Acoustic Radiation Force Impulse-Imaging for the evaluation of the thyroid gland: A limited patient feasibility study

Mireen Friedrich-Rust\textsuperscript{a}, Olga Romenski\textsuperscript{a}, Gesine Meyer\textsuperscript{a}, Nina Dauth\textsuperscript{a}, Katharina Holzer\textsuperscript{b}, Frank Grünwald\textsuperscript{c}, Susanne Kriener\textsuperscript{d}, Eva Herrmann\textsuperscript{e}, Stefan Zeuzem\textsuperscript{a}, Joerg Bojunga\textsuperscript{a,}\textsuperscript{*}

\textsuperscript{a}Department of Internal Medicine 1, J.W. Goethe-University Hospital, Frankfurt, Germany
\textsuperscript{b}Department of General and Visceral Surgery, J.W. Goethe-University Hospital, Frankfurt, Germany
\textsuperscript{c}Department of Nuclear Medicine, J.W. Goethe-University Hospital, Frankfurt, Germany
\textsuperscript{d}Department of Pathology, J.W. Goethe-University Hospital, Frankfurt, Germany
\textsuperscript{e}Institute of Biostatistics and Mathematical Modelling, Faculty of Medicine, J.W. Goethe-University, Frankfurt, Germany

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\textbf{A B S T R A C T}

\textbf{Purpose:} Real-time tissue elastography, a qualitative elastography method, has shown promising results in the diagnostic work up of thyroid nodules. However, to our knowledge no study has evaluated a quantitative elastography method in the thyroid gland. The present study is a feasibility study evaluating Acoustic Radiation Force Impulse-Imaging, a novel quantitative elastography method in the thyroid gland.

\textbf{Methods:} ARFI-imaging involves the mechanical excitation of tissue using short-duration acoustic pulses to generate localized displacements in tissue. The displacements induce a lateral shear-wave propagation which is tracked using multiple laterally positioned ultrasound “tracking” beams. Inclusion criteria were: thyroid nodules \( \geq 1 \) cm, non-functioning or hypo-functioning on radionuclide scanning, and cytological/histological assessment of thyroid nodule as reference method. All patients received conventional ultrasound, and examination of the thyroid gland including Power Doppler Ultrasound using a 9 MHz linear transducer, in addition real-time elastography (RTE) was performed at 9 MHz frequency and ARFI-imaging was performed at 4 MHz using Siemens (ACUSON S2000) B-mode-ARFI combination transducer.

\textbf{Results:} Sixty nodules in 55 patients were analyzed. Three nodules were papillary carcinoma. The stiffer the tissue the faster the shear wave propagates. The results obtained indicated that the shear wave velocity in thyroid lobes ranged between 0.5 and 4.9 m/s. The median velocity of ARFI-imaging in the healthy nodule-free thyroid gland, as well as in benign and malignant thyroid nodules was 1.98 m/s (range: 1.20–3.63 m/s), 2.02 m/s (range: 0.92–3.97 m/s), and 4.30 m/s (range: 2.40–4.50 m/s), respectively. While no significant difference in median velocity was found between healthy thyroid tissue and benign thyroid nodules, a significant difference was found between malignant thyroid nodules on the one hand and healthy thyroid tissue (\( p = 0.018 \)) or benign thyroid nodules (\( p = 0.014 \)) on the other hand. Specificity of ARFI-imaging for the differentiation of benign and malignant thyroid nodules was comparable with RTE (91–95%).

\textbf{Conclusions:} ARFI can be performed in the thyroid tissue with reliable results.

