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Diagnostic performance of combined use of automated breast volume scanning & hand-held ultrasound for breast lesions

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***Background & objectives*: Breast cancer being one of the most common malignant tumours among women, diagnostic modalities for early detection of the same become of paramount importance. In this context, the hand-held ultrasound (HHUS) and automated breast volume scanner (ABVS) could provide valuable information for clinicians to diagnose breast diseases. This study aimed to compare and evaluate the diagnostic performance of combined use of HHUS and ABVS for the differentiation of benign and malignant breast lesions.**

***Methods*: A total of 361 female patients, who underwent both HHUS and ABVS examinations were included in this study. ABVS and HHUS images were interpreted using the American College of Radiology Breast Imaging-Reporting and Data System (BI-RADS). The distributions of the BI-RADS categories and pathology results were shown as specific numbers. Kappa coefficients test (κ) was calculated to compare the diagnostic results amongst the ABVS, HHUS and ABVS combined with HHUS. The sensitivity, specificity, accuracy, positive predictive value (PPV) and negative predictive value (NPV) of the three diagnostic methods were calculated and their respective diagnostic performance was analyzed by receiver operator characteristic curve.**

***Results*: Of a total of 431 lesions, 153 (35.5%) were malignant and 278 (64.5%) were benign. With respect to the pathology results, the value of κ was 0.713 (*P*<0.001) for HHUS, κ=0.765 (*P*<0.001) for ABVS and κ=0.815 (*P*<0.001) for HHUS+ABVS. The sensitivity, specificity, accuracy, PPV and NPV for HHUS combined with ABVS were 96.08 (147/153), 88.49 (246/278), 91.18 (393/431), 82.12 (147/179) and 97.62 per cent (246/252) respectively. For HHUS, these were 90.20 (138/153), 84.17 (234/278), 86.31 (372/431), 75.82 (138/182) and 93.98 per cent (234/249) respectively; and for ABVS these were 92.16 (141/153), 87.05 (242/278), 88.86 (383/431), 79.66 (141/177) and 95.28 per cent (242/254), respectively. There was no significant difference amongst these three methods, but the diagnostic performance of HHUS combined with ABVS was better than, or at least equal to, that of HHUS or ABVS alone.**

***Interpretation & conclusions*: The results of this study suggest that ABVS is a promising and advantageous modality for breast cancer detection. Furthermore, the combination of HHUS and ABVS showed a more comparable diagnostic performance than HHUS or ABVS alone for distinguishing between benign and malignant breast lesions.**

Key words Automated breast volume scanner - breast cancer - breast imaging-reporting and data system - hand-held ultrasound - ultrasound

Breast cancer is the most common malignancy among women worldwide[1,2]. The incidence and mortality of female breast cancer in 2018 were 46.3/10^5 and 13.0/10^5, respectively[3,4]. At present, however breast cancer still lacks effective aetiological prevention measures. Detection and diagnosis of early-stage tumours through innovation of diagnostic technologies may provide reliable and timely information for clinical treatment. For example, evidence suggests that mammography-based screening can decrease mortality during the early stages in Western countries[5]. However, its performance declines in young women and those women with dense breasts (≥50% dense tissue) because of its low sensitivity[6].

Breast ultrasound (US) is often used as a supplement to mammography because it is widely available, relatively inexpensive and well-tolerated by patients[7]. The advantages of US make it the most commonly used method for breast lesion examination in women with small or dense breasts[8]. Nevertheless, hand-held US (HHUS) has major limitations in that it requires time and skill for the detection of non-palpable tumours, lack of standardization due to variability in operator experience and lack of image reproducibility[9-11].

With the continuous development of modern US technology, the emergence of three-dimensional (3D) US to some extent compensates for the shortcomings of traditional HHUS. In recent years, the automated breast volume scanning (ABVS) system is a new and promising technology for clinical diagnosis of breast diseases[12]. The ABVS system uses a computer to reconstruct a series of 2D image information to form a 3D image. In addition to displaying the conventional sagittal and transverse sections, it can also display a coronal plane parallel to the skin and measure the volume of the breast mass. ABVS provides more valuable information for clinicians to diagnose breast diseases. Several studies[13,14] have shown that the diagnostic efficacy of ABVS is better than HHUS, but the similar diagnostic performance of these are also demonstrated[15]. Hence, further studies are required in order to explore the diagnostic value of different US methods in the clinical setting. In the present study, we evaluated and compared the diagnostic efficacy of HHUS and ABVS for the differentiation of benign and malignant breast lesions based on Breast Imaging-Reporting and Data System (BI-RADS) features.

