Virtual Biopsy and Three Dimensional Ultrasound for Radio Frequency Ablation of Thyroid Nodules

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Aims and objectives

Free-hand Ultrasound (US) plays an important role in thyroid diagnostics as a real-time examination, not ionizing and non-invasive, cost effective, ideal also for repetitive follow-up and able to give information about anatomy (B-Mode modality), hemodynamics (Color, Power Doppler) [1,2] and tissue stiffness, i.e. Elastosonography [3].

Furthermore, US is the most used imaging technology for guiding fine needle aspiration biopsy [4] and minimally invasive treatments of the thyroid, for instance Radio Frequency Ablation (RFA), Ethanol injections [5] or Laser [6].

A recently published Consensus Statement and Recommendations review article [7] describes a moving shot technique under local anesthesia as a safe and effective RFA procedure (moving technique necessary especially for the prevention of voice change). Moreover, a continuously monitored US-guided tracing of the electrode tip is mandatory during RFA. Evaluation of the internal vascularity of the nodules is requested. Three orthogonal nodule diameters, in order to calculate the volume of the nodule, have to be measured and evaluated, also after the treatment, and for follow up at 1-2, 6 and at 12 months after RFA procedure, as well as every 6-12 months thereafter, depending on the status of the treated nodules [7].

The present work is a technological analysis and evaluation of advanced US technologies (Virtual Biopsy, Three-dimensional reconstruction, Elastosonography, Color and/or Power Doppler and low mechanical index Contrast enhanced US - CEUS) that can answer to the practical needs of RFA of thyroid nodules.

The innovative Virtual Biopsy technology allows virtual needle visualization during the above mentioned moving shot technique. To assess the results of the RFA procedure a comparison between pre-post ablation is also performed by three-dimensional real-time US acquisition of the interested area, acquired both with motorized probe as well free-hand US probe coupled with Electromagnetically (EM) tracking system.

Furthermore, the procedure was enhanced by a Motion Compensation (MC) technique, using a Motion Control Sensor (MCS), which corrected possible subject's voluntary, or involuntary movements, for patient's and sonographer's increased comfort and easier US scanning.

Methods and materials

A. Subject Predisposition

Five patients (4 female, 1 male) with benign thyroid nodules (mean age = 57, range = 42-70) underwent US examination and RFA ablation of the thyroid nodule, after signing a written informed consent. The RFA was performed using a RF Generator-M2004 (equipped with pump RFP 100 and jar for system cooling) with 6 cm and 10 cm radio frequency electrodes RFT-0710N (RF Medical Co., Ltd., Seoul, Korea).

The subject was lying on the examination bed, with the neck slightly hyper-extended and positioned on a head support, in order to keep the neck as stable as possible (Fig. 1).

All the subjects were anesthetized by a US-guided percutaneous approach at the level of the targeted area, using Naropina 7.5 mg (AstraZeneca S.p.A., Basiglio, Milano, Italy).

