

Assessment of Thyroid Gland in Children with Point-of-Care Ultrasound (POCUS): Radiological Performance and Feasibility of Handheld Ultrasound in Clinical Practice

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What is already known on this topic?

Point-of-Care Ultrasound (POCUS) refers to the use of portable ultrasound machines to perform quick and focused ultrasound examinations at a patient's bedside or point-of-care. POCUS can be performed by all health workers with specific training to use POCUS.

What this study adds?

The radiological performance and feasibility of POCUS was investigated using a handheld ultrasound device (HHUSD) in children from the perspective of the thyroid gland. A pediatric endocrinologist, equipped with sufficient training in thyroid ultrasonography evaluation, incorporated the HHUSD as a routine tool for clinical examinations in outpatient settings. These can effectively assess normal thyroid tissue in pediatric patients. Moreover, the HHUSD proved to be useful in detecting thyroid pathologies.

Abstract

Objective: Point-of-Care Ultrasound (POCUS) refers to the use of portable ultrasound machines to perform quick and focused ultrasound examinations at a patient's bedside or point-of-care. POCUS can be performed by all health workers with specific training to use POCUS. The aim of this study was to investigate the radiological performance and feasibility of POCUS using a handheld ultrasound device (HHUSD) in children for examining the thyroid gland.

Methods: A pediatric endocrinologist performed thyroid imaging in children referred to our hospital with suspected thyroid disease using an HHUSD. The same children underwent ultrasonography (US) imaging using the same device by the first radiologist, and a second radiologist performed thyroid US using an advanced high-range ultrasound device (AHUSD) (defined as the gold-standard method) within two hours. The data obtained by the three researchers were compared with each other.

Results: This study included 105 patients [68.6% girls (n = 72)] with a mean age 12.8 ± 3.6 years. When the thyroid volume was evaluated, a strong correlation was found between the measurements of the three researchers (AA vs. MG: $r = 0.963$, AA vs. GT: $r = 0.969$, MG vs. GT: $r = 0.963$, $p < 0.001$). According to the Bland-Altman analysis for total thyroid volume, AA measured 0.43 cc [95% confidence interval (CI): -0.89-0.03] smaller than MG, and 0.11 cc (95% CI: -0.30-0.52) larger than GT, whereas MG measured 0.52 cc (95% CI: 0.09-0.94) larger than GT. When evaluated for the presence of goiter and nodules, a near-perfect agreement was found between the results of the three researchers (AA vs. GT; $\kappa = 0.863$, MG vs. GT; $\kappa = 0.887$, $p < 0.001$, and AA vs. GT; $\kappa = 1.000$, MG vs. GT; $\kappa = 0.972$, $p < 0.001$, respectively). When evaluated in terms of the longest axis of nodules, a high correlation was found between the measurements of the three researchers (AA vs. MG; $r = 0.993$, AA vs. GT; $r = 0.996$, MG vs. GT; $r = 0.996$, $p < 0.001$). When evaluated in terms of the final diagnosis, the evaluations of the three researchers showed excellent agreement with each other (AA vs. GT; $\kappa = 0.893$, MG vs. GT; $\kappa = 0.863$, $p < 0.001$, accuracy rate AA vs. GT: 93.3%; MG vs. GT: 91.4%).

Cite this article as: Anık A, Gök M, Tuzcu G. Assessment of Thyroid Gland in Children with Point-of-Care Ultrasound (POCUS): Radiological Performance and Feasibility of Handheld Ultrasound in Clinical Practice. J Clin Res Pediatr Endocrinol. 2024;16(3):271-278



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Conflict of interest: None declared
Received: 11.09.2023
Accepted: 13.03.2024



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Conclusion: A pediatric endocrinologist, equipped with sufficient training in thyroid US evaluation, incorporated HHUSD examination as a routine clinical tool in an outpatient setting. It was shown that, they could effectively assess normal thyroid tissue in pediatric patients. Moreover, the HHUSD proved to be useful in detecting thyroid pathologies. However, it is important to note that for a more comprehensive evaluation of thyroid nodules, including detailed assessment and Thyroid Imaging Reporting and Data System (TIRADS) classification, patients should be referred to radiology departments equipped with AHUSD systems. These specialized devices, along with the expertise of radiologists, are essential for in-depth evaluations and accurate classification of thyroid nodules.

