European Federation of Societies for Ultrasound in Medicine and Biology guidelines 2015 on interventional endoscopic ultrasound

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The recently published guidelines of the European Federation of societies for ultrasound in medicine and biology (EFSUMB) on interventional ultrasound (INVUS)-guided procedures[1,2] summarize the intended interdisciplinary and multiprofessional approach. A foreword,[3] an introduction,[4] the aims of EFSUMB guidelines on INVUS[5] as well as a guide to the EFSUMB website[6] have been published. Over the last 10 years, EFSUMB has published guidelines and recommendations on the use of different ultrasound techniques. Contrast enhanced ultrasound (CEUS) guidelines were first introduced by EFSUMB in 2004,[7] updated in 2008,[8] 2011,[9] and 2012.[10,11] In addition, an introduction into dynamic CEUS for quantification of tumor perfusion was published as well.[12] EFSUMB elastography guidelines were introduced in 2013[13,14] followed by guidelines of the World Federation of Ultrasound in Medicine and Biology 2 years later.[15-17] Those guidelines on CEUS and elastography included recommendations and comments on the emerging endoscopic ultrasound (EUS)-guided applications of these techniques. We also refer to the currently published textbook on INVUS, which was also a motivation for more evidence-based recommendations.[18,19] The EFSUMB activities could guide an approach to our societies, the Euro EUS Scientific Committee, Asia Pacific EUS Task Force and Latin American Chapter of EUS and their respective journal, EUS, to prepare and publish not only high-value reviews[20-24] but also guidelines.[4,25,26]

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INTERVENTIONAL ULTRASOUND GUIDELINES

The recently published guidelines consist of six main parts that are published in Ultraschall in der Medizin/ European Journal of Ultrasound:[1,2,4,27-32]

1. Part I: General aspects
2. Part II: Abdominal diagnostic procedures
3. Part III: Abdominal treatment procedures using the transcutaneous approach
4. Part IV: EUS-guided interventions: General aspects and EUS-guided sampling

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5. Part V: EUS-guided therapeutic interventions
6. Part VI: Ultrasound-guided vascular interventions.

Part I: General aspects

This part deals with general principles 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.[1,2]

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 workup of these patients, and not always will an ultrasound-guided procedure be the most appropriate imaging tool. This is clearly detailed with an evidence-based assessment of the diagnostic route and the final imaging approach to resolve the clinical situation.[31,32]

Part III: Abdominal treatment procedures using the transcutaneous approach

Therapeutic abscess drainage and the drainage of pancreatic pseudocysts, interventional tumor ablation techniques,[33] interventional treatments for cysts in general, and specifically parasitic diseases (PAIR for echinococcosis), enrich our daily practice.[34,35] Hence, do established therapeutic procedures such as percutaneous transhepatic cholangiography and drainage, percutaneous endoscopic gastrostomy, percutaneous ultrasound-guided gastrostomy, biliary and urinary bladder drainage, and nephrostomy.[27] Symptom-oriented palliative care interventions are an important issue that concludes the chapter.[36]

Part IV: Endoscopic ultrasound-guided interventions: General aspects and endoscopic ultrasound-guided sampling

EUS is now widely regarded as one of the supreme disciplines 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 computed tomography and magnetic resonance imaging technologies. EUS has made "hidden places" accessible for diagnostic and therapeutic interventions. EUS-guided sampling was introduced in the early 1990s[37] and 20 years later was proclaimed to have afforded a "disruptive innovation effect" for pancreatic pathology.[38] It combines most advanced high-resolution ultrasound imaging of lesions within the wall and in the vicinity of the gastrointestinal tract with safe and effective tissue acquisition using fine needles of 25–19 gauge. The fourth part of the guidelines deals with indications and clinical impact of EUS-guided sampling and tries 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,[39,40] and therefore evidence-based recommendations are given for almost all steps of EUS-guided sampling as well as for safe performance.[30] The first international guidelines on EUS-guided sampling were published in 2011 and 2012 by the European Society of Gastrointestinal Endoscopy.[41,42] In the approximately 5 years since the preparation of these ground-breaking guidelines, scientific literature in EUS-guided sampling has expanded dramatically. The recommendations of the EFSUMB guidelines are now based on 21 meta-analyses describing the performance of EUS-guided sampling in solid and cystic pancreatic lesions, biliary strictures, and masses and mediastinal lymph nodes. The majority of those meta-analyses (15 out of 21) and more than 50% of all available studies on EUS-guided sampling (1570 out of 3014 papers) have been published in the years from 2012 to 2015. High-quality evidence (randomized controlled studies, systematic reviews and meta-analyses, guidelines) has been published in the last 4 years, for example, comparing the diagnostic efficiency of fine needles of various diameters, evaluating the impact of on-site cytology and of molecular analyses, and describing the occurrence and outcome of atypical findings in EUS-guided sampling of solid pancreatic lesions.[43-48] Studies demonstrating a very high diagnostic efficacy of 25 gauge aspiration needles for diagnosis of solid pancreatic neoplasms as well as the emergence of new types of "histology needles" have broadened the opportunities of EUS-guided sampling.[43,49] Recently, the role of on-site cytology has been questioned by several studies showing an incremental yield of combining smear cytology with cell block or tissue core assessment and molecular studies in terms of diagnostic