B. Image Acquistion and RFA Guidance

For all the examinations and RFA guidance, an Esaote MyLabTwice US system (Esaote S.p.A., Genova Italy), equipped with Virtual Navigation option [8], allowing real-time image fusion of 3D US with 2D US scans, was employed. Moreover, Esaote LA523, LA533, LA332 Linear array probes and BL433 Volumetric Linear array probe (LA523 - Operating Bandwidth: 4-13 MHz; LA332 - Operating Bandwidth: 3-11 MHz; LA533 - Operating Bandwidth: 3-13 MHz; BL433 - Operating Bandwidth: 4-13 MHz) with different reusable tracking brackets with sensor mounted (Esaote Virtual Navigator electromagnetic sensor receiver dedicated support for LA523 and BL433; CIVCO 639-042 for LA533; CIVCO 639-031for LA332 - CIVCO Medical Solutions, Kalona, Iowa, USA) were used. Virtual Navigator tracking of the RFA electrode and real-time fusion imaging between 3D and 2D US data on the US system was possible by an electromagnetic tracking system, consisting of a transmitter on a fixed position, a small receiver mounted on the US probe through a dedicated support and the MCS, applied on the patient's skin close as much as possible to the examined area (in this case, the patient's sternal heads conjunction). A proper disc support for the sensor and a blockage with plaster strips were used in order to maintain the MCS as steady as possible. The transmitter, whose position is considered to be the origin of the reference space system, corrected by the data coming from the MCS, was kept steady by a proper support, while the position and the orientation of the US probe in the created 3D space was provided by the receiver unit. The same electromagnetic tracking system, provided for the US probe, was used also for the RFA electrodes tracking. The receiver support used was a CIVCO VirtuTrax (VTrax) Instrument Navigator (CIVCO Medical Solutions, Kalona, Iowa, USA). The magnetic field produced by Virtual Navigator EM tracking system is stronger at the transmitter site and it fades with distance from the transmitter: the magnetic field is lower than the Earth's magnetic field at a distance of 78 cm from the transmitter, therefore the MCS movement freedom was possible within 78 cm. The EM transmitter was properly positioned to keep all sensors (i.e., US probe, MCS and VTrax) in the most homogeneous region, sited around 50 cm from the source. A non-metallic table was used to reduce as much as possible the interferences with the created electromagnetic field. The MC precision test was already performed and described in a previously published study [9].

The treatment area was a sterile zone which required the use of sterile covers for the US probes and also for the VTrax tool (CIV-Flex Sterile Covers, CIVCO Medical Solutions, Kalona, Iowa, USA).

C. Three-Dimensional US, Fusion Imaging and RFA Procedure

Before starting the Virtual Biopsy and the three-dimensional US (motorized probe or 3D Pan) procedures, a check of the accuracy of the electromagnetic field was performed: the same point coordinates were measured twice in two different spatial orientations by a dedicated registration pen, with the electromagnetic sensor mounted in. Precision lower than 0.2 cm was considered acceptable.

Virtual Biopsy, enabled by the Virtual Navigator technology, gave to the operator the possibility to plan the RFA electrode path even before its insertion. The RFA electrode insertion was guided in plane and out of plane with proper graphical indications in both situations. The Virtual Biopsy was used considering the single plane 2D US scan alone or considering also the fusion between the 3D Pan acquisition and the 2D Us scan, in order to enlarge the field of view and to have three-dimensional view of the examined and treated area.

A particular visualization tool of the Virtual Biopsy, the Intelligent Positioning system, allowed to activate a sort of viewfinder at the level of the tip of the RFA electrode, in order to help the operator to reach the desired target.

The three-dimensional US acquisition was performed both using a 3D motorized linear probe, electromagnetically tracked in order to enable the fusion imaging between the acquired 3D volume and the 2D US real-time acquisitions, and also using the 3D Pan technology which enabled the use of the same 2D probe for the acquisition of free-hand electromagnetically tracked US volumes.

The 3D Pan tool, based on the electromagnetic field positioning capabilities of Virtual Navigator technology and already employed in other clinical applications [9,10], enabled the gluing of different 3D US neck volumes and the navigation within. The operator had the possibility to use the usual 2D transducers (LA533 and LA332) for volume acquisitions and then to shift to the 2D real-time fusion imaging with the pre-acquired 3D US volume, without any re-synchronization procedure between 3D and 2D views.

A thick layer of sterile US gel (Aquasonic 100, Parker Laboratories Inc, Fairfield, New Jersey, USA) was used to ensure a complete coupling between the transducer and the examined subject's skin, to avoid black cones and dark areas on the US image and to prevent excessive pressure on the examined area, in order not to change the neck tissue shape and position.

Custom color ball targets were placed on the acquired 2D scans directly or on the 3D US volume, in order to identify the thyroid areas that have to be scanned and treated more precisely, applying different tools for increased diagnostic confidence. Patients underwent US guided RFA treatments for benign thyroid nodules and also Elastosonography around the US-visible nodule, Color Doppler or Power Doppler plus low mechanical index CEUS in order to study the vascularization of the thyroid nodule and its volume. SonoView US contrast media was administered before and after the treatment (Bracco S.p.A., Milano, Italy).

