

EFSUMB guidelines 2015 on interventional ultrasound

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Abstract

Ultrasound-guided interventions have revolutionized the everyday clinical practice during recent decades. The new interventional ultrasound (INVUS) guidelines of the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) are an expression of interdisciplinary and multiprofessional viewpoints, some of which represent different approaches; this reflects reality in all its diversity. Particular attention has been given to clinical significance including the level of evidence and the more practical grade of recommendation. The review refers to the history of interventional ultrasound and comments on the current EFSUMB guidelines.

Keywords: guidelines, recommendations, biopsy, drainage

Introduction

The European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) purpose has always been to promote the exchange of scientific knowledge in the field of ultrasound (US) [1]. Over the last decade, EFSUMB has produced a series of Guidelines and Recommendations regarding different ultrasound applications. Contrast-enhanced ultrasound (CEUS) guidelines were first introduced by EFSUMB in 2004, centred on liver applications [2]. The CEUS liver guidelines were then updated in 2008 [3] and 2012 [4,5]. The current version was a successful joint WFUMB (World Federation of Ultrasound in Medicine and Biology) – EFSUMB venture simultaneously published in *Ultraschall in der Medizin / European Journal of Ultrasound (EJU)* [4] and *Ultra-*

sound in Medicine and Biology (UMB) [5]. EFSUMB CEUS non-liver guidelines were also recently published, expanding the clinical indications for CEUS to almost 30 applications [6]. In addition an introduction into dynamic contrast enhanced Ultrasound (DCE-US) for quantification of tumour perfusion was published as well [7]. The first elastography guidelines worldwide were introduced and published by EFSUMB in 2013 [8,9].

The successful EFSUMB guidelines published in the official journal “*Ultraschall in der Medizin / European Journal of Ultrasound*” have gained widespread attention. The impact factor (IF) of the journal has climbed to an impressive 4.9, which is the highest IF of an interdisciplinary ultrasound journal worldwide. The Guidelines and Good Clinical Practice Recommendations are freely available to download from the EFSUMB website. EFSUMB has also embarked on setting up an atlas of images to illustrate the various Clinical Recommendations and Guidelines published, which includes a variety of CEUS and elastographic applications [1] (www.efsumb.org).

The introduction of any new diagnostic or treatment tools and guidelines typically follows a pattern [10,11]. It is worth mentioning that new and often valid methods are not always or are only rarely supported by the highest ranking level of scientific evidence, namely randomized

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controlled trials. Often these innovations are so obviously of benefit that randomized controlled trials involving older, less safe or less effective techniques could be deemed unethical. The expert opinions expressed within the Guidelines are independent and free of bias, based on the best evidence for clinical practice and any potential conflict of interest of each individual author is disclosed in the online version for a maximal transparency. This should always be expected for guidelines drafted according to modern standards [12].

We also refer to the current published textbook on interventional ultrasound which was also a motivation for more evidence-based recommendations [13,14].

An introduction into the history of interventional ultrasound

Clinical ultrasound was first introduced in the sixties in the fields of ophthalmology, neurology (echoencephalography using A-mode ultrasound), obstetrics & gynecology and internal medicine including cardiology [15]. The “First World Congress on Ultrasonic Diagnostic in Medicine” was held in Vienna in 1969 including two reports on ultrasound guided interventions [16]. Kratochwil described how to avoid the placenta using ultrasound guidance.

To appreciate the significance, e.g., of the first reports on liver biopsy, we must recall the traditional diagnostic tools available fifty years ago. The liver was examined using a new standard technique applying the Menghini needle following percutaneous localization [17-22]. On the other hand, a suspected tumor was considered at least a relative contraindication to needle biopsy, and so that the technique could not be used for the selective sampling of tumor nodules in the liver [23]. The only imaging modality available at that time for the percutaneous biopsy of nonpalpable organs and structures was classic radiography [13]. In recent decades more and more advantages have been reported [13,14,24-26] and even the spleen can be safely biopsied nowadays [27].

