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Medical Policy

Subject:	Quantitative Ultrasound for Tissue Characterization		
Document#:	RAD.00067	**Publish Date:**	04/13/2022
Status:	New	**Last Review Date:**	02/17/2022

Description/Scope

This document addresses quantitative ultrasound to evaluate visceral organs and other anatomic structures by using imaging data and software to analyze tissue characteristics. This technology is being explored as a noninvasive means to identify tissue traits without performing biopsies or using contrast agents.

Note: Elastography is a type of tissue characterization and is not addressed in this document.

Position Statement

Investigational and Not Medically Necessary:

Quantitative ultrasound for tissue characterization is considered **investigational and not medically necessary** for all indications.

Rationale

Quantitative ultrasound (QUS) for tissue characterization is being explored as a noninvasive means to evaluate visceral organs and other anatomic structures by exploiting imaging data and software to evaluate tissue characteristics. In contrast to brightness (B-mode) grayscale ultrasound (US) imaging that delivers qualitative information on anatomy, QUS extricates fundamental properties of a tissue based on the interactions of propagating US waves with the tissue microstructure. These US sub-resolution quantitative signatures of the tissue microstructure are then used to construct a measurement of a global physical quantity within a region of interest (ROI) or to provide parametric images for diagnosis (Cloutier, 2021).

Proponents of this technology have suggested that QUS be used for various indications, including but not limited to:

- Assessing clinical tumor response to treatment(s)
- Assessing hepatic steatosis and non-alcoholic fatty liver disease (NAFLD)
- Assessing fetal lung maturity.

Recent advances in technology have led to the incorporation of artificial intelligence (AI) applications with QUS to improve image quality and inter- and intra-observer variability.

Although other methods such as computed tomography (CT) and magnetic resonance imaging (MRI) maybe used to assess pathologies, QUS offers some unique advantages. For example: QUS for tissue characterization is non-ionizing in nature, requires no shielding or contrast agents, utilizes conventional power sources, provides real-time results and is portable (which could make it especially well-suited to point-of-care applications). However, when compared to these same imaging technologies, the value of QUS for tissue characterization is affected by some major drawbacks: inter- and intra-observer variability, poor image quality and heterogeneity of the specific parameter(s) studied (for example, spectral slope [SS], spectral intercept [SI], midband fit [MBF], spacing among scatters[SAS], attenuation coefficient estimate [ACE], average scatter diameter [ASD], average acoustic concentration [ACC], and texture features [TF]). Additional limitations of QUS techniques include confounding effects of body habitus and ascites. Unlike with MRI based techniques, QUS cannot simultaneously quantify fat in other organs. (Tadayyon, 2016; Zhou, 2021).

At the time of this review, no medical societies were identified that specifically address the use QUS for tissue characterization. The peer-reviewed, published literature to date on the accuracy and efficacy of QUS for tissue characterization consists predominately of feasibility and cohort studies.

Monitoring or Predicting Response to Treatment
As an example of some of the published research related to the use of QUS for tissue characterization, Tadayyon and colleagues (2016) investigated QUS as a means to monitor therapeutic response by evaluating alterations in QUS parameters at various time points. The researchers assessed breast tumor response to chemotherapy using a k-nearest neighbor (KNN) model based on QUS measurements, such as SS, MBF, SAS, SI, ACE, ASD, ACC, and TF. They determined that the best response classification was reached with an accuracy of 60%. They later improved their technique by using artificial neural network (ANN) on these measurements. Using the ANN, the researchers achieved improved accuracy (96 ± 6%) and the area under the curve (AUC) (0.96 ± 0.08) compared to the KNN model (accuracy 65 ± 10%, AUC 0.67 ± 0.14).