3D Pan reconstruction and gluing algorithm of different US volumes could work using two different processes: "Preview" made a 3D global reconstruction, based only on the geometric and position information given by the probe position and orientation within the Virtual Navigator electromagnetic field, while "Auto", in addition to the information coming from the tracking system, performed a data analysis focused on tissue structure recognition, in order to find the best matching among the volumes. This could be particularly useful to compensate small movements, due to breathing and/or little tissue compression caused by the US probe during scanning. Major tissue deformation leads to a failure of the automatic gluing process.

Images for this section:

Fig. 1: Patient's position on the examination bed with the head slightly hyper-extended and positioned over a head support

Results

Virtual Biopsy guided RFA treatment (Fig. 2) was performed in all the five scheduled patients for thermal ablation of benign thyroid nodules. One nodule was treated in each subject. The Virtual Biopsy was used with the fusion between the real-time 2D scan and the already acquired 3D US volumes of the same patient. In two patients the 3D US acquisition was performed using the 3D motorized probe BL433 while the 2D US guidance of the RFA electrode and the acquisitions of the 2D US scans for the real-time fusion imaging with the 3D US, was performed with the 2D linear array LA523.

In the remaining patients the LA533 and LA332 probes (for 2 subjects and 1 subject, respectively) were used for needle guidance using the Virtual Biopsy tool and also for 3D Pan acquisitions of thyroid volumes. The number of volumes acquired was dependent by the size of the nodule to be treated (2 volumes was the average). LA533 and LA332 probes have a dual-possibility hand grip design, pinch grip and palmar grip (appleprobe design), in order to provide a neutral wrist position. This resource represented an additional operator's comfort option during long RFA sessions. Moreover, the presence of a single tracking sensor on the probe enabled the operator to handle the transducer in both pinch grip and palmar grip [11].

Due to the small array width of the LA332 probe (36 mm) which enabled high maneuverability on short necks, and due to its low frequency and high depth scanning capability, the probe was used with the TPView, enlarged field of view imaging technology, in order to obtain the scanning sector size of a convex, with the improved coupling capability of a linear probe.

The scanning velocity during Virtual Navigator 3D Pan acquisitions didn't affect the reconstruction as the probe spatial position was recorded at more than 50Hz, in this way it was guaranteed a perfect re-alignment of the acquired US [9,10].

Virtual Navigator 3D Pan volumes were acquired scanning longitudinally the neck surface. Two US volumes (with 12 seconds scan time for each US 3D acquisition) were fused together with 3D Pan tool, in order to obtain a panoramic volume of almost half thyroid containing the target nodule. The obtained Pan volume was achieved with the Auto gluing algorithm. A surface shift after the US volumes gluing was noted: the reason of this shift can be found in the pressure applied on the probe during the neck volume acquisitions. Different tissue densities of the neck areas can lead to different compressions during scanning. The Auto gluing algorithm works recognizing and matching the inner structures of the scanned volumes (focused on the re-alignment of inner structures) and leaving a discontinuity reconstruction only at the surface level, considered the "less interesting" part of the reconstructed volume.

The target thyroid nodule and its surrounding tissues were examined also performing ElaXto. Elastosonography was performed for tissue stiffness evaluation of the nodule and the surrounding thyroid areas. In terms of elasticity, the nodule, with respect to the surrounding thyroid parenchyma, resulted harder, as shown in the ElaXto color coded map. The elastosonography evaluation of the nodule and the surrounding thyroid parenchyma stiffness was performed also during real-time simultaneous visualization of 2D US scan, fused with the glued US volume. Elastosonography helped the operator to clearly detect the target nodule, being stiffer than the thyroid surrounding parenchyma. Bi-dimensional US ElaXto examination was performed in different directions, scanning the nodule on several planes containing different nodule views, in order to include the whole area around the nodule (Fig. 3).

Virtual Navigator 3D Pan acquisitions (Fig. 4) were performed taking care of maintaining an overlapping region among the different US volume acquisitions and to limit the shadowing effect as much as possible, avoiding poor probe-tissue coupling with consequent reduction in image quality, in order to obtain high quality B-Mode imaging in all the examined volumes.