Keywords: Bedside ultrasound, handheld ultrasound device, hyperthyroidism, hypothyroidism, imaging, pediatric, point-of-care ultrasound

Introduction

Sonographic evaluation of the thyroid gland is routinely performed by radiologists to diagnose various thyroid diseases in children, including autoimmune thyroiditis, thyroid nodules, thyroid cancer, and goiter (1,2). Effective communication between clinicians and radiologists is central to accurate assessment and proper management of these conditions (3).

With advancements in ultrasonography (US) technology, the range of US products has expanded to include mobile devices that enable bedside examinations. These devices complement the traditional fixed US equipment found only in radiology departments. Commonly referred to as Point-of-Care Ultrasound (POCUS) in the literature, these devices are categorized into three types: laptop-associated devices, hand-carried systems, and handheld ultrasound devices (HHUSD). The introduction of these systems brings us closer to the realization of the “ultrasound stethoscope” concept (4).

The advances in POCUS technology are outpacing clinical studies conducted on the clinical performance of these technologies. Therefore, we believe that further research should be conducted to assess the clinical performance of POCUS. Such studies are crucial for advancing the development of this technology and realizing the concept of the ultrasound stethoscope. We propose that these studies should encompass various organ systems, different pathologies, and even different age groups. Clinical performance is influenced by both the device’s capabilities and the proficiency of the user.

HHUSDs have gained significant interest and attention in recent years (5). Studies have shown that they have high diagnostic accuracy and can be used for various applications, such as abdominal, cardiac, and musculoskeletal imaging (6,7). However, there is no research specifically into the use of HHUSD for thyroid imaging in children. In the present study, we focused on evaluating the clinical performance of HHUSD in children with suspected thyroid disease. We conducted a comparison between one HHUSD and the gold standard advanced high-range ultrasound device

(AHUSD) and aimed to assess the performance of pediatric endocrinologists who have received sufficient basic training in thyroid US. We evaluated the performance of a pediatric endocrinologist and two radiologists who had substantial expertise in conducting thyroid US. By considering both user expertise and device performance, we aimed to gain comprehensive insights into the clinical application of HHUSD for thyroid imaging in children.

Methods

Study Subjects

The university hospital where the study was conducted is a tertiary healthcare center located in a city with a population of over 1,000,000. It is the only pediatric endocrinology center in the city and provides services to all types of pediatric endocrinology patients. This study included pediatric patients aged 5-18 years who were referred to our hospital with suspected thyroid disease, including neck swelling, symptoms of hypothyroidism or hyperthyroidism, family history of thyroid diseases, and abnormalities in thyroid function tests.

Height was measured using a Harpenden stadiometer with a precision of 0.1 cm, while weight was measured using a scale with a precision of 0.1 kg (SECA, Hamburg, Germany). Subjects were weighed with all clothing removed, except for undergarments. Body mass index (BMI) was calculated by dividing weight (kg) by the square of height in meters (m²). A BMI at or above the 95th percentile, according to data from healthy Turkish children was defined as obesity (8). Serum thyroid hormones, anti-thyroid peroxidase (TPO), and anti-thyroglobulin (TG) antibody levels were measured using standard methods on blood samples obtained from all patients under appropriate conditions.

Ultrasonography

After obtaining informed consent from the patients and their parents, a pediatric endocrinologist (AA) with 13 years of clinical experience in pediatric endocrinology and one year of thyroid US experience performed thyroid US imaging at the out-patient clinic using a Sonostar C5PL