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1. Introduction

A classical criterion of malignancy is a hard or firm consistency upon palpation or ultrasound probe pressure [7,23]. Previously this attribute was subjective and dependent on the experience of the examiner. However, with the introduction of ultrasound-based elastography methods reproducible qualitative assessment of tissue consistency became available. Acoustic Radiation Force Pulse (ARFI)-Imaging is a novel ultrasound-based elastography method enabling quantitative measurement of tissue stiffness. The aim of the present study was to introduce the ARFI principle, to evaluate whether a quantitative elastography works in the thyroid gland and can be performed with reliable results within the healthy thyroid gland and benign nodules, and to compare it as a diagnostic tool with real-time elastography elasticity. Previous studies have shown that ARFI can be performed in the tissue such as liver, kidney, spleen and pancreas [11]. In addition, studies have shown that ARFI can be used as a non-invasive method for the staging of liver fibrosis [10].
Thyroid nodules are a common finding in regions with inadequate iodine supply and are reported in 33% of unselected adults between the age of 18 and 65 years [26]. Ultrasound is a clinically adequate method for the detection of thyroid nodules. Ultrasound with high frequency (7.5–13 MHz) ultrasound probe is optimal for the evaluation of thyroid tissue, since it has a high resolution in superficial tissue (0–7 cm) such as the thyroid. However, differentiation between benign and malignant thyroid nodules by conventional ultrasound alone is not possible [13]. Therefore, radionuclide scanning and fine needle aspiration biopsy (FNAB) are presently used as supplementary diagnostic methods in the evaluation of thyroid nodules with a size of ≥10 mm [7,8]. While hyper-functioning thyroid nodules have a very low risk of malignancy, non-functioning and hypo-functioning nodules need [12] further work-up by FNAB which is the method with the highest specificity (60–98%), but with a varying specificity of 54–90% [17,21,25,29]. A classical criterion of malignancy is a hard or firm consistency [7,23]. Real-time elastography (RTE) is a reproducible qualitative assessment of tissue consistency. A meta-analysis (which includes the results of several studies) reported a mean sensitivity and specificity for the diagnosis of malignant thyroid nodules by RTE of 92%, and 90%, respectively [5,5].

In the present study, conventional Ultrasound, Real-time Elastography (RTE), and Acoustic Radiation Force Impulse (ARFI-Imaging), which are described in more detail in the Section 2. are performed in thyroid tissue and compared to each other. While RTE is a qualitative elastography method, ARFI-imaging is a quantitative elastography method. Therefore, besides conventional ultrasound, both methods (RTE and ARFI) might supplement each other in the diagnostic work up of thyroid disease and thyroid nodules. The advantage of ARFI-imaging is that the same acoustic wave is send into the tissue independent of the examiner pressing the button to start measurement, while for RTE the examiner needs to perform small compressions to the tissue which may vary.

2. Materials and Methods

2.1. Patients

Informed consent was obtained from all patients and the study was performed in accordance with the ethical guidelines of the Helsinki Declaration and approved by the local ethics committee. The study period was from April 2009 to August 2010. All patients presenting to our endocrinology department for work-up of thyroid nodules were evaluated for inclusion in the study. Inclusion criteria were the presence of a thyroid nodule ≥10 mm, non-functioning or hypo-functioning on radionuclide scanning, and FNAB of this nodule performed within the last 3 months or FNAB and/or surgery planned at the time of ultrasound examination and finally performed within the study period. Exclusion criteria were cystic lesions of completely liquid nature, and no cytology by FNA or histology by surgery planned at the time of ultrasound examination and finally the nodule performed within the last 3 months or FNAB and/or histology by surgery of the thyroid nodule within the study period.

All patients received an ultrasound of the thyroid gland, including Duplex and Doppler ultrasound, followed by RTE and ARFI-imaging. Cytology with follow-up ultrasound or histology was used as reference method for the diagnosis of a benign or malignant thyroid nodule.

2.2. Fine needle aspiration cytology/histology

All included patients received either cytology using FNAB and/or histology from thyroid surgery to verify the diagnosis. FNAB was performed with a 25-gauge needle attached to a 20 ml syringe. Adequacy of aspirates was defined according to the guidelines of the Papanicolaou society [1].