The complete duration of the US thyroid examination was increased by 4 minutes in average, due to the US volume acquisitions. The MCS was used and positioned on the patient's sternal heads conjunction.

Custom color volumetric ball targets, visible on both 2D US and 3D Pan volume, were used in order to better identify the interesting areas. Color Doppler, Power Doppler, Pulsed Wave Doppler evaluations were performed also during real-time simultaneous visualization of 2D US scan fused with the glued US volumes, in order to make a hemodynamic assessment of the nodule and of the surrounding areas. Elastosonography was used in order to recognize thyroid stiffer regions.

The Virtual Biopsy tracked RFA treatments were performed with 6 cm electrodes (in 2 patients) and 10 cm electrodes (in 3 patients), depending on the size and depth of the nodule to be treated. Both RFA tools were electromagnetically tracked within the Virtual Navigator reference space using the CIVCO VTrax. A proper bending of the electrode was performed by the operator (in order to overcome obstacles to properly ablate the nodule) securely keeping the RFA electrode tip within the width of the Virtual Biopsy virtual needle graphical representation ("arrow-shaped" region).

At the moment of the insertion of the RFA electrode, due to tissue compression and to minor neck movements of the patient, a minor fine tuning was necessary in order to maintain properly fused together the 3D acquisition with the 2D real-time scanning.

CEUS was performed before the treatment to check nodule vascularization and exact dimensions. 3D US acquisitions were preformed both regarding CEUS and also regarding conventional B-Mode acquisitions in order to acquire the volume for volumetric measurements and in order to use the pre-treatment volume during the US guidance of the RFA tool. Especially during the gas out phase of the thermal ablation treatment, the real-time fusion imaging of the pre-treatment 3D acquisition was used for visual control of the area already treated with respect to the nodule area still to be treated.

The Virtual Biopsy needle tip virtual visualization was used in order to help the operator during the moving shot technique (Fig. 5) so that he/she is able to move frequently the RFA electrode tip securely also during the gas out phase of the treated tissues. The gas out creates a physical limit for the US propagation which did not allow the operator to clearly see directly the real electrode tip, therefore relying mostly only on its virtual representation offered by the Virtual Biopsy technology.

After the treatment, the nodule was re-acquired with the 3D probe in three 3 patients and with the 3D Pan technology on 2 patients, in order to compare the volume of the nodule before and after the RFA treatment. This procedure was performed in B-Mode modality and also with CEUS (Fig. 6).

Images for this section:

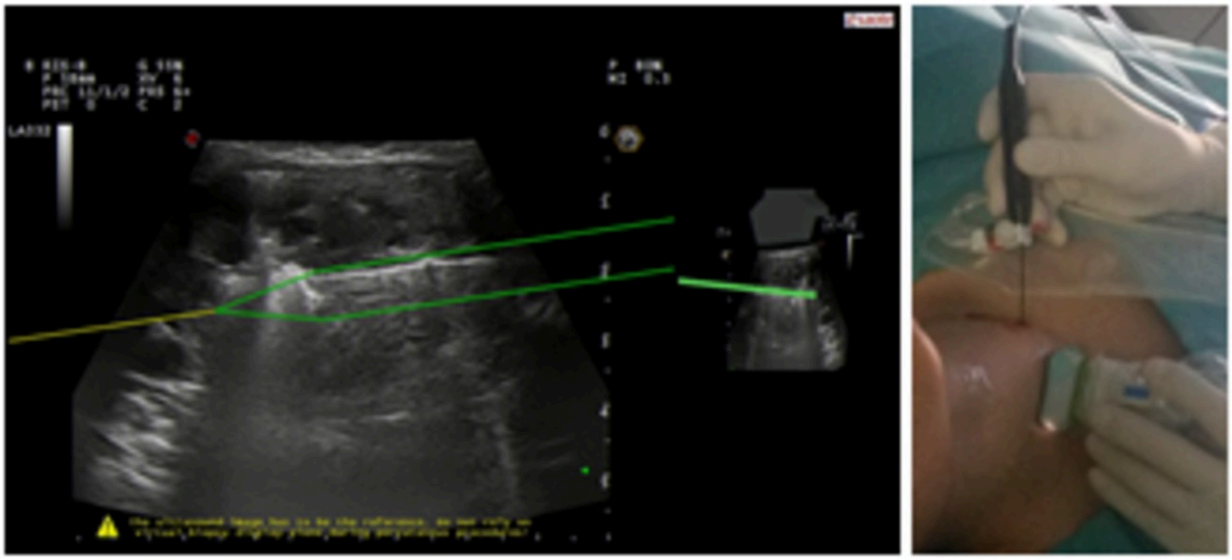

Fig. 2: Left: Virtual Biopsy representation with virtual RFA electrode path shown as a green "arrow", indication of the electrode expected path both regarding the 2D US image and also the 3D representation of the needle and the relative position of the probe in a three-dimensional space. Right: real position of the Linear array probe (LA332) and the RFA electrode during the RFA treatment

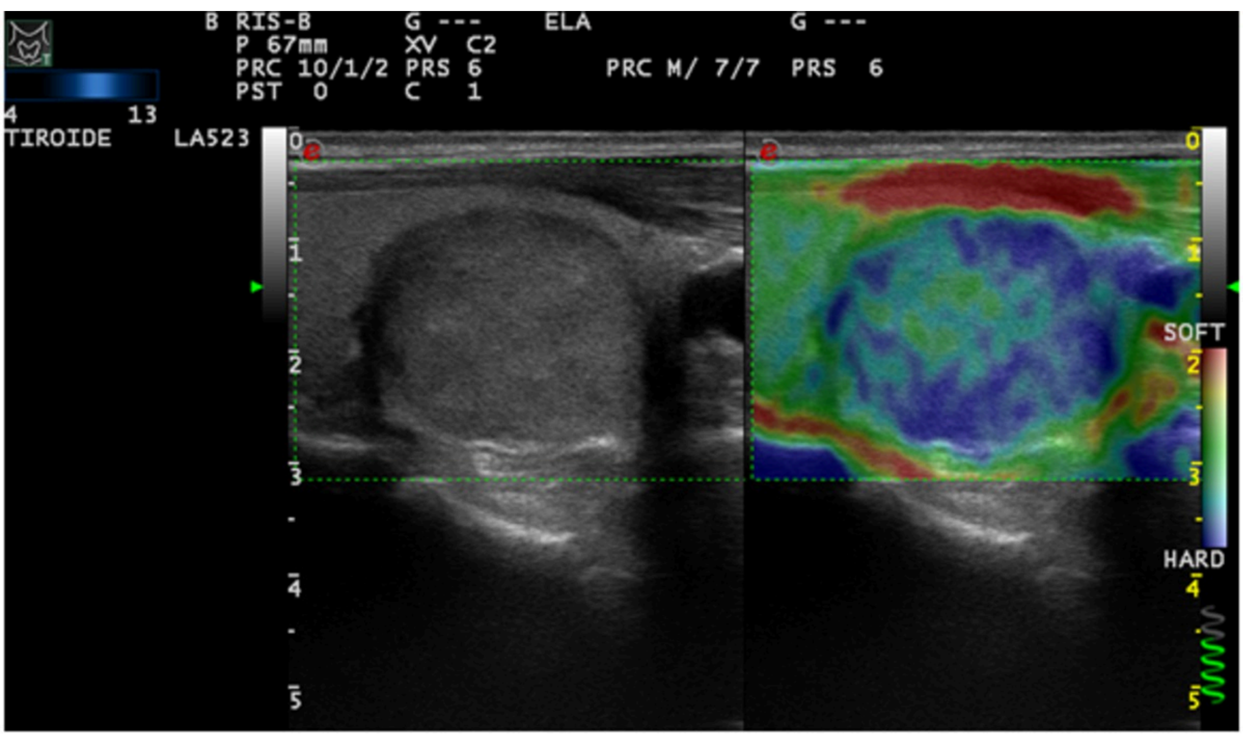

Fig. 3: Bi-dimensional US ElaXto examination for tissue stiffness evaluation of the nodule and the surrounding thyroid areas