Material & Methods

Patient selection: This study was approved by the Institutional Review Board of the First Hospital Affiliated to Dalian Medical University, PR China and informed consent was obtained from all participants. A total of 361 female patients were prospectively enrolled in this study between October 2017 to September 2018. The considered data included information on a total of 431 breast lesions from 361 patients (median age: 46 yr; range: 16-82 yr)

Inclusion criteria: 361 patients received both HHUS and automated breast volume scanner (ABVS) examination, and all cases were confirmed by fine-needle aspiration biopsy or surgical pathology.

Exclusion criteria: Women with large breast bumps or bumps protruding from the skin surface; those with obvious ulcers, purulent and other infections on the breast surface; women with breast implants; those who have been diagnosed with malignant tumours and prior received treatment and pregnant or breastfeeding women were excluded from the study.

Hand-held ultrasound (HHUS) and automated breast volume scanner (ABVS) based examination: The HHUS examination was performed on an S2000 US system with the integrated Siemens 14 L5 linear transducer (5-14 MHz; Siemens Medical Solutions, CA, USA). The patient was placed in the supine position with both arms elevated above the head, fully exposing the bilateral breasts and underarms. The US 14 L5 probe was used to scan the all breast quadrants by multiple tangential, multiple angles and radial views centred on the nipple. After the lesion was found, its size, shape, border, edge, orientation, internal and posterior echo, calcification, axillary lymph node and other manifestations were observed. At the same time, if a suspicious lesion was detected during the US examination (without elastography), the colour Doppler flow imaging was applied to observe the distribution of blood flow signals and measure the arterial blood flow velocity and resistive index. All information was recorded in detail and necessary HHUS images were saved to the computers.

The ABVS examination was performed using the ACUSON S2000 automated breast volume scanner (ABVS) with an integrated Siemens 14 L5BV linear transducer (5-14 MHz; Siemens Medical Solutions, CA, USA). For the ABVS examination, the patient was placed in the same positions as the HHUS. The system adjusts the scanning parameters (gain, depth, frequency, *etc*.) on the basis of the patient's breast size in order to obtain the best images. Since ABVS is performed by a technician, pressure applied is just enough to get the probe closer to skin. The patient's bilateral breasts were sequentially scanned in three directions (lateral, anteroposterior and medial position). In women with larger breasts, four or five acquisitions of each breast were at times needed. Each view acquired up to about 300 2D images and reconstructed the breast in the coronal plane, from the skin to the chest wall and each part was scanned for approximately 60 sec, and the distance between each layer of the image was 0.05 cm. The obtained image series were sent to a dedicated workstation and combined to form a 3D US image that could be examined in multiplanar reconstructions. The readers used the positioning, measurement, amplification and other adjustment functions of the system workstation to observe and analyze the 3D images. The location, size, shape, direction, edge, boundary, echo type, posterior echo characteristics and calcification of the lesions were described and recorded.

Imaging assessments: Imaging assessments were performed according to the revised BI-RADS grading standard of the American Institute of Radiology in 2013[16]. The BI-RADS assessment results for HHUS, ABVS and joint were classified into following categories: 0=incomplete, 1=normal, 2=benign, 3=probably benign (<3%), 4=suspicious and 5=highly suggestive of malignancy (91-100%). The category 4 lesions were further classified into 4a=low suspicious (2-10%); 4b=moderate suspicious (10-50%) and 4c=highly suspicious (50-90%). Since the breast lesions of BI-RADS category 4a generally have a low risk of malignancy (2-10%) and its pathological results are usually not expected to be malignant, hence BI-RADS category 4b was used as the criteria to differentiate between benign and malignant breast lesions. The highest BI-RADS results in HHUS and ABVS was as a result of a joint application. All the HHUS images were interpreted by an experienced US examiner during the scan and all the ABVS images were independently interpreted by two qualified sonographers based on the BI-RADS lexicon published in 2013[16]. Both US examiners had more than five years of experience each in ABVS image interpretation so, the final assessment of ABVS images was decided only after both the sonographers' concurred with each other's diagnosis.

