EFSUMB Guidelines on Interventional Ultrasound (INVUS), Part I
General Aspects (Short Version)

EFSUMB Leitlinien Interventioneller Ultraschall (INVUS), Teil I
Allgemeine Aspekte (Kurzversion)

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- guideline
- ultrasound guidance
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- microbiology
- safety

Abstract

This is the first part of the Guidelines on Interventional Ultrasound of the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) and covers all general aspects of ultrasound-guided procedures (short version; the long version is published online).

Zusammenfassung

Der erste Teil der Leitlinien „interventionelle Sonografie" der European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) erörtert die allgemeinen Aspekte sonografisch gestützter und assistierter diagnostischer und therapeutischer Interventionen im Abdomen (Kurzversion; die Langversion ist online publiziert).

Introduction

Ultrasound (US), both as a diagnostic modality as well as a guidance technique for interventional procedures, has developed into an invaluable tool in virtually all medical specialties. The real-time nature of US combined with low cost and high availability, has allowed US to become the modality of first choice for guidance of a broad variety of interventional procedures.

The history of interventional US (INVUS) goes back to the 1960 s, when reports on the utility of US to guide renal biopsies, pleural fluid aspiration, and A-mode US-guided amniocentesis were published [1]. In the 1970 s and 1980 s, the technological development of US systems and transducers was significant, and US systems with real-time grayscale imaging (B-mode) and Doppler mode became commercially available and widely distributed. During these two decades, the classic INVUS techniques of biopsy and drainage/puncture were further refined to become established techniques. First reports of US-guided tissue ablation appeared in the 1980 s, but the different ablation techniques did not become established and clinically implemented until the 1990 s [2].

Interventional ultrasound (INVUS) consists of a variety of diagnostic as well as therapeutic procedures, and may be performed with a variety of equipment and different types of transducers. INVUS is now an integrated part of transcutaneous abdominal and superficial (small part) US. Furthermore, INVUS is a natural component of various endoluminal US exams such as transrectal, transvaginal, transbronchial and transgastric (endoscopic) US. Finally, INVUS is also feasible during intra-operative and laparoscopic US.

Performing a competent INVUS procedure involves the successful combination of theoretical knowledge and practical skills at a high level:
- Knowledge of normal and pathologic US anatomy including pitfalls and artifacts
- Knowledge of the puncture principle and auxiliary US techniques such as Doppler and CEUS
- Knowledge of the INVUS apparatus used including all potential complications
- Dexterity and stereotactic skills.

Part I of the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) Guidelines on interventional ultrasound adresses general aspects of US-guided interventions. The methods of guideline development are described in the introduction to the EFSUMB Guidelines on Interventional Ultrasound [3]. Levels of evidence (LoE) and Grades of Recommendations (GoR) have been assigned according to the Oxford Centre for Evidence-based Medicine criteria (March 2009 edition) [http://www.cebm.net/oxford-centre-evidence-basedmedicine-levels-evidence-march-2009] [3].

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Imaging and INVUS

Ultrasound guidance for interventional procedures is utilized on different levels ranging from a "courtesy" look with the transducer prior to placing a pleural or ascitic drainage catheter to using sophisticated techniques of contrast-enhanced ultrasound (CEUS) fusion imaging with CT or MR imaging [4].

B-mode imaging

In preparation for a US-guided procedure, it is important to choose the appropriate transducer and imaging program (presetting/application) and to select the correct interventional apparatus. Whenever US visibility is an issue, CEUS or fusion imaging should be considered.

Recommendation 1

Ultrasound is safe and effective for selecting punctures site and subsequent guidance. (LoE 4, GoR C). Strong consensus (100 %).

Doppler imaging

If any doubt exits as to whether the lesion is vascular or avascular, color Doppler should be applied. If this still does not solve the ambiguity, CEUS should be considered.

Recommendation 2

Ultrasound color Doppler can be helpful to avoid inadvertent puncture of vascular structures. (LoE 4, GoR C). Strong consensus (100 %).

CEUS

A CEUS-guided intervention can be performed in much the same way as any routine US-guided procedure. Often two injections of contrast may be required: a preliminary injection to identify the lesion and plan the intervention strategy and a second injection to perform the procedure. A continuous contrast infusion throughout the entire procedure may be used. CEUS is indicated in several situations and aspects of interventional US.

Biopsy from viable areas

With CEUS, the viability of tumor tissue, signified by the presence of vascularity, can be reliably evaluated, and CEUS-guided biopsy increases the diagnostic yield by 10 % and decreases the false negative rate especially in large tumors with areas of necrosis [5, 6].