The first aspiration biopsy was reported by Martin and Ellis [28]. The technique was mainly applied for palpable masses, using radiological guidance, or during surgery. The introduction of the Menghini needle in 1958 allowed “blind” percutaneous liver parenchyma biopsy [20]. The localization of focal liver lesions and smaller fluid collections is only possible using imaging guidance which was introduced in the seventies. Berlyne reported on A-mode guided percutaneous renal biopsy using an intravenous pyelogram to localize the kidney [29]. In addition, Rettenmaier reported on the real time advantages of ultrasound guiding renal biopsy [30]. The introduction

of ultrasound guided biopsy permits differential diagnosis of non-palpable focal masses [31].

In the following years the two still current techniques have been described in more detail; the free hand [31] versus biopsy transducer guided techniques using A-mode and compound techniques [16,32]. Obviously, free-hand technique simplifies hygiene measurements.

First A-mode was introduced especially for structural analysis and also guidance of interventions followed by the widely used somewhat slow compound techniques and also later by faster grayscale (B-mode) technology introducing Vidoson 635 by Siemens [33].-

In the following years mechanical or electronic real-time scanners were developed by a variety of companies worldwide for improved “tissue characterization” [15]. The viduson technology was also used for biopsy guidance using free hand technique [34] or transducer mounted devices [35].

A homemade linear array transducer with a central aperture was introduced by Holm in 1974 for e.g., amniocentesis [36]. An alternative design of a linear array device with a side-mounted needle guide was introduced as well [37]. Easier to handle sector scanners were introduced to guide biopsies by Aloka [38]. A triangular needle channel was introduced by Toshiba for guidance at an oblique angle to the ultrasound beam [39,39]. The experience was summarized in the following years [15,40]. The knowledge of interventional ultrasound techniques using real time B-mode evolved rapidly resulting into the first important textbook [36].

The analysis of cytological specimens was preferentially performed in many centers [41-45]. The fundamental equivalence between aspiration cytology and histology had already been demonstrated by Sheila Sherlock [46] and others [47].

An 22 gauge cutting needle was introduced in 1981 [48]. The following year a commercially available modification of the Menghini needle called the Surecut needle [47] and the true cut needle devices came into widespread use [15]. It could be difficult to detect the needle tip in the tissue, especially when a liner-array scanner was used. The ultrasound pulse travels parallel to the needle shaft and is not backscattered by the smooth needle surface, resulting in the absence of a definite tip echo on the screen. This prompted the development of special needles with transverse grooves at the tip. These grooves cause considerable (back) scattering of the sound, analogous to the reflector on a bicycle, giving rise to conspicuous echoes. But these needles were relatively expensive and more traumatizing than needles with a smooth surface. Examiners with good mechanical skills could score the needle tip themselves with a small file, producing a

similar effect. Needles with a plastic sheath had better echogenicity but created a higher (frictional) resistance during insertion. Needle guidance and the detectability of different needles were published as well [49].

Clinical need forces technical inspiration for further improvements. The improvement of ultrasound scanners resulted in a much better resolution allowing to avoid unnecessary biopsy and drainage of smaller target sites especially in the liver [34,50] and kidney [51] and a little later in the pancreas [52,53]. The initially diagnostic puncture and later also drainage of pancreatic pseudocysts was reported as well by the same group [54]. The puncture and drainage of the dilated pancreatic duct was reported as well. The intraductal system was confirmed by contrast imaging using X-ray. Antegrade cholangiography was described in the same way by the same group of interventionalists [39,55].

During this time the diagnostic aspiration of renal cysts was reported as well [56]. Soon thereafter, the ultrasound-guided percutaneous puncture of the (obstructed) renal pelvis for cytologic and microbiologic analysis was described as well as the antegrade pyelography and nephrostomy [57]. Cyst sclerosing destroying the secretory epithelium was first reported for renal cysts [58] and much later for hepatic cysts [59].