Statistical analysis: All cases were confirmed by histopathology. The distributions of the BI-RADS categories and pathology results are shown as specific numbers. Kappa coefficient test (κ) was calculated to compare the diagnostic results obtained between the ABVS, HHUS and ABVS combined with HHUS. The values of $\kappa<0$ indicated no agreement, κ: 0-0.20 slight, κ: 0.21-0.40 fair, κ: 0.41-0.60 moderate, κ: 0.61-0.80 substantial and κ: 0.81-1.00 almost in complete agreement. The sensitivity, specificity, accuracy, positive predictive value (PPV) and negative predictive value (NPV) of the three diagnostic methods were represented by specific numbers and the comparison of those between the three methods was tested by Chi-square test. Receiver operator characteristic (ROC) curve showed the diagnostic performance of ABVS and HHUS. The sensitivity, specificity and area under the curves are presented along with 95 per cent confidence intervals (CIs). SPSS software (Version 19.0; SPSS Inc., Chicago, IL, USA) was used to perform all statistical analyses. Statistical significance was assessed by two-tailed tests with an α level of 0.05. $P<0.01$ was considered a significant difference.

Results

Pathological diagnosis: Tables I and II show the joint distribution of pathology and diagnostic imaging results with BI-RADS categories. All the lesions were biopsied after procuring a formal written informed consent form each of the participating patients. A total of 431 lesions were found in 361 patients, pathological findings determined that 153 (35.5%) malignant lesions consisted 126 (82.4%) invasive breast carcinoma of no specific type, 11 (7.2%) invasive lobular carcinoma, 9 (5.9%) papillary carcinoma, 4 (2.6%) mucinous carcinoma and 3 (2.0%) Paget's disease and 278 (64.5%) benign lesions were 106 (38.1%) fibroadenomas, 54 (19.4%) breast hyperplasia, 45 (16.2%) adenosis, 37 (13.3%) intraductal papilloma, 16 (5.8%) granulomatous mastitis, 7 (2.5%) phyllodes tumour, 6 (2.2%) galactocele and 7 (2.5%) other benign lesions.

Fifteen benign lesions were diagnosed by HHUS (BI-RADS category 3: 2 lesions; 4a: 13 lesions; 12 benign lesions (BI-RADS category 3: 0 lesions; 4a: 12 lesions) were diagnosed using ABVS; and in case of HHUS combined with ABVS 6 benign lesions (BI-RADS category 3: 0 lesions; 4a: 6 lesions) were found (Table I). There were 44 malignant lesions diagnosed by HHUS (BI-RADS category 4b: 39 lesions; 4c: 5 lesions; 5: 0 lesions), for ABVS were 36 malignant lesions (BI-RADS category 4b: 32 lesions;

Table I. Pathological results of malignant lesions with Breast Imaging-Reporting and Data System

Pathological type (malignant)	HHUS (n)					ABVS (n)					HHUS + ABVS (n)					Lesions, n (%)
	3	4a	4b	4c	5	3	4a	4b	4c	5	3	4a	4b	4c	5	
Invasive breast carcinoma of no specific type	2	8	29	44	43	0	8	26	35	57	0	5	24	39	58	126 (82.4)
Invasive lobular carcinoma	0	1	2	3	5	0	2	1	3	5	0	1	1	3	6	11 (7.2)
Papillary carcinoma	0	2	6	1	0	0	2	4	3	0	0	0	7	2	0	9 (5.9)
Mucinous carcinoma	0	1	2	1	0	0	0	2	2	0	0	0	2	2	0	4 (2.6)
Paget's disease	0	1	2	0	0	0	0	3	0	0	0	0	3	0	0	3 (2.0)
Total	2	13	41	49	48	0	12	36	43	62	0	6	37	46	64	153 (100.0)

HHUS, hand-held ultrasound; ABVS, automated breast volume scanner

Table II. Pathological results of benign lesions with Breast Imaging-Reporting and Data System (BI-RADS)