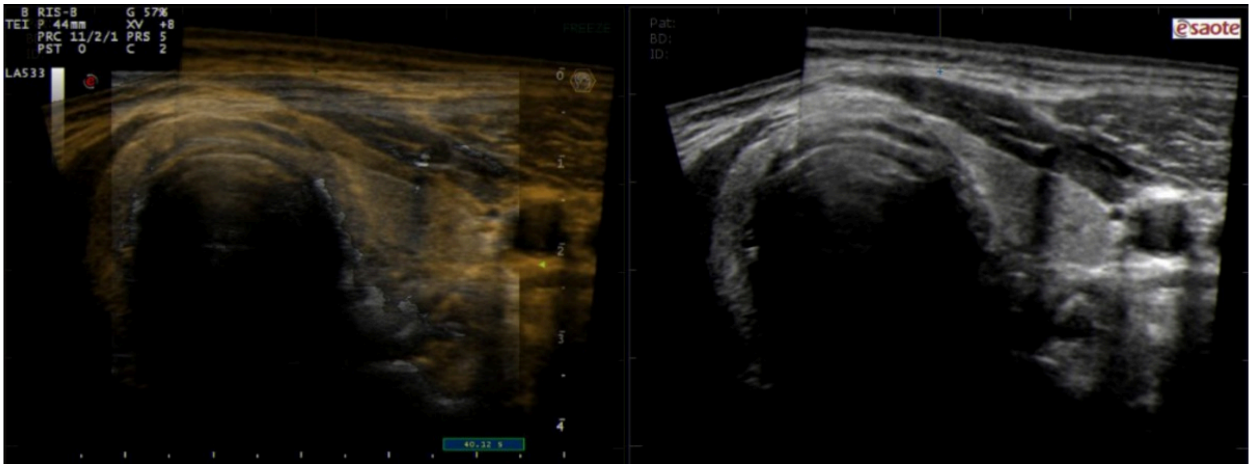

Fig. 4: Right: Virtual Navigator 3D Pan acquisition of 2 volumes of the thyroid, fused together with a 3 mm overlap. 3D Pan volume is then over imposed to the real-time 2D US acquisition of the thyroid in order to obtain a real-time fusion imaging between 2D US and 3D Pan US