HHUSD (Sonostar Technologies Co Ltd, Guangzhou, China). Within two hours, the same patients underwent thyroid US imaging using the same device (Sonostar C5PL HHUSD) by a radiologist (MG) with 15 years of experience and lastly, a detailed thyroid US imaging, using AHUSD Samsung RS80 (Gyeonggi-do, Republic of Korea) with LA2-9A linear probe by another experienced radiologist (GT) with 16 years of experience. The US data obtained by the pediatric endocrinologist and the two radiologists were noted in detail. The three dimensions of the thyroid gland (anterior-posterior “AP”, medio-lateral “ML” and longitudinal “Long”), volume, parenchymal echogenicity, size of any nodules, composition (solid, semisolid, cystic), and echogenicity of the dominant nodule, and final sonographic diagnosis were recorded. The calculation of the volume for each lobe was done individually using the formula for an ovoid ($\text{depth} \times \text{length} \times \text{width} \times \pi/6$) (9). The total thyroid volume was then determined by adding the volume of both lobes together. Thyroid volume standard deviation score (SDS) was calculated using the normal range for Turkish children (10). Those with a total thyroid volume >2 SDS were considered to have a goiter. To isolate the operator from device performance, we separately compared the pediatric endocrinologist who used HHUSD to the radiologist using the same device (AA vs. MG) and we also compared the radiologist who used HHUSD to the radiologist who used AHUSD (MG vs. GT). Lastly, we compared the pediatric endocrinologist who used HHUSD to the radiologist who used AHUSD (AA vs. GT).

Institutional Ethics Committee of Aydın Adnan Menderes University was provided (protocol no: 2022/142, date: 25.08.2022).

Definitions used for Final Diagnosis (11)

Normal: Patients with euthyroidism, negative anti-TPO and anti-TG antibodies, and normal US findings.

Hashimoto’s thyroiditis: Patients with euthyroidism/biochemical hypothyroidism, positive anti-TPO and anti-TG, and ultrasound findings consistent with thyroiditis.

Graves’ disease: Patients with biochemical hyperthyroidism, positive anti-TPO and anti-TG, and ultrasound findings consistent with thyroiditis.

Obesity-related changes: Patients with euthyroidism, negative anti-TPO and anti-TG, and parenchymal heterogeneity on ultrasound.

Statistical Analysis

The statistical analysis for this study was performed using IBM Statistical Package for the Social Sciences statistics

version 27.0 (IBM Corp., Armonk, NY, USA) and NCSS 11 (NCSS 11 Statistical Software, 2016, NCSS, LLC, Kaysville, Utah, USA, ncss.com/software/ncss). The normality of the data distribution was assessed through descriptive statistics, kurtosis and skewness coefficients, histograms, and the Shapiro-Wilk test. As the data were found to be non-normally distributed, Friedman’s test was used to compare the three groups. Pearson and Spearman’s correlation tests were employed for correlation analyses. Kappa and intraclass correlation coefficient (ICC) statistics were utilized to assess agreement. The agreement between the US measurements was evaluated using the Bland-Altman method. Type 1 error was determined as 5%.

Results

A total of 105 children [68.6% (n = 72) girls] were included. The mean age was 12.8 ± 3.6 years, with a median (range) of 13.0 (4.7-18.0) years. The reasons for referral were: 72.4% (n = 76) for abnormal thyroid function tests, 17.1% (n = 18) for neck swelling, 5.7% (n = 6) for symptoms of hyperthyroidism, and 4.8% (n = 5) for symptoms of hypothyroidism. The clinical and laboratory characteristics of the subjects are given in Tables 1 and 2.

There was a strong positive correlation between AA vs. MG, AA vs. GT, and MG vs. GT in terms of total thyroid volumes ($r = 0.963, 0.969, 0.963, p < 0.001$, respectively) (Table 3). The ICC for thyroid volumes was 0.963 [95% confidence

Table 1. The clinical characteristics of the subjects

	Mean \pm SD or % (n)
Age (years)	12.8 \pm 3.6
Gender (girl)	68.6 (72)
Height - SDS	0.1 \pm 1.2
Weight - SDS	0.2 \pm 1.5
Body mass index - SDS	0.2 \pm 1.4
Complaint	
Abnormalities in thyroid tests*	72.4 (76)
Neck swelling	17.1 (18)
Symptoms of hyperthyroidism	5.7 (6)
Symptoms of hypothyroidism	4.8 (5)
Final diagnosis	
Normal	23.8 (25)
Hashimoto thyroiditis	40.0 (42)
Nodule + Hashimoto’s thyroiditis	16.2 (17)
Graves’ disease	7.5 (8)
Obesity related changes	6.7 (7)
Solitary nodule	5.6 (6)

*Patients were referred from another hospital due to abnormal thyroid tests (high or low TSH, high FT3) during screening.