DiCenzo and colleagues (2020) conducted a multicenter study involving four locations in North America to develop a model for predicting response to neoadjuvant chemotherapy (NAC) in subjects with locally advanced breast cancer (LABC) using pretreatment QUS data. A total of 82 participants were included in the final analysis. Primary tumors were scanned using a clinical US system prior to NAC being started. The tumors were contoured, and radiofrequency (RF) data were acquired and processed from whole tumor ROI. QUS spectral parameters came from the normalized power spectrum, and texture analysis was carried out based on six QUS features (MBF, SI, SS, SAS, AAC and ASD) using a gray level co-occurrence matrix. Participants were divided into responder or nonresponder classes based on their clinical-pathological response. Classification analysis was completed using machine learning algorithms, which were trained to optimize classification accuracy. Cross-validation included a leave-one-out method. Using K-NN methodology, the authors found the best features to classify responders and nonresponders were identified as the AAC-HOM (homogeneity of the average acoustic concentration), SI-ENE, and SAS-ENE parameters. The researchers found that the KNN methodology reached a sensitivity of 91%, a specificity of 83%, and accuracy of 87%.

Dasgupta and colleagues (2020) investigated QUS based higher-order texture derivatives in predicting the response to NAC in individuals with locally advanced breast cancer (LABC). A total of 100 participants with LABC were scanned before commencing NAC. Five QUS parametric image-types were produced from radio-frequency data over the tumor volume. From each QUS parametric-image, 4 grey level co-occurrence matrix-based texture images were generated (20 QUS-Tex1), which were further processed to create texture derivatives (80 QUS-Tex1-Tex2). Study participants were classified into responders and non-responders based on clinical/pathological responses to treatment. Three machine learning algorithms based on linear discriminant (FLD), k-nearest-neighbors (KNN), and support vector machine (SVM) were employed to develop radiomic models of response prediction. A KNN-model supplied the best results with sensitivity, specificity, accuracy, and area under curve (AUC) of 87%, 81%, 82%, and 0.86, respectively. The most useful features in separating the two response groups were QUS-Tex1-Tex2 features. The 5-year recurrence-free survival (RFS) calculated for KNN predicted responders and non-responders using QUS-Tex1-Tex2 model were comparable to RFS for the actual response groups. The authors concluded that the QUS can detect tumor response before neoadjuvant chemotherapy with high accuracy using texture derivative analysis of parametric images using a machine learning approach.

In another study (Quiaoit, 2020), researchers reported the results of a multi-institutional study assessing the utility of QUS to predict final tumor response amongst subjects undergoing NAC. A total of 59 participants from three institutions in the United States were enrolled in the study. QUS data were collected prior to starting NAC and subsequently at weeks 1 and 4 during chemotherapy. Spectral tumor parametric maps were produced, and textural

features determined using grey-level co-occurrence matrices. Participants were divided into two groups (responders and non-responders) based on their pathological outcomes following surgery. Machine learning algorithms using Fisher's linear discriminant (FLD), K-nearest neighbor (K-NN), and support vector machine (SVM-RBF) were used to produce response classification models. A total of 36 participants were classified as responders and 23 as non-responders. Among all the models, SVM-RBF had the highest accuracy of 81% at weeks 1 and week 4 with area under curve (AUC) values of 0.87 each. The addition of week 1 and 4 features led to an improvement of the classifier models, with the accuracy and AUC from baseline features only being 76% and 0.68, respectively. The authors acknowledged limitations of this study include the small number of participating institutions and enrolled participants.

Tran and colleagues (2020) evaluated QUS to monitor responses to radical radiotherapy (RT) in individuals with node-positive head and neck malignancies. A total of 36 participants (33 males and three females) were included in this analysis. QUS spectral and texture parameters were obtained from metastatic lymph nodes 24 hours, 1 and 4 weeks after the initiation of RT. K-nearest neighbor and naive-Bayes machine-learning classifiers were used to generate prediction models for each time point. Response was measured after 3 months of RT, and subjects were classified as either complete or partial responders. Single-feature naive-Bayes classification functioned best with a prediction accuracy of 80, 86 and 85% at 24 h, week 1 and 4, respectively. The authors acknowledged that while the initial results of this study are promising, "further expansion of the study cohort to include patients from other institutions, and independent external validation, will help in testing the utility of the current feature set with the development of a reproducible feature set".