Biopsy of "invisible" or poorly visualized/delineated lesions

When previous CT, MR or PET-CT imaging has demonstrated a suspicious lesion and a biopsy for a definitive diagnosis is required but the lesion is not seen or is poorly visualized with US, CEUS may be helpful in two ways: 1) The target lesion may become "clearly visualized" on CEUS, or 2) Additional lesions that potentially render themselves more accessible to biopsy become evident and can then be biopsied under CEUS guidance [7 – 9].

Guidance, monitoring and follow-up in percutaneous thermal ablation of abdominal tumors

The ablation volume may be of a similar texture to the surrounding normal tissue on B-mode US, however, the clarity achieved with CEUS is playing an increasingly important role in monitoring post-ablation local recurrence and ablation volume viability, as well as demonstrating new lesions [10 – 14].

Emerging applications

Besides the indications for CEUS in interventional US described above, a number of other uses may serve as alternatives to existing techniques or offer a possible alternative where no current technique is available. Examples of indications include but are not limited to: A) replacement for a conventional X-ray contrast study, i. e., fistulography (including CEUS via nephrostomy catheter), B) diagnosis and monitoring of all stages of post-procedure bleeding, C) improved visualization of all types of fluid collections other than blood.

Avoidance of interventional procedures

CEUS may prevent patients from undergoing an interventional procedure with the associated morbidity e. g. liver biopsy if CEUS can allow for a definitive diagnosis of a malignant or benign abnormality.

Recommendation 3

CEUS can be helpful to avoid necrotic areas in percutaneous biopsy of intra-abdominal tumors. (LoE 3b, GoR C). Strong consensus (100 %).

Recommendation 4

CEUS can be helpful in identifying biopsy targets poorly or not visualized with fundamental B-mode. (LoE 4, GoR C). Strong consensus (100 %).

Recommendation 5

CEUS is safe, effective and comparable to CT and MRI in percutaneous ablation for guidance and procedural monitoring. (LoE 4, GoR C). Strong consensus (97 %).

Guiding techniques

The fundamental technique of INVUS (the puncture principle) is an alignment of two planes, namely the "scan plane" that shows the target pathology on the US screen and the "needle plane" containing the needle (or other INVUS device) approaching the target. Real-time visualization of the needle tip is possible using US due to the reflection from the metal in the needle [15]. The intensity of the display of echoes from the "needle plane" will depend on the needle size, the scanning depth, angulation and the US system. [4].

Needle guiding devices versus free-hand technique

To become familiar with the principle of US-guided puncture, it is recommended to use a steering device. A steering device is a plastic or metal device attached to the transducer, with a channel for the needle, which may be positioned at different angles (dependent on the US system). The path of the needle is shown on the US machine screen, but misalignment between the scan plane and the needle plane may occur if pressure/torque is ap-

plied to the transducer or the needle during the procedure or by patient movement. Prior to the interventional procedure, the target is imaged and a position where the puncture line crosses the target without crossing vital structures such as large vessels is marked on the skin. The steering device usually gives more confidence when inserting the needle, but is compromised by fewer degrees of freedom for needle manipulation during insertion.
In three studies these two techniques were evaluated in US phantoms. The two techniques had the same quality of biopsy specimen in one study, but the guided technique was faster than the free-hand technique (23 seconds versus 32 seconds) especially for less experienced evaluators [16 – 18]. One study evaluated the effect of training in US-guided biopsies by self-assessment questionnaires and found that training had a significant positive effect [19].

Transducers

If a needle guide is required, a limited number of transducers have this capability and this is vendor-dependent. Transrectal and transvaginal ultrasound-guided interventions may be performed, most often with a needle guiding device attached to the transducer [20].

Fusion imaging

Using electromagnetic needle tracking, the route of puncture is marked electronically on the screen. The needle tip is also specifically marked and when not in the scan plane, alters color and size according to the distance from the scan plane. The method has been used for small lesions in the retroperitoneum and pelvis, where visualization of the needle tip is particularly difficult. Fusion imaging has been successfully evaluated in several studies on focal liver lesions undetectable or difficult to visualize using conventional US, but visible on CT or MR imaging. In one study of 295 lesions undetectable on routine US, 96.5 % were correctly targeted and 90.2 % were successfully ablated [21].
Both in phantom and clinical studies, the rate of success increased when measured by the rate of obtaining an adequate sample [22, 23].