Pathological type (benign)	HHUS (n)					ABVS (n)					HHUS + ABVS (n)					Lesions, n (%)
	3	4a	4b	4c	5	3	4a	4b	4c	5	3	4a	4b	4c	5	
Fibroadenoma	62	38	6	0	0	63	39	4	0	0	74	28	4	0	0	106 (38.1)
Breast hyperplasia	13	34	7	0	0	15	33	6	0	0	23	26	5	0	0	54 (19.4)
Adenosis	11	28	5	1	0	13	26	5	1	0	22	20	3	0	0	45 (16.2)
Intraductal papilloma	3	23	10	1	0	2	27	8	0	0	6	22	8	1	0	37 (13.3)
Granulomatous mastitis	1	10	2	3	0	1	10	2	3	0	1	12	2	1	0	16 (5.8)
Phyllodes tumour	0	3	4	0	0	0	4	3	0	0	3	1	3	0	0	7 (2.5)
Galactocele	1	2	3	0	0	1	2	3	0	0	1	2	3	0	0	6 (2.2)
Other	0	5	2	0	0	0	6	1	0	0	0	5	2	0	0	7 (2.5)
Total	91	143	39	5	0	95	147	32	4	0	130	116	30	2	0	278 (100.0)

Table III. Results of Kappa statistics of HHUS, ABVS and HHUS+ABVS with pathological findings

Results	Pathology			Kappa
	Malignant	Benign	Total	
HHUS				
+	138	44	182	0.713***
−	15	234	249	
ABVS				
+	141	36	177	0.765***
−	12	242	254	
HHUS + ABVS				
+	147	32	179	0.815***
−	6	246	252	
Total	153	278	431	

***P<0.001. '+', positive; BI-RADS category 4b; 4c or 5; '–', negative; BI-RADS category 3 or 4a

4c: 4 lesions; 5: 0 lesions) and, for HHUS combined with ABVS there were 32 malignant lesions (BI-RADS category 4b: 30 lesions; 4c: 2 lesions; 5: 0 lesions); Table II. The reduced BI-RADS category 4b, 4c and 5 lesions were pathologically confirmed to be benign.

Consistency test: The kappa statistics between HHUS, ABVS and combined HHUS with ABVS along with the pathological findings are depicted in Table III. The kappa value between the HHUS and pathological findings was 0.713 (P<0.001), between the ABVS and pathological findings, it was 0.765 (P<0.001) and for HHUS+ABVS was 0.815 (P<0.001). The results of all the three groups were in agreement.

Diagnosis performance: When BI-RADS category was compared with the pathological results, there were 234 benign and 138 malignant lesions, while 59 lesions were misdiagnosed in the HHUS results. In case of the ABVS results, 242 benign and 141 malignant lesions were correctly diagnosed, while 48 lesions were misdiagnosed. In case of HHUS and ABVS combined, only 38 benign lesions were misdiagnosed and 246 benign and 147 malignant

Table IV. Diagnostic performance of automated breast volume scanner, hand-held ultrasound and hand-held ultrasound + automated breast volume scanner

Rate (%)	HHUS	ABVS	HHUS + ABVS	χ^2	*P*
SE	90.20 (138/153)	92.16 (141/153)	96.08 (147/153)	4.114	0.128
SP	84.17 (234/278)	87.05 (242/278)	88.49 (246/278)	2.310	0.315
AC	86.31 (372/431)	88.86 (383/431)	91.18 (393/431)	5.142	0.076
PPV	75.82 (138/182)	79.66 (141/177)	82.12 (147/179)	2.209	0.331
NPV	93.98 (234/249)	95.28 (242/254)	97.62 (246/252)	4.091	0.129

SE, sensitivity; SP, specificity; AC, accuracy; PPV, positive predictive value; NPV, negative predictive value

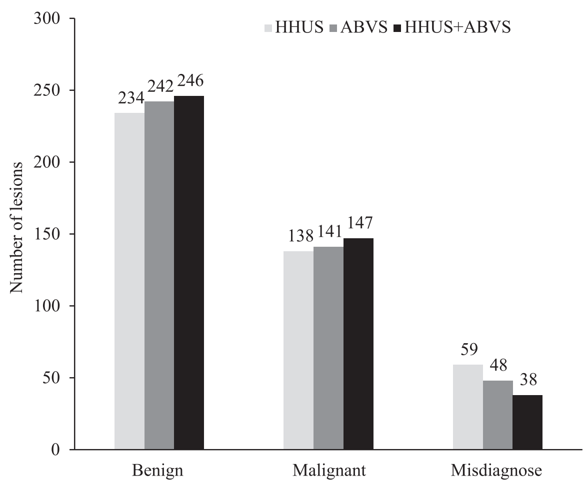

Fig. 1. The number of lesions correctly diagnosed and misdiagnosed by ABVS (Automated Breast Volume Scanner), HHUS (Hand-Held Ultrasound) and HHUS+ABVS.