2.3. Conventional ultrasound (B-mode and Doppler)

According to the guidelines of the American Institute of Ultrasound in Medicine (AIUM) thyroid ultrasound is indicated for the evaluation of palpable neck mass, abnormalities detected by other imaging examination or laboratory studies, evaluation of the presence, size, and location of the thyroid gland, evaluation of high-risk patient for occult thyroid malignancy, follow-up of thyroid nodules, evaluation for recurrent disease or regional nodal metastases in patients with proven or suspected thyroid carcinoma, and location of thyroid abnormalities or adjacent cervical lymph nodes for biopsy, ablation or other interventional procedures [2]. Ultrasound is best performed with high frequency (7.5–13 MHz) linear ultrasound probes, since this enables optimal depth penetration within the superficially located thyroid tissue (0–7 cm). For superficial organs such as the thyroid a linear ultrasound probe is optimal, while for deeper tissue a wider ultrasound field is needed and here for a curved probe is rather used. With B-mode ultrasound the following ultrasound criteria are risk factors for malignancy of a thyroid nodule: solitary nodule, hypoechoic nodule, nodule >10 mm, blurred margins, and microcalcifications [6,24]. In addition, Duplex and Power Doppler Ultrasound enables the determination of intranodular vascularisation, with is another important risk factor for malignancy [6,24]. Therefore, all patients received an ultrasound examination of the thyroid gland including Power Doppler Ultrasound using a 9 MHz transducer (Hitachi EUB-900, Hitachi, Tokyo, Japan).

The patients were positioned in a supine position with dorsal flexion of the head. The ultrasound examination was performed by experienced examiners blinded to the results of cytology. Thyroid nodules were evaluated for size, volume, echogenicity, echotexture, presence or absence of halo sign, presence or absence of microcalcification and/or macrocalcification. After B-mode ultrasound, power Doppler and Duplex imaging were performed [14].

2.4. Real-time tissue elastography (RTE)

Real-time elastography (Hitachi Real-time Tissue Elastography [HI-RTE], Hitachi Medical Corporation, Japan) is an imaging technique to directly reveal the physical property of tissue with conventional ultrasound probes. Tissue elasticity distribution is calculated by the strain and stress of the examined tissue. Under compression soft tissue changes its shape (e.g. from round to oval), while hard tissue does not significantly changes its shape (e.g. round stays round). The calculation of tissue elasticity distribution was performed in real-time and the examination results were represented as color-coded images over the conventional B-mode image. While blue color represents hard tissue, red and green color represents soft tissue [9,22]. Previous studies have shown that predominantly blue and completely blue nodules are a sign of malignancy, while predominantly green or completely green nodules are a sign of benign nodules [4,27]. Real-time elastography was performed with the EUB-900 ultrasound system (Hitachi, Tokyo, Japan) using the 9 MHz probe. The probe was placed on the neck and by applying millimeter movements towards the neck a pressure is applied. This pressure is shown on the monitor on a scale of 0–6 arbitrary units. According to the company of the ultrasound machine (Hitachi) a pressure of 3–4 units has the least artifacts and was therefore applied. The applied pressure, which is operator dependent, can hereby be standardized between the different examiners and also between the different measurements. Only images captured at a pressure of 3–4 units were used for interpretation of RTE results. The region-of-interest (ROI) for the elastography examination was selected by the operator and was standardized to include the nodule and surrounding normal thyroid tissue. The surrounding tissue is important, since RTE

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measures the relative stiffness within the ROI and the surrounding tissue is used as reference tissue. Video clips and single images were stored. Elasticity was classified into the following four different patterns: elasticity score (ES) 1: the nodule is displayed homogeneously in green (soft); ES 2: the nodule is displayed predominantly in green with few blue areas/spots; ES 3: the nodule is displayed predominantly in blue with few green areas/spots; ES 4: the nodule is displayed completely in blue (hard). In cases of cystic lesion, the solid component of the nodule was examined to exclude artifacts known to be caused by the cyst. The entire examination lasted approx. 5–10 min per patient.

2.5. Acoustic Radiation Force Impulse (ARFI)-Imaging

Acoustic Radiation Force Impulse (ARFI) imaging (Virtual Touch™ Tissue Quantification, Siemens ACUSON S2000) involves targeting of an anatomic region to be interrogated for elastic properties with a Region-of-Interest (ROI) cursor while performing real time B-mode imaging. Tissue within a ROI (10 × 5 mm) is mechanically excited using short-duration (~262 μs) acoustic pulses. The acoustic pulses generate localized tissue displacements within the ROI. The displacements induce a lateral shear-wave propagation which is tracked using multiple laterally positioned Ultrasound “tracking” beams [20]. By measurement of the time to peak displacement at each lateral location, the shear wave velocity within the tissue can be reconstructed [16,18]. The shear wave propagation velocity is proportional to the square root of tissue elasticity [19,28]. The stiffer the tissue the faster the shear wave propagates. Results are expressed in m/s with a measurement range of 0.5–4.9 m/s. An examination is shown in Fig. 1.