The first ultrasound-guided percutaneous aspirations of the pericardial sac was performed using a compound scanner with a dedicated biopsy transducer using A-mode imaging of the pericardial effusion and time motion TM-mode for cardiac pulsations [60]. Fine-needle biopsy of peripheral lung lesions under real-time ultrasound guidance was described soon thereafter [61]. For more information we refer to the recently published textbook [15].

Radiological guided interventions

The role of ultrasound in the field of radiology has been controversially discussed in the past. Interventional radiology has been experiencing a period of unprecedented growth during the last 30 years. Advances in equipment technology have facilitated the development of new treatment options including open magnetic resonance imaging techniques and have allowed refinements in existing techniques that have made established procedures safer. Ultrasound is considered from the radiologist's point of view at the forefront of this trend, because it is becoming increasingly recognized as the premiere guidance tool for an array of interventional techniques without any radiation exposure. The reason why ultrasound is cited as the guidance tool of choice for many procedures has been traditionally explained due to the real-time, ra-

diation free nature of the technique. The answer is more complex, however, and includes both technologic, political and economic considerations [62].

Interventional ultrasound (INVUS) guidelines

Ultrasound-guided interventions (procedures) have revolutionized the everyday clinical practice during recent decades [63-67]. The advantages of ultrasound-guided interventions include an unsurpassed sharpness of detail and excellent controllability consequent to the real-time visual display, the wide availability of ultrasound equipment, and a simple and straightforward, easy to learn practical technique. This makes it even more surprising that guidelines of interventional ultrasound have not been previously published. The new EFSUMB INVUS guidelines are an expression of interdisciplinary and multiprofessional viewpoints, some of which represent different approaches; this reflects reality in all its diversity. EFSUMB has accessed a wealth of experience from their expert contributors, who discussed the subject matter in a two-year process. Particular attention has been given to clinical significance (level of evidence and the more practical grade of recommendation). The principle of "do no harm" is expressed in repeated pleas to apply the techniques judiciously in everyday practice and not become fascinated with technology for its own sake. The decision to proceed with an interventional procedure is always an individual one and should be measured by its benefit for the patient [12,13].

The guidelines consist of six main parts that are published in *Ultraschall in der Medizin / European Journal of Ultrasound* [12,68-72]:

1. Part I: General aspects.
2. Part II: Abdominal diagnostic procedures.
3. Part III: Abdominal treatment procedures using the transcuteaneous approach.
4. Part IV: EUS-guided interventions: General aspects and EUS-guided sampling.
5. Part V: EUS-guided therapeutic interventions.
6. Part VI: Ultrasound-guided Vascular Interventions.

Furthermore, some chapters and multimedia material are also intended only for the EFSUMB website. Online versions help provide more details that do not fit in the limited available printed space, which focus on main issues supporting the recommendations.

Part I General aspects

This part deals with generalities that are important and relevant for all kind of INVUS procedures, diagnostic as well as therapeutic: B-mode imaging and the use of CEUS in INVUS procedures, guiding techniques

including fusion imaging, patient information, informed consent, and patient preparation, local anesthesia and sedation, hygiene management, puncture routes and accessing techniques, how to reduce and/or eliminate complications, and finally, how INVUS is organized locally [69].

Part II Abdominal diagnostic procedures using the transcutaneous approach

This part deals with the workup both in clinical terms and in imaging, prior to the use of an interventional procedure to either diagnose or treat an abnormality. The section is divided into both an organ specific discussion as well as targeting particular ‘niche’ areas that will concern readers of the guidelines. All imaging modalities play a role in the work-up of these patients, and an ultrasound-guided procedure will not always be the most appropriate imaging tool. This is clearly detailed with evidence-based assessment of the diagnostic route and the final image approach to resolve the clinical situation [68].