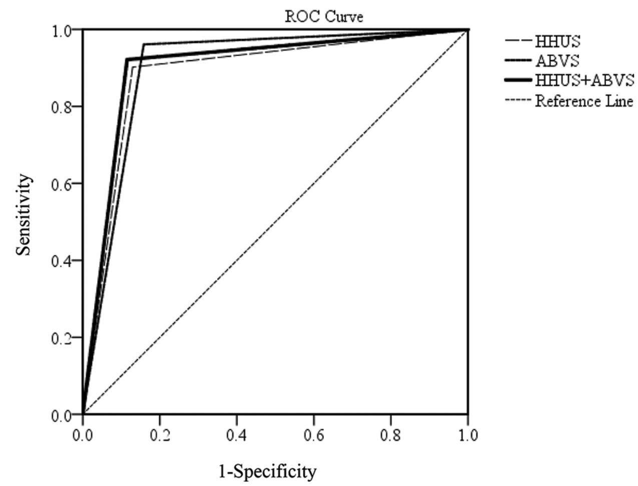

Fig. 2. AUC (Area under the curve) values: HHUS, ABVS and HHUS+ABVS were 0.886 (95% CI: 0.851-0.922), 0.901 (95% CI: 0.870-0.933) and 0.903 (95% CI: 0.870-0.936), respectively.

lesions were correctly diagnosed (Fig. 1). In Table IV, the sensitivity, specificity, accuracy, PPV and NPV of HHUS, ABVS and HHUS combined with ABVS were calculated. Although the diagnostic performance index amongst these three methods were similar, the sensitivity, specificity, accuracy, PPV and NPV for HHUS combined with ABVS were 96.08 per cent, 88.49 per cent, 91.18 per cent, 82.12 per cent and 97.62 per cent, for HHUS were 90.20 per cent, 84.17 per cent, 86.31 per cent, 75.82 per cent and 93.98 per cent and for ABVS were 92.16 per cent, 87.05 per cent, 88.86 per cent, 79.66 per cent and 95.28 per cent, respectively, suggesting that the diagnostic performance of HHUS combined with ABVS was better than, or at least equal to, that of HHUS or ABVS alone (Table IV). To establish diagnostic performance, ROC curves are illustrated in Fig. 2. The AUC values of using HHUS, ABVS and HHUS combined with ABVS were 0.886 (95% CI: 0.851-0.922), 0.901 (95% CI: 0.870-0.933) and 0.903 (95% CI: 0.870-0.936), respectively.

Discussion

Breast ultrasound imaging is usually the first diagnostic method for women younger than 35 yr and as a supplementary diagnosis of mammography in the diagnosis for women older than 35 yr[17]. HHUS is operator dependent and has poor repeatability, as usually only abnormalities noted are recorded and reported during scanning. If an abnormality is missed during the scanning, the rate of missed diagnosis will be increased. With the development of new US examination technology, the ABVS system has come to be used widely as a new breast cancer diagnosis technology[12]. It takes approximately 10-15 min for each patient from technician acquisition to reader interpretation[14]. The ABVS documents the entire breast images and can display them in three dimensions, and the breast lesions can be observed from all directions. This mode avoids the disadvantages of unskilled manual scanning and inexperience, and limits the possibility of missing lesions[18]. The high-frequency probe (14 MHz) provides doctors with images of sufficient quality and resolution. ABVS guarantees high safety for patients because there is no ionizing radiation and no injection of contrast agent. Compared with HHUS, the ABVS image shows the location, size, structure, morphology and spatial structure of the tissue and blood vessels more clearly and accurately, and it provides more informative information for clinicians' diagnosis and surgical planning[19]. In addition, the 'retraction phenomenon' of the coronal plane of ABVS has a high specificity, which greatly improves the diagnostic accuracy. Retraction phenomenon (Fig. 3), also known as the 'sun' sign, is produced by infiltration and erosion of the surrounding normal breast parenchyma by rapidly growing malignant lesions[11]. Recently, researchers have been paying considerable attention to the ABVS because of its good performance in detecting breast cancer in women with high-density breasts and because it is less operator dependent and provides better consistency as compared to HHUS[15].