At the time of study performance ARFI was only available for the curved ultrasound probe at 4 MHz for B-mode imaging. This probe and frequency is not optimal for thyroid tissue evaluation. A frequency of at least 7.5 MHz would be optimal, since it has a higher resolution. Nevertheless, resolution is more important for qualitative examination, while ARFI is a quantitative measurement and the resolution was high enough to enable the correct placement of the ROI within the thyroid tissue or nodule.

Ten successful measurements per patient were performed with the ROI placed in the healthy thyroid gland away from thyroid nodules (see Fig. 1). In addition, 10 successful measurements per patient were performed with the ROI placed in the thyroid nodule (see Fig. 2).

2.6. Statistical analysis

Statistical analysis was performed using SigmaPlot and SigmaStat for Windows (version 11.0, Systat Software, Inc., Germany) and BiAS for Windows (version 9.04, epsilon 2009, Frankfurt, Germany). For ARFI-imaging the median of all 10 measurements per subject and nodule or healthy thyroid gland was calculated and used for further analysis. Values of ARFI-imaging were not normally distributed and therefore expressed as median-values. Clinical and laboratory characteristics of patients were expressed as mean ± SD, median and range. Correlations were assessed by Spearman’s correlation coefficient. Kruskal–Wallis Test was used to compare ARFI-measurements in the healthy thyroid tissue, benign thyroid nodules and malignant thyroid nodules, respectively. A p-value less than 0.05 was judged to be statistically significant. The number of malignant thyroid nodules was too small to allow the calculation of sensitivity of ARFI for the diagnosis of malignant thyroid nodules. Only results on specificity could be given reliably due to the large number of patients with benign thyroid nodules. Reference limits of ARFI imaging of healthy thyroid tissue or benign thyroid nodules were given according to the 95% and 90% percentile.

3. Results

Fifty-nine patients with 65 non-functioning or hypo-functioning thyroid nodules met the inclusion criteria. Four patients were excluded because of nondiagnostic aspirate on FNAB without

![Fig. 1. B-mode ultrasound of the thyroid gland using the S2000, 4 MHz probe (Fig. 1A) and Acoustic Radiation Force Impulse Imaging with the ROI placed within the healthy thyroid tissue (Fig. 1B) measuring a velocity of 1.65 m/s.](image-url)
repeated FNAB or surgery during the study period. Therefore, 55 patients with 60 examined nodules were included in the final analysis. These were 36 women with a mean age of 52 (median 53, standard deviation 15, range 22–82 years) and 19 men with a mean age of 50 (median 49, standard deviation 12, range 26–76 years). All patients showed up with normal thyroid hormone values.

3.1. Cytology/histology

FNAB was performed of 57 nodules in 52 patients. Hereby, cytology revealed a benign nodule in 49 cases, a suspicious nodule in three cases, a papillary carcinoma in three cases, a follicular lesion in two cases. All indeterminate nodules (suspicious, follicular lesion) and malignant nodules on cytology were referred to surgery. Histology showed a papillary carcinoma in three nodules of three patients, and benign adenoma and/or regressive changes in all other patients. Nine additional patients were operated. In six of these patients, all with benign FNAB, surgery was advised due to goiter with multiple nodules; and in three of these patients FNAB was declined by the patients who preferred direct surgery. Histology revealed benign adenoma and/or regressive changes in all nine patients.

3.2. Conventional ultrasound

The mean size of the examined nodule was $23 \times 17 \times 17 \text{ mm}$ (volume–mean: $4.5 \pm 4.8 \text{ ml}$; median: $2.6 \text{ ml}$; range: $0.4$–$28 \text{ ml}$) for benign and $45 \times 26 \times 31 \text{ mm}$ (volume–mean: $34 \pm 48 \text{ ml}$; median: $12.6 \text{ ml}$; range: $1$–$90 \text{ ml}$) for malignant lesions. Thirty five nodules were located in the right thyroid lobe, 25 in the left lobe.

3.3. Real-time elastography (RTE)

Real-time elastography score ES 1 was found in two benign nodules; ES 2 in 50 benign nodules; ES 3 in seven nodules (five benign nodules and two papillary carcinoma); and ES 4 in one papillary carcinoma, respectively.