SDS: standard deviation (SD) score, TSH: thyroid-stimulating hormone

interval (CI): 0.949-0.974]. In the Bland-Altman analysis performed in terms of the correlation of detailed US measurements (right thyroid volume, left thyroid volume and total thyroid volume), a strong correlation was found between the measurements. The difference between the

measurements in terms of total thyroid volume was -0.43 [95% CI: (-0.89)-0.03] for AA vs. MG; 0.11 [95% CI: (-0.30)-0.52] for AA vs. GT; and 0.52 (95% CI: 0.09-0.94) for MG vs. GT (Figure 1, Table 3).

When evaluated in terms of the presence of goiter, the

Table 2. Laboratory characteristics of the subjects

	Median	Minimum	Maximum	25 P	75 P
Free T3 (pg/mL)	3.4	0.9	20.0	3.1	3.8
Free T4 (ng/dL)	1.0	0.5	3.8	0.9	1.1
TSH (uIU/mL)	1.7	0.0	49.0	1.0	4.1
Anti-TPO (IU/mL)	3.0	0.0	1000.0	3.0	579.0
Anti-TG (IU/mL)	3.0	0.0	1000.0	3.0	60.0

Anti-TPO: anti-thyroid peroxidase, Anti-TG: anti-thyroglobulin

Table 3. Comparison of thyroid volumes

	Right thyroid volume	Left thyroid volume	Total thyroid volume	
AA vs. MG	Mean of differences	-0.46	0.03	-0.43
	Upper limit of 95% CI	-0.80	-0.18	-0.89
	Lower limit of 95% CI	-0.13	0.25	0.03
	r	0.934	0.968	0.963
	p	< 0.001	< 0.001	< 0.001
AA vs. GT	Mean of differences	0.08	0.03	0.11
	Upper limit of 95% CI	-0.19	-0.19	-0.30
	Lower limit of 95% CI	0.35	0.26	0.52
	r	0.956	0.960	0.969
	p	< 0.001	< 0.001	< 0.001
MG vs. GT	Mean of differences	0.53	-0.02	0.52
	Upper limit of 95% CI	0.23	-0.28	0.09
	Lower limit of 95% CI	0.84	0.24	0.94
	r	0.938	0.955	0.963
	p	< 0.001	< 0.001	< 0.001

CI: confidence interval

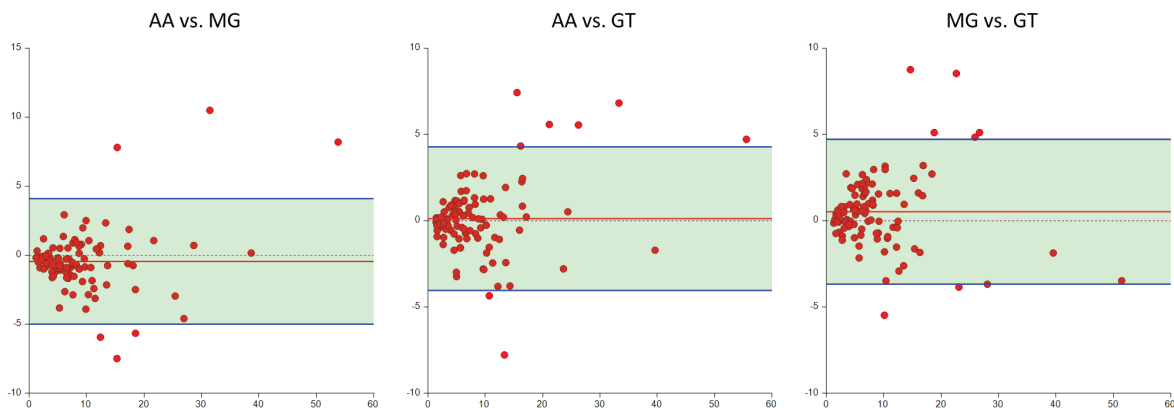


Figure 1. Bland-Altman analysis for total thyroid volumes. Red line (-0.43, 0.11, 0.52) is the bias (average of the differences between total thyroid volumes of AA vs. MG, AA vs. GT, MG vs. GT; respectively). Blue lines [(-5.00)-4.14, (-4.04)-4.26, (-3.67)-4.71] are the limits of agreement, respectively