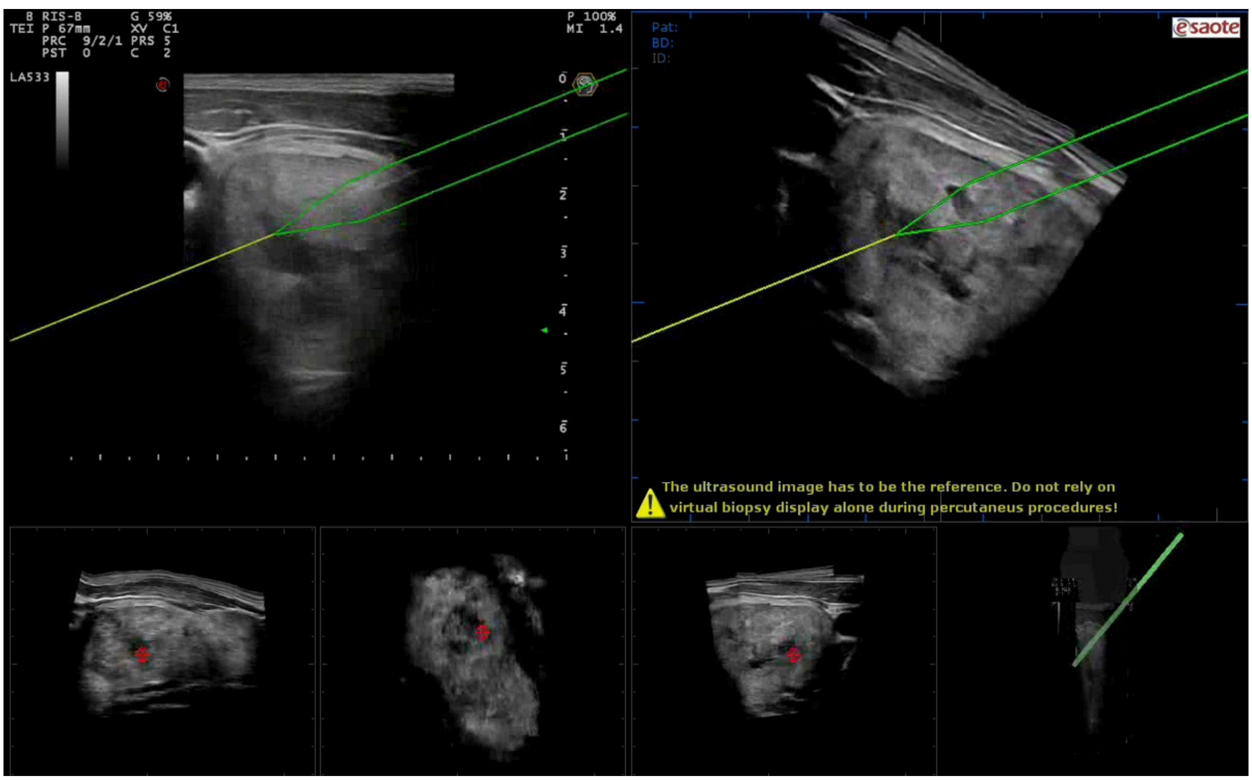

Fig. 5: Virtual Biopsy representation of the RFA electrode during the moving shot technique. The RFA electrode virtual representation is shown on the 2D US real-time image (upper row, left), on the 3D Pan (upper row, right), on the Coronal, Axial and Sagittal 2D US views and the 3D representation of the virtual position of the RFA electrode and relative position of the probe (lower row, from left to right)