Part III Abdominal treatment procedures using the transcutaneous approach

Therapeutic abscess drainage and the drainage of pancreatic pseudocysts, interventional tumor ablation techniques [73], interventional treatments for cysts in general and specifically parasitic diseases (PAIR for echinococcosis), enrich our daily practice. Established therapeutic procedures such as percutaneous transhepatic cholangiography and drainage (PTCD), percutaneous endoscopic gastrostomy (PEG), percutaneous ultrasound guided gastrostomy (PUG), biliary and urinary bladder drainage and nephrostomy. In the matter of interventional guidance and approach, it is often necessary to decide between the competing modalities of CT guidance and other imaging techniques, which in some cases can and should be used to complement one another. The role of ultrasound contrast agents in the preparation, support and guidance of interventional procedures is also addressed [74-77]. Symptom-oriented palliative care interventions are an important issue that concludes the chapter [78].

Part IV EUS-guided interventions: General aspects and EUS-guided sampling

EUS is now widely regarded as the central discipline in endoscopy. Initial enthusiasm over the diagnostic results obtained with 360° cross-sectional radial scanning has settled to a more realistic level, particularly since the advent of CT and MRI technologies. Endoscopic ultrasound has made “hidden places” accessible for diagnostic and therapeutic interventions. EUS-guided sampling was introduced in the early 1990s and 20 years later was proclaimed to have afforded a “disruptive innovation effect” for pancreatic pathology [79]. It combines the most advanced high-resolution ultrasound imaging of lesions

within the wall and in the vicinity of the gastrointestinal tract and provides safe and effective tissue acquisition. The guidelines deal with indications and clinical impact of EUS-guided sampling and try to balance advantages and drawbacks in comparison with image-guided percutaneous biopsy. Needle choice and biopsy technique as well as specimen processing are crucial for success [80,81], and therefore evidence-based recommendations are given for almost all steps of EUS-guided sampling as well as for safe performance [71].

In combination with fine-needle aspiration using curved linear-array instruments, and with the use of Doppler, contrast enhanced endoscopic ultrasound [26,82,83], and elastography, EUS has finally become a state-of-the-art, minimally invasive alternative to exploratory surgery in many situations-not only for diagnostic but also for therapeutic purposes.

Part V EUS-guided therapeutic interventions

Soon after the introduction of EUS-guided fine-needle aspiration, the therapeutic potential of EUS-guidance was discovered, and the first successful attempts of EUS-guided celiac plexus neurolysis, pseudocyst drainage, and cholangiopancreatography were reported [26,83]. The spectrum of EUS-guided therapeutic procedures has broadened since those first steps, and scientific literature on EUS-guided treatment is prospering. This is reflected by evidence-based recommendations on EUS-guidance of tumour ablation therapy, injection treatment of the celiac plexus, vascular interventions, drainage of pancreatic and non-pancreatic fluid collections and -not least- drainage procedures of the biliary tree and pancreatic duct. EUS-guided therapeutic techniques are compared with their percutaneous alternatives to help the clinician in choosing the most appropriate solutions for challenging therapeutic problems [72].

Part VI Ultrasound-guided Vascular Interventions

Real-time US-guidance for central venous access was performed for the first time in 1986 [84] and is supported by overwhelming evidence; it is now regarded as being a key safety measure in modern medicine. Systematic analysis of scientific literature shows, that US-guidance may also facilitate efficacy and reduce adverse events in peripheral venous access and endovascular interventions. Moreover, recommendations endorse the use of ultrasound to detect complications of vascular access and US-guided treatment of arterial pseudoaneurysms [70].

Perspectives

Extraabdominal ultrasound guided interventions

The current EFSUMB INVUS guidelines mainly focus on abdominal procedures, whereas the lung and

mediastinum [6,85], thyroid [86], musculoskeletal organ system and other important applications in obstetrics and gynecology are not mentioned. Future EFSUMB plans might concentrate on such recommendations.

Conflict of interest: none

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