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● *Original Contribution*

COMBINATION OF SONOELASTOGRAPHY AND TIRADS FOR THE DIAGNOSTIC ASSESSMENT OF THYROID NODULES

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Abstract—To evaluate the diagnostic performance of elastography alone and combined with Thyroid Imaging Reporting And Data System (TIRADS) for the assessment of non-autonomous thyroid nodules. We included 244 thyroid nodules and analyzed the visual elasticity scores, strain value (SV) and TIRADS classification. Histologic examination revealed 38 malignant (16%) and 206 benign nodules. The SV was lower in malignant nodules than in benign with an optimal cutoff ≤0.225. The visual elasticity scores showed a better diagnostic performance than the SV measurement. The risk for malignancy increased with higher TIRADS category. The sensitivity, specificity, positive predictive value and negative predictive value of TIRADS were superior to sonoelastography. The combination of TIRADS ≥4C and SV ≤0.225 showed the highest odds ratio to predict malignancy. Kwak-TIRADS classification is superior to elastography for the differentiation of benign and malignant thyroid nodules. Our data demonstrate that a high TIRADS class alone is predictive for thyroid carcinoma and the clinical relevance of sonoelastography is negligible. (E-mail: simoneschenke@web.de) **© 2017 World Federation for Ultrasound in Medicine & Biology. All rights reserved.**

Key Words: **Elastography, TIRADS, Thyroid cancer, Thyroid ultrasound, Strain value, Visual elasticity scores, Risk stratification.**

INTRODUCTION

The evaluation of thyroid nodules poses a challenge. In Germany, with a prevalence of up to 40% in people aged 46–65 y most of the nodules are benign and usually no surgery is required (Schumm-Dräger and Feldkamp 2007). However, in Germany the incidence of thyroid cancer increased markedly in the past years with 6000 new cases diagnosed in 2012 (Robert Koch Institut 2015; Vorländer et al. 2010). Gray-scale ultrasound (US) is excellent for the detection and characterization of thyroid nodules, but the accuracy for the differentiation between benign and malignant lesions based on single criteria is low (Friedrich-Rust et al. 2016). Recently, some authors suggested a US-based tool for stratifying the risk of malignancy of thyroid nodules because of a constellation of suspicious ultrasound features—Thyroid Imaging Reporting And Data System (TIRADS) (Grant et al. 2015; Ha et al. 2016; Horvath et al. 2009, 2017; Russ 2016). Kwak et al. (2011) showed in a first study that the risk for malignancy increased with the number of suspicious US features. In a further study, Kwak et al. (2013) revised their TIRADS by introducing a risk score because of the different probabilities of malignancy of each suspicious US feature. However, both TIRADS did not respect functionality of the thyroid nodules. The German national guidelines recommend a scintigraphy in the assessment of thyroid nodules ≥10 mm to differentiate autonomous nodules from hypofunctioning ones, because in autonomous nodules malignancy can be excluded with a high negative predictive value and no further investigation is required (German Society of Nuclear Medicine 2003; Giovanella et al. 2010).

Sonoelastography (also known as real-time elastography [RTE] or strain elastography) was introduced as a complementary tool to gray-scale US, which reflects the relationship between external compression and tissue deformation or strain. Soft tissue structures are more compressible than harder ones and a firm nature of a lesion is associated with a higher risk of malignancy. By use of this technique, three types of elasticity assessment can be acquired: (i) visual scoring measured by means of colors within the nodule, (ii) semiquantitative measurement of

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strain value (SV)—for example, if a 100-mm object has a strain of 1 mm, the strain value is expressed as 1—within a region of interest (ROI) as an absolute value and (iii) the calculation of a strain ratio (SR) of the SV in the nodule and the SV in the adjacent thyroid tissue as a reference region (Kwak and Kim 2014; Moon et al. 2012; Vorländer et al. 2010).

For visual evaluation of thyroid nodules, two elasticity scores are well-established: the three-point scale of elasticity scores (ES 1–3) published by Rago et al. (2010) and the four-point scale of elasticity scores (ES 1–4) according to Asteria et al. (2008).