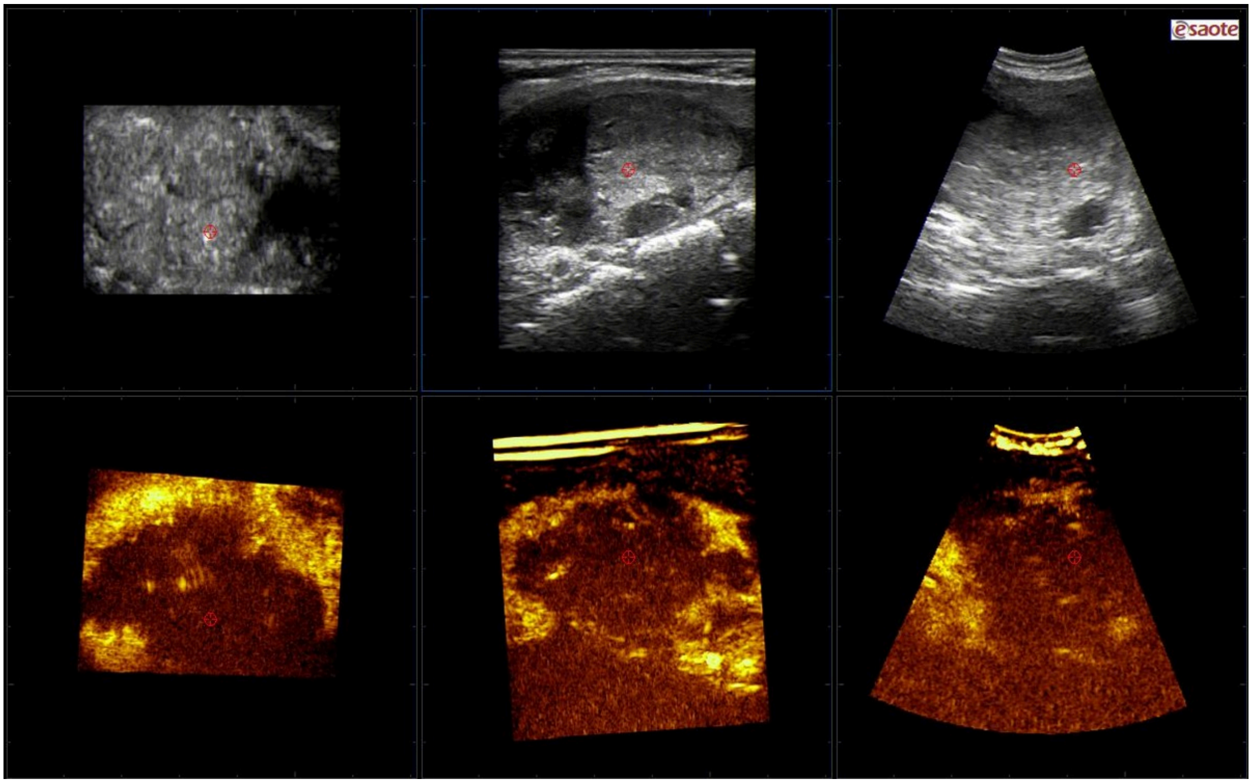

Fig. 6: Comparison of the B-Mode 3D representation of the thyroid nodule target of the RFA treatment before the treatment (upper row; from left to right: Coronal, Axial, Sagittal views), with the CEUS 3D representation of the same nodule after the RFA treatment (lower row; from left to right: Coronal, Axial, Sagittal views)

Conclusion

In this preliminary study, Virtual Biopsy technology facilitated the RFA electrodes insertion. With its graphical representation of the electrode tip insertion point and the planning of the path within the area to be treated, it represented a valuable tool for improved practical confidence. The confidence is even increased by the possibility to monitor in real-time the tissue stiffness with elastosonography and the hemodynamics of the nodule and surrounding areas using Doppler technologies and CEUS.

Virtual Biopsy technology enabled a secure visualization of the RFA electrode tip during the complex shot moving technique, also during the gas out phases of the ablation procedure, which gave the operator a bad or completely dark view of the treated area. Furthermore, the presence of nerves (i.e. vagus or laryngeal) and vessels (i.e. carotid artery, internal jugular vein) in the treated area, requires a high level of attention during the procedure.

Virtual Navigator real-time fusion imaging can help, during the gas out phases of the RFA treatment, the correct and complete visualization of the area already treated respect to the one still present. This, enhancing the overlap of the 3D pre-treatment volume over the 2D real-time acquisition.

Virtual Navigator 3D Pan technology showed to be a reliable and easy tool that fused 3D US thyroid anatomical data with bi-dimensional US scans. Real-time Color Doppler, Power Doppler, CEUS and Elastonography evaluations were performed, while navigating within the 3D Pan volume, in order to respectively analyze the hemodynamic and stiffness characteristics of the examined area.

Custom color targeting of the nodule allowed the operator to easily identify and spatially localize the targets, navigating within the whole picture given by the 3D Panoramic view. The EM tracked free-hand acquisition enabled the operator to cover all the areas of interest.

The extended duration of the treatment time for the 3D US acquisitions (before and after the treatment) was balanced by the increased level of confidence and the easier navigation within the 3D US volume for both the treatment and checking phase.

For all the patients a satisfactory visual matching between the US volume and the relative 2D US was obtained.

All the ablation treatments were successfully performed without any patients' complication.

The 3D Pan technology was highly preferred to the traditional 3D US acquisition performed with the volumetric probe, as it was not necessary to change any probe between the 3D acquisition and the 2D scanning. Moreover, the 3D probe was too large in order to perform a correct and secure RFA treatment with the required shot moving technique. The substitution of the probe was performed three times: one for the initial volume acquisition, one for the 2D scan and the RFA electrode guidance and one for the final volume acquisition for the ablated area check with respect to the initial volume. The substitution of the EM receiver between a 2D and a 3D probe increased the use of sterile covers, therefore increasing the overall costs of the treatment.

MCS is an innovative technology that corrected subject's movements, in order to simultaneously increase patient's and operator's comfort and to ease US scanning and US-guided treatment procedures.

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