measurements of all three researchers showed near-perfect agreement (AA vs. MG; $\kappa = 0.887$, AA vs. GT; $\kappa = 0.863$, MG vs. GT; $\kappa = 0.889$, $p < 0.001$). The measurements of all three researchers demonstrated substantial agreement when assessing parenchymal echogenicity (AA vs. MG; $\kappa = 0.685$, AA vs. GT; $\kappa = 0.771$, MG vs. GT; $\kappa = 0.730$, $p < 0.001$). A near-perfect agreement was again observed among all three researchers' evaluations when assessing the presence of nodules (AA vs. MG; $\kappa = 0.972$, AA vs. GT; $\kappa = 1.000$, MG vs. GT; $\kappa = 0.972$, $p < 0.001$) (Table 4).

When evaluated for the presence of nodules and considering AHUSD as the gold standard method, nodules were detected in a total of 23 patients (22%). Among these cases, 43.5% ($n = 10$) were identified as cystic nodules, 21.7% ($n = 5$) exhibited semisolid nodules, and 34.8% ($n = 8$) presented with solitary nodules (AA vs. MG; $\kappa = 0.864$, AA vs. GT; $\kappa = 0.864$, MG vs. GT; $\kappa = 0.858$, $p < 0.001$). The features that

can predict malignancy in solid nodules, such as irregular margins and microcalcifications, could not be evaluated with HHUSD. When evaluated in terms of the last diagnosis according to the AHUSD 23.5% ($n = 25$) of the patients were diagnosed as normal, 40.0% ($n = 42$) had Hashimoto's thyroiditis, 16.2% ($n = 17$) had coexistence of nodules and thyroiditis, 7.5% ($n = 8$) had Graves' disease, 6.7% ($n = 7$) had obesity-related changes, and 5.6% ($n = 6$) had solitary nodules (Table 1). The final diagnoses of all three researchers showed near-perfect agreement (AA vs. MG; $\kappa = 0.871$, AA vs. GT; $\kappa = 0.910$, MG vs. GT; $\kappa = 0.884$, $p < 0.001$). The ICC for the long axis of the nodule was 0.995 (0.989-0.998). In the Bland-Altman analysis performed in terms of the correlation of nodule size, a strong correlation was found between the measurements. The difference between the measurements of the nodule size was 0.49 [95% CI: (-0.30)-1.27] for AA vs. MG; 0.26 [95% CI: (-0.32)-0.83] for AA vs. GT; and -0.25 [95% CI: (-0.87)-0.38] for MG vs. GT (Figure 2).

Table 4. Comparison of goiter, parenchymal heterogeneity, and nodule

		Goiter			Parenchymal heterogeneity			Nodule		
		Radiologist handheld US (MG)		Kappa p	Radiologist handheld US (MG)		Kappa p	Radiologist handheld US (MG)		Kappa p
		Positive	Negative		Positive	Negative		Positive	Negative	
Pediatric endocrinologist (AA)	Positive	71	4	0.887 <0.001	66	8	0.685 <0.001	82	0	0.972 <0.001
	Negative	1	29		6	25		1	22	
Pediatric endocrinologist (AA)	Radiologist standard US (GT)		0.863 <0.001	Radiologist standard US (GT)		0.771 <0.001	Radiologist standard US (GT)		1.000 <0.001	
	Positive	71		4	69		5	82		0
Radiologist handheld US (MG)	Positive	70	2	0.889 <0.001	67	5	0.730 <0.001	82	1	0.972 <0.001
	Negative	3	30		7	26		0	22	