Recommendation 6

A needle guiding device is recommended for deeply located lesions, especially for less experienced users. The biopsy technique to use depends on the examiner's skills and the accessibility of the target. (LoE 4, GoR C). Strong consensus (100 %).

Recommendation 7

Use of an electromagnetic needle tracking device with a free-hand technique has the same success rate as biopsy using a needle guiding device. (LoE 4, GoR C). Strong consensus (100 %).

Recommendation 8

Image fusion with CT or MR may be helpful for ultrasound-guided biopsy in lesions difficult to visualize on ultrasound. (LoE 4, GoR C). Strong consensus (100 %).

Patient information, informed consent, and procedure documentation

Patient information

Patients should be informed about the objective of the planned procedure, the possible complications and alternative procedures that may arise. Written information should be phrased in layman's terms, assuming little knowledge of medical procedures. It should include particulars about the aim, necessity, procedure, possible risks, side effects or complications as well as benefits of the proposed procedure, and information about possible alternatives. Information should be given at an appropriate time to help patients make a decision without any pressure. Written information does not replace the need for oral information, ensuring that the patient has understood the content of the written information and has the opportunity to ask questions.

Informed consent

Informed consent should be obtained when the planned procedure is complex and involves significant risk and/or side effects and when there may be consequences for the patient's employment or social or personal life. Consent might be given in writing or orally depending on the national legislation, and should always be documented in the patient record. It is important to establish that the patient has sufficient information to make an informed decision to proceed with the procedure and there should be a detailed face-to-face discussion with the patient.
Consent must be given freely, without pressure from any person, which would invalidate the consent process. Patients should be advised honestly, accurately and clearly, based on the best interest of the patient with due acknowledgement of the risks and benefits involved. Consent should always be obtained before sedation is given.

Legal aspects

Informed patient consent provides the lawful justification for carrying out an interventional procedure. There is no legal requirement for consent to be written, or be in a particular form. However, a signed written consent form provides documentary evidence of consent and is recommended for any intervention carrying risks. If procedures are performed as part of a clinical research study, formal written consent to participate in the study is used, and the written patient information and consent form should be approved by the institutional committee for ethics in research.

Procedure documentation

The informed consent should be documented and preserved in the patient record as an important legal document.

Recommendation 9

Information about the INVUS procedures must be given to the patient or their representative. (LoE 5, GoR D). Strong consensus (100 %).

Recommendation 10

Informed consent is mandatory prior to all INVUS procedures and should be documented in the patient record. (LoE 5, GoR D). Strong consensus (100 %).

Patient preparation

Preparation of the patient who is undergoing any US-guided intervention depends on the type of procedure and the status of the patient. The preparation includes patient information and consent and precautions to minimize procedure-related complications. There are substantial national variations in patient preparation and the conducting of INVUS procedures.

Precautions to minimize hazards

The INVUS procedure should be performed in a calm atmosphere of competence and trust. The planned procedure should have a clear indication, and the result should either be therapeutic or diagnostic. For diagnostic procedures, the result should have an impact to alter the treatment plan for the patient. Written protocol instructions for the INVUS procedure increase patient safety, and secure a more uniform procedure. Some departments also apply checklists to ensure that the patient is completely prepared and all equipment is present. Application of local anesthetics, potentially combined with sedation should be considered part of every INVUS procedure. Some INVUS procedures with fine needles are performed on an outpatient basis, while others require hospitalization. Patients should be dressed accordingly.

Relevant blood tests including coagulation status plus enquiring about anticoagulative medication is mandatory and the results should be available before every interventional procedure.

Fasting is beneficial with regards to possible complications regarding general anesthesia. However, fasting status does not substantially influence visualization during the procedure [24]. The use of water, laxatives and anti-flatulent medication may improve the visualization of the retroperitoneal area in some patients [25].

For most INVUS procedures the risk is low for contamination if a procedure is performed under sterile conditions. A single dose of antibiotic prophylaxis is recommended at many centers for procedures in which sterile cysts are traversed and after endoluminal interventional procedures such as transrectal or transvaginal biopsies.

Post-interventional observation

Clinical observation is needed for at least two hours, when most complications tend to arise. In uncertain cases a repeat US examination should be performed prior to discharge. The timing of discharge is dependent on the invasiveness of the procedure, and hospitalization is recommended in the case of postprocedural complications.

Recommendation 11

Patient preparation should include procedure information, informed consent, relevant medical history and laboratory data. (LoE 5, GoR D). Strong consensus (100 %).

Recommendation 12

An INVUS procedure should have an indication, and the results should influence patient management. (LoE 5, GoR D). Strong consensus (100 %).