Thus, 52 of 57 nodules (91%) with the final diagnosis of benign nodules showed ES 1–2, and all nodules (100%) with the final diagnosis of thyroid cancer showed ES 3–4.

Using ES 3–4 for the diagnosis of malignant thyroid nodules and ES 1–2 for the diagnosis of benign thyroid nodules, specificity of RTE was 91% (95%-CI: 81–97%).

3.4. Acoustic Radiation Force Impulse (ARFI)-imaging

The stiffer the tissue the faster the shear wave propagates. The results obtained indicate that the shear wave velocity measured in the healthy nodule-free thyroid gland ranged from 1.04–4.40 m/s. The median velocity of ARFI-imaging in the healthy nodule-free thyroid gland was 1.98 m/s (mean: $2.12 \pm 0.59 \text{ m/s}$, range: $1.20$–$3.63 \text{ m/s}$). In two patients no measurement in the healthy thyroid gland was possible due to multinodular goiter. The single measured velocities in benign and malignant thyroid nodules ranged from 0.62–4.75 m/s, and 2.09–4.90 m/s. The median velocity of ARFI-imaging in benign thyroid nodules was 2.02 m/s (mean: $2.08 \pm 0.74 \text{ m/s}$, range: $0.92$–$3.97 \text{ m/s}$). The median velocity of ARFI-imaging in the three malignant thyroid nodules was 4.30 m/s (mean: $3.73 \pm 1.16 \text{ m/s}$, range: $2.40$–$4.50 \text{ m/s}$) (see Fig. 3).
activity and specificity of 92%, and 90%, respectively, for RTE for the
which summarizes the results of several studies) reported a sensi-
elastography method in the thyroid gland. A recent meta-analysis
roid gland evaluated Real-time Elastography (RTE) as a qualitative
using ultrasound devices. Previous elastography studies in the thy-
clinical practice enabling the determination of tissue elasticity
RTE was significant with 0.31 (p = 0.017). One of the three malignant thyroid nodules had a median veloc-
was to perform a feasibility study of ARFI in thyroid tissue. One of the three malignant thyroid nodules had a median veloc-
while no significant difference in median velocity was found between healthy thyroid tissue and benign thyroid nodules (p = 0.93) (see Fig. 4), a significant difference was found between healthy thyroid tissue and malignant thyroid nodules (p = 0.018), as well as between benign and malignant thyroid nodules (p = 0.014), respectively (see Table 1). The upper reference velocity of benign thyroid nodules using the 95%-percentile was 3.3 m/s, and using the 90%-percentile 3.1 m/s. Using these cut-offs the specificity of ARFI-imaging for the diagnosis of malignant thyroid nodules was 95% (95%-CI: 85–99%), and 91% (95%-CI: 81–97%), respectively. One of the three malignant thyroid nodules had a median velocity of 2.4 m/s only. This thyroid nodule was small with 15 × 11 × 12 mm in size and revealed B-mode ultrasound criteria of malignancy such as hypoechoic nodule, microcalcification, blurred margin and intranodular hypervascularization, as well as an elastography Score E54 (blue = hard = malignant nodule).

The median success-rate of ARFI-measurement (number of valid measurements divided by the number of all measurements performed) was 100% in the healthy thyroid (mean: 99.6 ± 3%, range: 77–100%), and 100% in thyroid nodules (mean: 97.6 ± 10%, range: 42–100%). The intra-observer variability expressed as the mean standard deviation of 10 measurements at one location was 0.35, the overall standard deviation was 0.82.

The Spearman correlation coefficient between the velocity measured with ARFI-imaging and the elasticity score measured with RTE was significant with 0.31 (p = 0.017).