US: ultrasonography

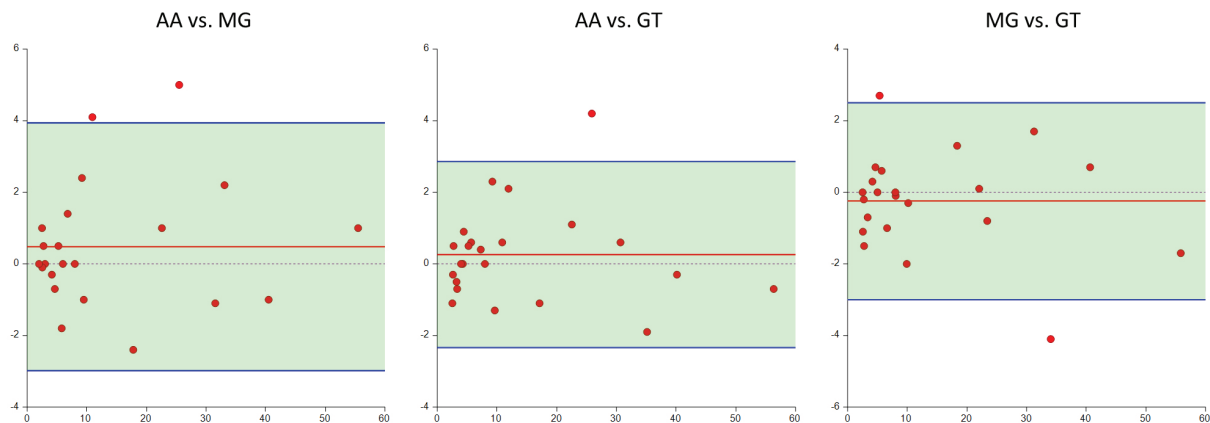


Figure 2. Bland-Altman analysis for nodule long axes. Red line (0.49, 0.26, -0.25) is the bias (average of the differences between nodule long axes of AA vs. MG, AA vs. GT, MG vs. GT; respectively). Blue lines [(-2.96)-3.94, (-2.34)-2.86, (-2.97)-2.53] are the limits of agreement, respectively

Discussion

The results of the present study showed a high correlation and near perfect agreement between the measurements and evaluations of the three researchers in terms of three-dimensional measurements of the thyroid, thyroid volume, presence of goiter, presence of nodules, the longitudinal plane of nodules, and final diagnosis. Additionally, the Bland-Altman analysis showed that the differences in measurements between the researchers were within acceptable limits. This study is the first clinical trial demonstrating the effectiveness of HHUSD performed by clinicians in the thyroid US examination in children.

Thyroid US is a gold standard imaging modality in the evaluation of thyroid nodules and other thyroid disorders (12,13). However, the accuracy of this imaging modality depends on several factors, including the experience and skill of the user, the ability to integrate US findings with the patient's clinical history and examination, and the quality of the US device. US is a highly accurate modality when performed by an experienced user (14). However, clinical findings are an important part of the accurate final diagnosis, so these findings need to be shared between the clinician and the radiologist. Several studies have shown that integrating clinical information with US findings can improve the diagnostic accuracy of thyroid US (15,16). Due to the significant outpatient workload in radiology departments, obtaining a US examination can pose challenges. If HHUSD were part of the clinical evaluation by the clinician, this would eliminate the unnecessary workload for the radiology departments (17,18).

POCUS systems have become an integral part of patient evaluation in departments, such as emergency services, anesthesia, intensive care, and general surgery, where triage or urgent assessment is required. They are now incorporated into the teaching curriculum and guidelines of these specialties (19). The widespread availability of HHUSD has made accessing POCUS systems easier, leading to increased use of these systems (20). At this point, the question arises as to whether POCUS systems should be included as part of the physical examination during routine outpatient services, not just for patients requiring urgent evaluation. If HHUSD becomes part of the examination, it would enable radiology departments to provide intensive outpatient services to minimize unnecessary patient burden and ensure triage for patients who require this service (21). Consequently, this could reduce the number of unnecessary diagnostic tests and decrease the unnecessary costs imposed on the healthcare system.