Quantification of Hepatic Fat

Han and colleagues (2020a) conducted a study to develop and evaluate deep learning algorithms that use radiofrequency data for NAFLD assessment, with MRI-derived proton density fat fraction (PDFF) as the reference. This study was a secondary analysis of 204 prospectively enrolled adult research subjects with NAFLD and control participants without liver disease. The parent study used a different US analysis technique. For this study, researchers developed and evaluated deep learning techniques in the same participants. Study participants were consecutively recruited by an expert hepatologist from a single institution between February 2012 and March 2014. Inclusion criteria required participants to be at least 18 years of age and willing and able to participate. NAFLD in participants was defined as MRI PDFF of 5% or greater, with other causes of steatosis excluded. The control group (MRI PDFF ,5%) had no liver disease based on comprehensive clinical and laboratory testing performed under the supervision of and interpreted by the hepatologist. All participants received same-day US and chemical shift–encoded MRI of the liver. Subjects were randomly divided into an equal number of training and test groups. The training group was utilized to develop two algorithms via cross-validation: a classifier to diagnose NAFLD (MRI

PDFF ≥ 5%) and a fat fraction estimator to predict MRI PDFF. Both algorithms utilized one-dimensional convolutional neural networks. The test group was used to gauge the classifier for sensitivity, specificity, positive predictive value, negative predictive value, and accuracy and to evaluate the estimator for correlation, bias, limits of agreements, and linearity between predicted fat fraction and MRI PDFF. A total of 204 subjects were analyzed, 140 had NAFLD (mean age, 52 years 6 14 [standard deviation]; 82 women) and 64 were control participants (mean age, 46 years 6 21; 42 women). In the test group, the classifier calculated 96% (95% confidence interval [CI]: 90%, 99%) (98 of 102) accuracy for NAFLD diagnosis (sensitivity, 97% [95% CI: 90%, 100%], 68 of 70; specificity, 94% [95% CI: 79%, 99%], 30 of 32; positive predictive value, 97% [95% CI: 90%, 99%], 68 of 70; negative predictive value, 94% [95% CI: 79%, 98%], 30 of 32). The estimator-calculated fat fraction correlated with MRI PDFF (Pearson r = 0.85). The mean bias was 0.8% (P = .08), and 95% limits of agreement were -7.6% to 9.1%. The predicted fat fraction was nonlinear with an MRI PDFF greater than 18% and linear with an MRI PDFF of 18% or less (r = 0.89, slope = 1.1, intercept = 1.3). The researchers concluded deep learning algorithms employing radiofrequency US data are accurate for diagnosis of NAFLD and hepatic fat fraction quantification when other causes of steatosis are eliminated. The authors acknowledged that the generalizability of the study results is limited because RF data are not yet readily available on all commercial ultrasound systems. Additionally, because the ultrasound data were acquired from a single scanner platform and by a single physician, the cross-platform and cross-operator generalizability of the algorithms remains to be demonstrated.

In another study, Han and colleagues (2020b) evaluated the relationship of QUS parameters to encoded MRI-derived proton density fat fraction (MRI PDFF) and to develop multivariable QUS models to identify hepatic steatosis and quantify hepatic fat. Adults with known NAFLD or who were suspected of having NAFLD were prospectively recruited and underwent QUS and chemical shift-encoded MRI liver examinations. Liver biopsies were performed when clinically indicated. The correlation between seven QUS parameters and MRI PDFF was assessed. By using leave-one-out cross validation, two QUS multivariable models were evaluated: a classifier to distinguish participants with NAFLD versus participants without NAFLD and a fat fraction estimator. Classifier performance was summarized by AUC operating characteristic curve and area under the precision-recall curve. Fat fraction estimator performance was appraised by correlation, linearity, and bias. A total of 102 participants, 78 with NAFLD (MRI PDFF ≥ 5%) were evaluated. A two-variable classifier yielded a cross-validated area under the receiver operating characteristic curve (AUROC) of 0.89 (95% confidence interval [CI]: 0.82, 0.96) and an area under the precision-recall curve of 0.96 (95% CI: 0.93, 0.99). The cross-validated fat fraction forecasted by a two-variable fat fraction estimator was correlated with MRI PDFF (Spearman ρ = 0.82 [P<0.001]; Pearson r = 0.76 [P<0.001]). The mean bias was 0.02% (P=0.97), and 95% limits of agreement were ± 12.0%. The predicted fat fraction was linear with MRI PDFF (R 2 = 0.63; slope, 0.69; intercept, 4.3%) for MRI PDFF of 34% or less. The

researchers concluded that the QUS approach yielded excellent correlation with MRI proton density fat fraction for hepatic steatosis assessment in NAFLD.