The present study reports HHUS, ABVS and combined use of HHUS and ABVS for the evaluation of benign and malignant lesions of the breast. The results showed that the combination of HHUS and ABVS showed a better diagnostic performance in the BI-RADS grading diagnosis of breast lesions than the HHUS and ABVS alone. In addition, agreement rate is a parameter that is usually considered as performance indicator for a new experimental diagnostic method from a methodological point of view[15]. According to our results, the values of Kappa among HHUS, ABVS and HHUS combined with ABVS with pathological results were either substantial or ideal (HHUS: κ=0.713; ABVS: κ=0.765; HHUS+ABVS: κ=0.815). Of these, the combination of HHUS and ABVS has certain advantages. It has been found through our research that the ability of the three methods to detect breast lesions is extremely consistent. It was suggested that the feasibility of ABVS could be used as a supplement tool to HHUS to evaluate breast lesions. ABVS is based on conventional US and optimizes the scanning method and the reading mode. Moreover, the stable detection capabilities are a prerequisite for this technology to be applied to breast examination[20]. The consistency between HHUS and ABVS with the pathological findings established the basis for the combined use of these two methods when applied to the diagnosis of breast diseases[13]. Our study showed that the sensitivity, specificity, accuracy, PPV and NPV of ABVS were slightly higher than HHUS. This finding was similar to previous studies[21-24]. ABVS can be more complete than HHUS for evaluating breast lesions because ABVS could improve breast lesion analysis by the additional coronal-plane imaging which provides for a better observation of lesion margin and each sectional plane of the saved volume can be visualized avoiding non-standardized documentation[25]. However, the same parameters for HHUS combined with ABVS were higher than ABVS or HHUS alone. To a certain extent, results from the present study implied HHUS combined with ABVS was favourable to improve the diagnostic performance. It was also supported by evidence from ROC analysis.

Combined use of ABVS and US for breast lesions is feasible. In ABVS examination, some atypical benign lesions are easily misdiagnosed as malignant[26]. In this study, there was one case of irregular fat necrotic nodules (located in the glandular layer, without capsules and uneven internal echoes). For this lesion, using ABVS it was difficult to identify whether this was a malignant breast lesion. Also since ABVS cannot display blood flow signals such a distinction was not possible. Therefore, in the actual diagnosis of breast cancer, the use of ABVS system combined with HHUS to diagnose breast lesions can make up for the lack of blood flow detection. This combined diagnostic mode can make the judgement of BI-RADS classification of breast lesions more accurate, and conducive to the differentiation of benign and malignant tumours. Furthermore, this combined procedure can also be introduced in breast cancer screening to detect and accurately diagnose breast lesions in women as early as possible. Based on published research evidence and the results of this study, it can be concluded that the combination of ABVS and HHUS is a more effective method to distinguish benign and malignant breast lesions.

The present study did have several limitations. First, ABVS is not without shortcomings as it cannot detect the blood flow and evaluate the elasticity of the lesion. These two parameters play important roles in the BI-RADS grading diagnosis of the lesion. Second, the uneven pressure on the breast during the scanning (squeeze too much or insufficient fit) and the patient's breathing movement would make the 3D image appear distorted and hence, prone to false positives and mistakes. For large, hard, prominent masses that protrude from the surface of the gland, it is prone to blurring of the tissue surrounding the mass. Hence, experienced operators are important in the ABVS imaging acquisition process. Third, the participants had not been categorized according to their breast density in our study. Women with different breast densities may show different findings. Besides, this study was a single-site study with a relatively small number of patients, which could be lacking in representativeness.

In summary, ABVS is a promising and advantaged modality for detecting breast lesions. Our data suggest that HHUS combined with ABVS is practically more useful a method for diagnosis. The automated 3D imaging approach of ABVS and the effective detection of blood flow signals by HHUS led to the assumption that the combination of these two methods may be lucrative in is detecting more clinical lesions.

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Conflicts of Interest: None.

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