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Contrast-Enhanced Ultrasound for the Evaluation of Focal Liver Lesions – a Multicenter Trial in Romania

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Focal liver lesions (FLL) are frequently discovered in daily practice during routine ultrasound and, sometimes, require the use of extensive investigations for a correct diagnosis, thus increasing the costs and duration of diagnosis. On the other hand, due to screening strategies for patients with liver cirrhosis, FLL are discovered very early in these patients and they must be evaluated in order to establish a therapeutic strategy (including transplantation, surgical resection or percutaneous ultrasound-guided procedures).

Contrast-enhanced ultrasound (CEUS) using second generation contrast agents is a relatively new imaging modality that allows characterization of FLL and also positive diagnosis based on the vascular pattern of the lesion [1-8]. The advantages of this method are the relatively low cost as compared with other imaging modalities and it can be performed immediately after standard abdominal ultrasound. Consequently, a reliable diagnosis can be obtained approximately after 5-10 minutes (total duration of CEUS) [9-10].

The place of CEUS in the diagnostic algorithm of FLL is not very well established. The European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) issued the first Guidelines regarding the use of CEUS in 2004, revised in 2008, including the main indications of this method. However, some of the data included in the guidelines, as well as the accuracy of the method and the percentage of patients with "conclusive" CEUS findings has been constantly questioned, including some recent articles [11].

Romanian Society of Ultrasound in Medicine and Biology (SRUMB) initiated a Multicentric Trial of Contrast-Enhanced Ultrasound in Focal Liver Lesions The purpose of this study is to establish the value of CEUS in the evaluation of de novo FLL in clinical practice in Romania.

In Romania, CEUS that is applied to patients with liver focal lesions has certain particularities:

– for the moment CEUS is not refunded by the national insurance system. This is the main reason why patients apply for this method less frequently as compared with other E.U. countries.

– however, gastroenterologists and hepatologists who work in university hospitals or private clinics use high quality ultrasound equipment with specific contrast software. Thus, for these specialists, CEUS is the first diagnostic method employed in recently discovered FLL.

The study will include consecutive patients discovered with one to three newly discovered FLL during standard ultrasound, if the ultrasound study is not conclusive for the positive diagnosis. State-of-the-art CT/MR or histopathological exam should be available for all patients.

The patient data will be registered online, using the study site: study.umfcv.ro, while the trial was registered in clinicaltrials.gov (Identifier NCT01329458). The number, size and location of FLL will be documented using the Couinaud classification. The indication for CEUS study shall be documented in every patient. Each examination will last about 5 min after bolus injection and will be documented by 4 video files no longer than 30 seconds

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each, containing: the standard study, the arterial phase, the portal phase and the late phase. Additional loops can be stored whenever it is considered necessary. The ultrasound films in the original ultrasound format (preferable avi), uncompressed, will be stored in digital format.

This study was registered on clinicaltrials.gov and received approval from the institutional ethical review board. A dedicated website (http://study.umfcv.ro) was developed by the University of Medicine and Pharmacy of Craiova. **This website** provides hosting and support for many multicentre studies. Until the 1st of July 2011, thirty-nine physicians from eight university centers joined the study. The majority of them are from Bucharest. In the first four months, 209 patients with focal liver lesions had been enrolled in the study. Hepatocellular carcinoma was predominant CEUS diagnosis (70 patients), followed by haemangioma and liver metastases.

More information: http://study.umfcv.ro.

References

1. Strobel D, Seitz K, Blank W, Schuler A, Dietrich C, von Herbay A. Contrast-enhanced Ultrasound for the Characterization of Focal Liver Lesions-Diagnostic Accuracy in Clinical Practice (DEGUM multicenter trial). Ultraschall Med 2008; 29: 499-505.
2. Tranquart F, Le Gouge A, Correas JM, et al. Role of contrast-enhanced ultrasound in the blinded assessment of focal lesions in comparison with MDCT and CEMRI: Results from a multicentre clinical trial. EJC 2008; 6: 9-15.
3. Braun B. Focal liver processes: "better is the enemy of good": CEUS in the fast lane. Ultraschall Med 2009; 30: 329-32.
4. Wilson SR, Greenbaum LD, Goldberg BB. Contrast-enhanced ultrasound: what is the evidence and what are the obstacles. Am J Roentgenol AJR 2009; 193: 55-60.
5. Wang WP, Wu Y, Luo Y, Li R, Zhou XD, Zhang J et al: Clinical value of contrast-enhanced ultrasonography in the characterization of focal liver lesions: a prospective multicenter trial. Hepatobiliary Pancreat Dis Int 2009; 4: 370-376.
6. Trillaud H, Bruel JM, Valette PJ, et al: Characterization of focal liver lesions with SonoVue®- enhanced sonography: International multicenter-study in comparison to CT and MRI. World J Gastroenterol 2009; 15: 3748-3756.
7. Quaia E, Calliada F, Bertolotto, et al: Characterization of focal liver lesions with contrast-specific US modes and a sulfur hexafluoride-filled microbubble contrast agent: diagnostic performance and confidence. Radiology 2004; 232: 420-430.
8. von Herbay A, Vogt C, Willers R, Häussinger D. Real-time imaging with the sonographic contrast agent SonoVue: differentiation between benign and malignant hepatic lesions. J Ultrasound Med 2004; 23: 1557-1568.
9. Albrecht T, Blomley M, Bolondi L, et al. for the EFSUMB Study Group. Guidelines for the use of contrast agents in ultrasound. Ultraschall Med 2004; 25: 249-256.
10. Claudon M, Cosgrove D, Albrecht T, et al. Guidelines and good clinical practice recommendations for contrast enhanced ultrasound (CEUS). Update 2008. Ultraschall Med 2008; 29: 28-44.
11. Giorgio A, Calisti G, Giorgio V. CEUS and HCC: Are the 2008 EFSUMB Guidelines Still Valid or Has Their Wash-Out Already Started? Ultraschall Med 2011; 32: 315-316.