Jeon and colleagues (2021) evaluated the diagnostic performance of QUS parameters for the assessment of hepatic steatosis in individuals with NAFLD using MRI-PDFF as the reference standard. In this single-center prospective study, 120 participants with clinically suspected NAFLD underwent US examination for RF data acquisition and chemical shift-encoded liver MRI for PDFF measurement. Using the RF data analysis, the attenuation coefficient (AC) based on tissue attenuation imaging (TAI) (AC-TAI) and scatter-distribution coefficient (SC) based on tissue scatter-distribution imaging (TSI) (SC-TSI) were calculated. The correlations between the QUS parameters (AC and SC) and MRI-PDFF were assessed using Pearson correlation coefficients. The diagnostic performance of AC-TAI and SC-TSI for identifying hepatic fat contents of ≥ 5% (MRI-PDFF ≥ 5%) and ≥ 10% (MRI-PDFF ≥ 10%) were measured using receiver operating characteristic (ROC) analysis. The significant clinical or imaging factors correlated with AC and SC were examined using linear regression analysis. The subjects were classified based on MRI-PDFF: < 5% (n = 38), 5–10% (n = 23), and ≥ 10% (n = 59). AC-TAI and SC-TSI were correlated with MRI-PDFF (r = 0.659 and 0.727, p < 0.001 for both). For identifying hepatic fat contents of ≥ 5% and ≥ 10%, the areas under the ROC curves of AC-TAI were 0.861 (95% confidence interval [CI]: 0.786–0.918) and 0.835 (95% CI: 0.757–0.897), and those of SC-TSI were 0.964 (95% CI: 0.913–0.989) and 0.935 (95% CI: 0.875–0.972), respectively. The authors concluded multivariable linear regression analysis demonstrated that MRI-PDFF was an independent determinant of AC-TAI and SC-TSI. A limitation of the study included potential population biased toward NAFLD, as only 31.7% of the subjects were normal (MRI-PDFF < 5%); this does not reflect the prevalence in the general population. Additionally, although the QUS technique based on RF data analysis can be implemented in clinical US systems, it is not readily available in all clinical US systems.

Predicting Fetal Lung Respiratory Morbidity
Bonet-Carne and colleagues (2015) developed and evaluated the performance of QUS of fetal lungs for predicting neonatal respiratory morbidity as an alternative to testing using amniotic fluid. The investigators used the OUTEX and PHOTEX databases to access texture images acquired using different controlled parameters such as spatial resolution, illumination, and rotational angles. More than 13,000 non-clinical images and 900 fetal lung images were used to develop a computerized method based on texture analysis and machine learning algorithms, trained to forecast neonatal respiratory morbidity risk on fetal lung US images. The method, termed 'quantitative US fetal lung maturity analysis' (quantusFLM™), was then validated blindly in 144 neonates that were, delivered between 28 + 0 to 39 + 0 weeks gestation. Lung US images in Digital Imaging and Communication in Medicine (DICOM) format were acquired within 48 hours of delivery and the ability of the software to predict neonatal respiratory morbidity, defined as either respiratory distress syndrome or transient tachypnea of the newborn, was ascertained.

The researchers reported the Mean (SD) gestational age at delivery was 36 + 1 (3 + 3) weeks. Among the 144 neonates, 29 (20.1%) cases of neonatal respiratory morbidity were identified. Quantitative texture analysis calculated neonatal respiratory morbidity with a sensitivity, specificity, positive predictive value, and negative predictive value of 86.2%, 87.0%, 62.5% and 96.2%, respectively. The authors concluded QUS fetal lung maturity analysis predicted neonatal respiratory morbidity with an accuracy comparable to that of tests using amniotic fluid.