4. Discussion

In recent years, new technologies have been introduced into clinical practice enabling the determination of tissue elasticity using ultrasound devices. Previous elastography studies in the thyroid gland evaluated Real-time Elastography (RTE) as a qualitative elastography method in the thyroid gland. A recent meta-analysis (which summarizes the results of several studies) reported a sensitivity and specificity of 92%, and 90%, respectively, for RTE for the diagnosis of malignant thyroid nodules [5]. However, to our knowledge no study has evaluated a quantitative elastography method in the thyroid gland. The present study is a feasibility study evaluating Acoustic Radiation Force Impulse-Imaging, a novel quantitative elastography method in the thyroid gland. The present study shows that ARFI-imaging can be performed in the thyroid gland with a median velocity in the healthy thyroid gland of 1.98 m/s and in benign thyroid nodules of 2.02 m/s. The stiffer the tissue the faster the shear wave propagates. The results obtained indicate that the shear wave velocity in thyroid lobes ranged between 0.5 and 4.9 m/s with the highest values reported for malignant thyroid nodules ranging from 2.09 to 4.90 m/s. These results are in agreement with previous studies evaluating ARFI of the liver with velocities ranging from 0.84 in healthy liver to 3.83 m/s in liver cirrhosis [10]. Reasonable reference levels of ARFI-imaging for benign thyroid nodules can be defined at levels of 91–95% and specificity was than similar to the specificity of RTE. In this study, specificity of RTE was comparable to previous studies with 91% [5]. Further studies should evaluate whether the quantitative ARFI-imaging and the qualitative RTE might supplement each other to further improve the specificity for the diagnosis of malignant thyroid nodules. Both methods for themselves reach a specificity of 91–95%, but possibly the combination could reach specificity close to 100%.

Only three malignant thyroid nodules were included in the present study, therefore the calculation of specificity, positive predictive value (PPV), negative predictive value (NPV) and Likelihood ratio (LR) was not justified. However, 5% of malignant thyroid nodules as reported in the present study are representative of the patient population reporting for diagnostic work-up of thyroid nodules and is in accordance with the literature [3,15]. Nevertheless, the aim of the present study was to evaluate whether a quantitative elastography method such as ARFI works in the thyroid gland and can be performed with reliable results within the healthy thyroid gland and benign nodules and this could be demonstrated in the present study. The results of the measurement in malignant nodules as compared to benign nodules (4.30 m/s vs. 2.02 m/s) suggests, that this method might be useful in the diagnostic work-up of thyroid nodules differentiating between benign and malignant thyroid nodules.

The present study has some limitations:

The number of malignant thyroid nodules was too small to draw conclusions concerning the value of ARFI-imaging for the diagnosis of malignant thyroid nodules. Only results on specificity could be given reliably. Nevertheless, the aim of the present study was to perform a feasibility study of ARFI in thyroid tissue.

One of the three malignant thyroid nodules had a median velocity of “2.4 m/s” only, falling into the normal range category. This thyroid nodule was small with only 15 × 11 × 12 mm in size. Since the size of the ROI for ARFI-measurement is 1 cm at present, the measurement could have included healthy thyroid tissue, which could be responsive for the lower velocity. However, the nodule revealed criteria of malignancy using B-mode/Power-Doppler ultrasound, as well as using RTE [5,24]. This supports the combination of different ultrasound-based approaches such as conventional ultrasound with qualitative (RTE) and quantitative (ARFI)-elastography. This limitation of ARFI-imaging will be improved by a 7.5 MHz frequency linear probe with a ROI for ARFI-measurement of only 4 × 5 mm in size, which is presently under development by Siemens Medical Solutions. The higher frequency will allow an examination with better resolution of thyroid tissue, which will enable that B-mode ultrasound and Power Doppler and ARFI of the thyroid can be performed with the same probe. A recent study demonstrates, that RTE can be performed in thyroid nodules of 3–10 mm in size and is suitable for the diagnosis of microcarci-noma of the thyroid gland [30]. At present, the size of the ROI for ARFI-imaging is a limitation, but will be comparable to RTE with

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the new probe with a ROI of $4 \times 5$ mm. The smaller ROI will enable the evaluation of thyroid nodules $<10$ mm.

The intra-observer variability expressed as the mean standard deviation of 10 measurements at one location was 0.35 as compared to 0.82 for all measurements. However, compared to the mean difference of 2.28 m/s between benign and malignant thyroid nodules, the intraobserver variability would not have any effect on the differentiation of benign and malignant thyroid nodules. A further improvement is expected with the development of the above mentioned new probe here, too.

In summary, the present study demonstrates the feasibility of Acoustic Radiation Force Impulse-Imaging of the thyroid gland. This new quantitative elastography method can be performed with high ($>90\%$) specificity in the diagnostic work-up of thyroid nodules. A further improvement is expected with the development of the above mentioned new probe here, too.

Reference