The results of the present study indicate that the effective use of POCUS systems relies on two essential components.

The first component pertains to the appropriateness of the HHUSD used for the specific organ system, while the second component relates to the user's adequate knowledge and skill level for conducting sonographic examinations. Our study demonstrated that HHUSD when employed by a properly trained non-radiologist clinician exhibits a strong correlation with the gold standard, which involves the use of an AHUSD by an expert radiologist specialized in sonography. Our results showed that the HHUSD method proved to be effective in detecting thyroid nodules and distinguishing between cystic and solid nodules. However, limitations in the device's resolution capabilities hindered its ability to adequately address features indicative of malignancy in solid nodules, such as the presence of microcalcifications and irregular margins. Given the limited number of patients with solid nodules in the present study, making definitive conclusions would be unreliable and there is a need for more comprehensive research on the role of these devices in Thyroid Imaging Reporting and Data System (TIRADS) scoring. Our findings have highlighted the current limitations of HHUSD and underscore the necessity for further advances in their development. Furthermore, specialties seeking to integrate these systems into routine clinical practice must ensure that proper training is incorporated into their educational programs. In this regard, we propose the inclusion of radiology rotations during pediatric endocrinology training for these specialties and the implementation of certification programs that require periodic retraining in this area following the completion of residency.

Our study possesses several notable strengths. Firstly, we utilized two distinct US systems, providing a comparative analysis between them. Secondly, the participation of a pediatric endocrinology clinician along with two radiologists in the study ensured diverse perspectives and expertise in the evaluation process. Additionally, our patient group consisted of both individuals with normal thyroid function and those with various thyroid pathologies, enabling a comprehensive comparison of normal and pathological data. Furthermore, we implemented an internal evaluation process wherein measurements were independently assessed by the observers at different times, ensuring a blind evaluation unaffected by each other's observations. These strengths collectively enhance the robustness and validity of our study.

Study Limitations

Our study does have certain limitations that should be acknowledged. Firstly, it is important to note that there are various generations of HHUSD available in the market, but we

utilized a single standard device for our evaluation. Therefore, the findings may not directly generalize to other generations or models of HHUSD. Secondly, our study focused on evaluating the performance of the HHUSD specifically when used to evaluate thyroid tissue, which is a superficial tissue. It is worth mentioning that the performance of US devices may vary when imaging deeper tissues. Thus, our study's results may not fully reflect the performance of HHUSD in imaging deep tissues. Considering these limitations, future studies should explore the performance of different generations or models of HHUSD on various tissue types, including deeper structures, to provide a more comprehensive understanding of their capabilities and limitations.

Conclusion

The present study demonstrated that when a pediatric endocrinologist, equipped with sufficient training in thyroid US evaluation, incorporates the HHUSD as a routine tool for clinical examinations in outpatient settings, they can effectively assess normal thyroid tissue in pediatric patients. Moreover, the HHUSD proved to be useful in detecting thyroid pathologies. However, it is important to note that for a more comprehensive evaluation of thyroid nodules, including detailed assessment and TIRADS classification, patients should still be referred to radiology departments equipped with AHUSD. These specialized devices, along with the expertise of radiologists, are essential for in-depth evaluations and accurate classification of thyroid nodules.

Acknowledgement

We express our gratitude to Sercan Öztürk for his contributions to statistical analysis.

Ethics

Ethics Committee Approval: Institutional Ethics Committee of Aydın Adnan Menderes University was provided (protocol no: 2022/142, date: 25.08.2022).

Informed Consent: Informed consent was obtained from those included in the study.

Authorship Contributions

Surgical and Medical Practices: Ahmet Anık, Göksel Tuzcu, Concept: Ahmet Anık, Mustafa Gök, Design: Ahmet Anık, Mustafa Gök, Data Collection or Processing: Mustafa Gök, Göksel Tuzcu, Analysis or Interpretation: Ahmet Anık, Göksel Tuzcu, Literature Search: Mustafa Gök, Göksel Tuzcu, Writing: Ahmet Anık, Mustafa Gök, Göksel Tuzcu.

Financial Disclosure: The authors declared that this study received no financial support.

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