yield and accuracy as well as by two multicenter randomized studies showing equal results of on-site cytopathologist-guided sampling and of performing a standardized number of needle passes in solid pancreatic tumors.[50,51] Prompted by the advent of personalized, targeted treatments in visceral oncology, a paradigm shift has occurred onto cytopathological and molecular subtyping of EUS-samples from various neoplasms.[52-54] These recent developments are reflected by up-to-date recommendations on needle choice, cell-block and tissue core preparations, the role of on-site cytopathological assessment as well as on using a complimentary approach combining cytopathological, and histopathological assessment of samples.[30] Evidence was added also in the important field of guidance and targeting of EUS-guided sampling by advanced endosonographic tools for tissue characterization (real-time elastography and contrast-enhanced EUS). Acknowledging significant variations in practice and outcome between examiners and EUS centers worldwide,[55,56] quality indicators are suggested to be implemented in clinical practice to allow for performance monitoring and benchmarking of EUS-guided sampling techniques.[30] Based on an analysis of data regarding the reporting and reliability of cytopathology in EUS-guided sampling, the guideline recommends to use a standardized and validated classification system for cytopathology reporting.[30] An addendum on important terms used in the literature of EUS-guided sampling provides further details of the 55 evidence-based recommendations in the guidelines on EUS-guided sampling.

The EFSUMB guidelines emphasize that by the combination of fine needle aspiration using curved linear-array instruments, and the use of Doppler, contrast-enhanced EUS,[57-59] 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: Endoscopic ultrasound-guided therapeutic interventions

The fifth part of the EFSUMB guidelines deals with the therapeutic interventions that can be provided by the means of EUS guidance. EUS-guided therapeutic techniques are compared with their percutaneous alternatives to help the clinician choose the most appropriate solutions for challenging therapeutic problems.[28]

The two most established techniques are EUS-guided celiac plexus neurolysis and pseudocyst drainage. They were described soon after the introduction of EUS-guided fine needle aspiration[60,61] and since then have been investigated in numerous research trials.[62-67] The expert panel found high levels of evidence in the literature to demonstrate the superiority of both techniques versus a percutaneous approach. On the other hand, the effectiveness of EUS-guided celiac plexus block injecting anesthetic and steroid drugs instead of absolute alcohol for the treatment of pain in patients with chronic pancreatitis is still debated.[68,69]

EUS-guided drainage of the biliary duct and the gallbladder has become a valid alternative to percutaneous drainage after failed attempts with endoscopic retrograde cholangiopancreatography. However, several technical aspects and its safety profile are still debated. The advent of lumen-apposing metals stents has significantly simplified the EUS-guided approach and probably has opened a new era of EUS-guided interventions on the biliary tree.[70-75] However, EUS-guided drainage of the pancreatic duct to relieve pain in patients with ductal obstruction has been reported in a limited number of patients with uncertain balance between clinical outcome and side effects.[76,77]

EUS-guided vascular interventions are rapidly expanding, comprising treatment of bleeding in patients with portal hypertension, treatment of nonvariceal bleeding and pseudo-aneurysms as well as new indications such as portal vein pressure measurement.[78-81] As far as treatment of extra-esophageal and fundal varies is concerned, significant advantages have been reported using a forward view echoendoscope specifically developed for EUS-guided therapies. It combines the advantages of a frontal endoscopic view with a forward viewing ultrasound beam that allows for a straight approach onto target lesions.[82,83]

Finally, EUS-guided tumor therapy has attracted a lot of interest in recent years. In particular, EUS-guided ethanol injection for the treatment of pancreatic cysts and neuroendocrine tumors, EUS-guided radiofrequency ablation for inoperable pancreatic tumors and EUS-guided injection of anti-tumoral agents were reported.[84-89] However, positive results are still lacking both in terms of safety and efficacy. As a result, EUS-guided tumor therapy should still be considered investigational.

Part VI: Ultrasound-guided vascular interventions

Evidence-based recommendations support the use of ultrasound to guide ultrasound procedures and to detect complications of vascular access and US-guided treatment of arterial pseudoaneurysms.[29]

OTHER ULTRASOUND-GUIDED INTERVENTIONS

Other US-guided interventions have been reported[90-92] but are not the topic of this editorial.

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