Several studies showed promising results for the use of sonoelastography combined or not-combined with conventional US (Azizi et al. 2015; Cantisani et al. 2012; Çakal et al. 2015; Esfahanian et al. 2016; Friedrich-Rust et al. 2016; Shao et al. 2015; Vorländer et al. 2010; Wang et al. 2012). Russ et al. (2013) included the results of sonoelastography in a TIRADS and reported an improved sensitivity and negative predictive value compared with gray-scale US alone. In contrast, studies completed in past years have not confirmed the usefulness of sonoelastography (Aliasgarzadeh et al. 2014; Kagoya et al. 2010; Lippolis et al. 2011; Moon et al. 2012; Zhang et al. 2016).

The aim of our study was to evaluate the diagnostic performance of sonoelastography alone and combined with the former TIRADS according to Kwak et al. (2011) for the assessment of non-autonomous thyroid nodules.

MATERIALS AND METHODS

Because of the retrospective design of our study, the requirement of informed consent was waived. The data were obtained using a standard-of-care clinical protocol and performed in accordance with the ethical guidelines of the Helsinki Declaration.

Patients

We retrospectively analyzed an institutional database for patients who were examined by thyroid sonoelastography in our daily routine between 2009 and 2016 (n = 321 patients), only including patients who underwent thyreoidectomy (n = 200 patients). The indication for surgery was set multifactorial (nodular goiter, hypofunctioning thyroid nodules, MIBI-positive thyroid nodules, undetermined or suspicious fine-needle aspiration cytology, nodular goiter with cervical symptoms and suspicious US features).

Exclusion criteria were hyperfunctioning thyroid nodules in the scintigraphy (n = 6 patients), incidental papillary microcarcinomas, sonoelastographies stored without colors and sonoelastographies with too high or too low levels at the Quality Indicator scale. We thus included 194 patients (150 women and 44 men) with 244 thyroid nodules.

Thyroid US and RTE

The thyroid US and the sonoelastography were performed by three sonographers (S.S., M.Z., L.H.) with appropriate experience for the methods (more than 5 y for all investigators). Both, conventional sonography and RTE were conducted using a Hitachi EUB 5000 G (Hitachi, Ltd., Tokyo, Japan) and a Hitachi Avius Hi Vision (Hitachi, Ltd.), each equipped with a linear probe with a frequency of 5–10 MHz.

The patients were in supine position and the probe was placed on the thyroid. The compression was slightly and continuously performed using a hardware-specific 8-point Quality Indicator scale (Fig. 1, here 1–4). As a reference for reproducibility and to minimize inter- and intra-observer variability, all examiners only stored sonoelastographies that showed a level 3–5 at the Quality Indicator scale. In a preliminary study, we did not find a

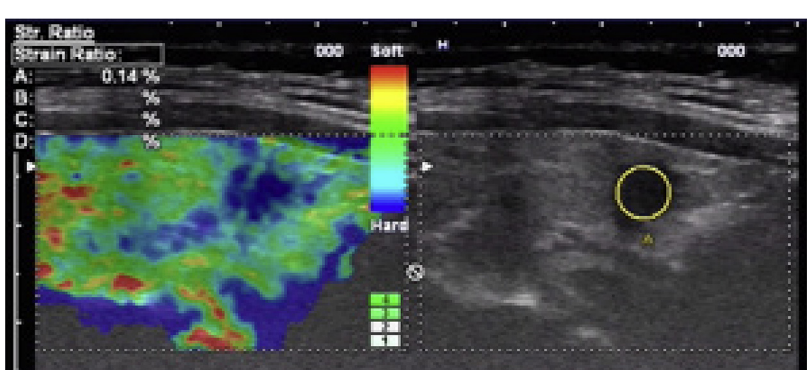

Fig. 1. SV measurement (0.14) with ROI technique (ROI size adjusted to the nodule size) on gray-scale B-mode ultrasound (*right screen*) and superimposed colored elastogram (*left screen*)—split by the color scale (soft to hard), as well as the Quality Indicatos scale (1/2 [*white*] to 3/4 [*green*]), (histopathology: papillary thyroid carcinoma pT1a). SV = strain value; ROI = region of interest.