.106 in HRUS). Both EUS and HRUS showed limitations regarding the correct diagnosis of the T stage. Jang et al. reported that the accuracy of HRUS for predicting the depth of invasion of GB cancer was higher than that of EUS or CT (62.9 %, 55.5 %, and 44.4 % respectively) [9]. Therefore, our results supported Jang et al.'s study demonstrating that when used for GB cancer imaging HRUS is comparable to EUS.

Distinguishing neoplastic from non-neoplastic GB polyps would be important in the practical clinical management of GB lesions. In previously published reports, findings of polyps larger than 1 cm in size, a single polyp, a lobulated margin, a vascular core seen on colour Doppler, and internal hypoechoic foci were found significantly more frequently in neoplastic than in non-neoplastic polyps [3, 17, 18]. Risk factors for neoplastic polyps were as follows: size (larger than 1 cm), older patients, a single lesion, combined with a GB stone, and a symptomatic lesion. Among these factors, the size is used as the most common predictor of potential cancer in older patients [3, 14, 17–20]. Even when considering these findings, there are still limitations for differentiating neoplastic from non-neoplastic polyps. In our study, the sensitivity and specificity of HRUS for differentiating neoplastic from non-neoplastic polyps were each 80 %, while those of EUS were 73 % and 85 %, respectively. The size, multiplicity, and patient age showed significant differences in neoplastic and non-neoplastic polyps ($p < 0.05$), although a patient's sex demonstrated no significant difference. These results were similar to those of our previous study, i.e. with the sensitivity and specificity of HRUS being 66.67 % and 89.13 %, respectively) [3].

Our current study has several limitations. First, as it was conducted retrospectively, there is the possibility of a selection bias, and as we included only surgically proven cases, our enrolled patients could not represent the entire spectrum of GB cancer and polyps. Second, ultrasound is an operator-dependent imaging modality. To obtain adequate images using HRUS, the operator must have sufficient clinical experience. In addition, a poor sonic window is one of the shortcomings of the modality, and it is influenced by patient factors such as obesity and respiratory cooperation.

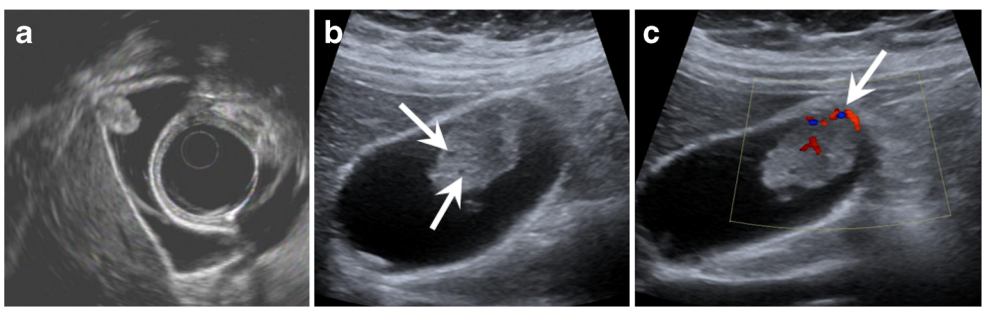

Fig. 4 Low-grade tubular adenoma of the gallbladder in a 68-year-old female. **A**. EUS image shows a 1.4-cm-sized and iso- to hypoechoic polypoid lesion in the gallbladder fundus without internal hypoechoic foci. EUS image suggests a neoplastic polyp of the gallbladder. **B**. HRUS image demonstrates an iso- to hypoechoic polypoid lesion with internal hypoechoic foci (*arrows*). **C**. Colour Doppler HRUS image shows feeding vessels at the base of the polyp (*arrow*). HRUS images suggest a neoplastic polyp of the gallbladder

Table 4 Comparison of parameters for neoplastic and non-neoplastic polyps of gallbladder

		Non-neoplastic polyp	Neoplastic polyp	*p*
Sex	M	11	13	0.419
	F	9	17	
Age		52.5 + 13.2	66.1 + 10.3	0.000
Multiplicity	Single	8	21	0.035
	Multiple	12	9	
Size (cm)		1.0 + 0.28	1.9 + 0.85	0.000

In conclusion, transabdominal HRUS showed a considerable degree of diagnostic accuracy for evaluating GB cancer and neoplastic polyps, which was comparable to that of EUS. Moreover, considering the convenience for the patient and operator, HRUS is competitive for GB imaging. Therefore, we believe that HRUS will assume a major role regarding the differential diagnosis of GB cancer and polyps.

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Among 88 patients who were enrolled in our study, thirty-one patients have been previously reported in our previous paper published in *AJR* 2015; 204:W150–W159. However, the study purposes of these two studies were different. The previously published paper evaluated the accuracy of high-resolution sonography with combined low- and high-MHz transducers with that of conventional sonography for gallbladder cancer and polyps. However, the current study compares the diagnostic performance of transabdominal high-resolution ultrasound with endoscopic ultrasound.

Methodology: Retrospective, diagnostic study, performed at one institution.

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