In another study, (Ghorayeb, 2017) reported the results of a retrospective study on the development of quantusFLM. The QUS fetal lung maturity analysis was used to determine if QUS could be used to differentiate premature (< 37 weeks' gestation) from mature (≥ 37 weeks' gestation) fetal lungs. Images were obtained from Voluson E8 US systems (GE Healthcare, Milwaukee, WI). An ROI was chosen in each fetal lung image at the level of the four heart chambers from an area that appeared most representative of the overall lung tissue and had the least shadow. Ultrasonic tissue heterogeneity (heterogeneity index) based on dynamic range calculation was performed for all lung images. This quantification was performed with a custom-made software program that used a dithering technique based on the Floyd-Steinberg algorithm, in which the pixels are changed into a binary map. Regression analysis was used to determine the correlation and functional association between the gestational age and the heterogeneity index. The AUROC was used to identify the optimal heterogeneity index cutoff point for differentiating preterm from mature fetal lungs. A total of 425 fetal lung US images (313 preterm and 112 term) were evaluated. Quantitative texture analysis forecasted gestational age with sensitivity and specificity of 87.9% and 92.0%, respectively, based on the optimal ROC cutoff point. The authors concluded that QUS texture analysis of fetal lung tissue can differentiate preterm fetal lungs from term fetal lungs and decreased fetal lung heterogeneity on US imaging is associated with preterm fetuses.

Summary
QUS for tissue characterization is an evolving technology that shows promise. Applying AI to QUS has the potential to provide real-time feedback to the sonographer during imaging acquisition, image quality control, and automatic ROI selection. However, currently, the peer reviewed scientific literature data do not permit conclusions regarding the relative merits of QUS for tissue characterization. Some of the limitations of the available data include poor image quality (such as poor spatial resolution and high noise), a lack of standardization of imaging acquisition parameters (such as image resolution) and procedures that vary among different institutions. Additionally, the peer-reviewed literature consists primarily of cohort studies and lacks randomized controlled trials that compare QUS for tissue characterization to tissue evaluation techniques that are considered standard of care in the medical community. Well-designed studies are needed that demonstrate the use of QUS for tissue characterization results in improved clinical outcomes.

Background/Overview

Examples of QUS devices that have received 510(k) clearance by the United States Food and Drug Administration (FDA) include, but are not limited to:

- Aplio Diagnostic Ultrasound System (Toshiba Medical Systems; Tustin, CA)
- ACUSON Diagnostic Ultrasound System (Siemens; Issaquah WA)
- LOGIQ E10 (GE Medical Systems, Wauwatosa WI).

Artificial intelligence (AI). AI includes several subfields including machine learning (ML) which aims to enable computers to conduct certain tasks based on previous experience. ML algorithms include, but are not necessarily limited to, deep learning (DL), support vector machine (SVM), naïve Bayes, random forest, and artificial neural network (ANN), (Zhou, 2021)

Definitions

Artificial intelligence: A category of computer science devoted to creating systems to perform tasks that would ordinarily require human intelligence; the vast field of science that has the goal of creating intelligent machines.

Artificial neural network: Computing systems inspired by biological neural networks to carry out various tasks with a huger a.

Attenuation: The reduction in intensity and power of sound waves as they travel through tissue.

Attenuation coefficient estimate (ACE): A measure of the quantity of radiation attenuation by a given thickness of absorber.

Brightness mode (B-mode): The US mode which provides two-dimensional images in grayscale for anatomical assessment.

Hepatic steatosis: An accumulation of excess fat in the liver, also known as fatty liver disease.

K-nearest neighbors (KNN): A nonparametric style of supervised learning algorithm used for both regression and classification; one of the basic classification algorithms in Machine Learning.

Neonatal respiratory morbidity: Also known as transient tachypnea of the newborn

Non-alcoholic fatty liver disease (NAFLD): A type of fatty liver disease that is not related to heavy alcohol use.

Texture analysis: Computerized methods that analyze medical images and identify subtle changes in the aspect, or texture, that are not visible to the human eye. These textural patterns are then used to train algorithms to predict clinical information (Bonet-Carnes, 2015).

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

0689T	Quantitative ultrasound tissue characterization (nonelastographic), including interpretation and report, obtained without diagnostic ultrasound examination of the same anatomy (eg, organ, gland, tissue, target structure)
0690T	Quantitative ultrasound tissue characterization (nonelastographic), including interpretation and report, obtained with diagnostic ultrasound examination of the same anatomy (eg, organ, gland, tissue, target structure)

ICD-10 Diagnosis

All diagnoses

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Peer Reviewed Publications:

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Websites for Additional Information

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
New	02/17/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.