Recommendation 13

Antibiotic prophylaxis is not recommended, but should be considered on an individual basis. (LoE 5, GoR D). Strong consensus (100 %).

Local anesthesia and sedation

Many of the INVUS procedures are relatively rapid to perform and have a low to moderate pain level so that they are ideally suited to be conducted solely under local anesthesia.

Local anesthesia technique

A good anesthetic technique is important since effective local anesthesia may eliminate the need for sedation. For liver biopsies, when approaching the liver capsule, local anesthetic should be instilled during a short breath-hold to avoid injuries to the capsule [26]. Some interventionalists prefer to administer local anesthesia under US guidance to ensure adequate analgesia along the planned puncture tract. Vasoconstrictors (e. g. epinephrine) are used to reduce absorption of local anesthetics into the systemic circulation [27]. Adding epinephrine to lidocaine solutions causes local vasoconstriction and increases the duration of analgesia and may also reduce post-procedural bleeding from the puncture site [28]. INVUS procedures using very thin needles may be performed without any anesthesia. Some INVUS procedures are empirically painful (and often protracted) and therefore require sedation in addition to the local anesthesia. Examples of these include nephrostomy, ablation, and transrectal or transvaginal drainage. Furthermore, anxious or confused patients may benefit from sedation. Almost all ablations and all INVUS procedures in children are performed under general anesthesia.

Administration of moderate and deep sedation is a complex procedure with several potential complications and should only be done under the responsibility of a person with documented knowledge and experience regarding the pharmacology, indications and contraindications for the use of sedative agents, as well as the role of pharmacologic antagonists. The type of anesthetic used and the degree of sedation should always be evident in the medical records.

Recommendation 14

Administration of local anesthesia and sedation may be beneficial in terms of patient comfort and safety and should be considered for INVUS procedures. (LoE 5, GoR D). Strong consensus (100 %).

Recommendation 15

Administration of drugs for sedation should be reserved for personnel with knowledge and experience according to national legal regulations (LoE 5, GoR D). Strong consensus (97 %).

Hygiene management in INVUS

General hygienic requirements

Hygienic requirements have to be tailored to the specific diagnostic procedure being performed.

Personal protective equipment and coverings

There is a differentiation between major and minor invasive procedures with or without an increased risk of infection. For minor invasive procedures that are not associated with an increased risk of infection, it is sufficient to perform a hygienic hand wash, wear a protective decontaminated or disposable gown and sterile gloves. Major procedures or minor invasive procedures that are associated with an increased risk of infection or body fluid splashes additionally require a surgical cap, surgical mask, sterile protective surgical gown and sterile gloves [29]. Sterile gloves are donned over the air-dried or sterile towel-dried hands following surgical hand antisepsis (surgical scrub). It is thought that surgical masks prevent contamination of medical personnel and can also protect patients, especially immunocompromised patients, although there is little evidence to support this. Further research is needed [30].

Disposable transducer covers

Only sterile, disposable transducer covers should be used in interventional procedures [31]. Sterile transducer covers do not eliminate the need for transducer decontamination [32 – 34]. Sterilization of the transducer after use is necessary in procedures with a high risk of contamination.

Ultrasound gel

The ultrasound gel used in interventional ultrasound procedures should be sterile and a new sachet should be used for each patient [35 – 43].

Hand and skin disinfection

Hand antisepsis is the most important measure for protecting both staff and patients in everyday practice. Fingernails should be trimmed short and round. Nail polish and artificial nails should not be used, as these shield microorganisms from the effects of hand antiseptics. Hands should be free of injuries, especially in the nail bed, and free of inflammatory processes. Watches, jewelry, and rings should not be worn. Hygienic hand disinfection is always performed before and after patient contact, regardless of whether protective gloves will be or have been used. Contact time of disinfectant varies with the agent, the infection risk of the procedure and the type of skin [44, 45]. In interventional US procedures such as percutaneous liver biopsy or the percutaneous aspiration of ascites, hygienic hand antisepsis is considered sufficient. In other procedures such as PTCD, nephrostomy, or tumor therapies that are classified as an operative or minor invasive procedure with an increased risk of infection, an aseptic technique is essential [46 – 48]. The skin preparation begins with thorough cleansing of the skin with sterile sponges held on (Kocher) forceps. The boundaries of the skin prep should be wide enough to allow for possible adjustment of the entry site, and therefore of the sterile drapes, without contaminating the puncture needle.

Decontamination of ultrasound transducers

Ultrasound transducers used in image-guided interventional procedures are generally classified as semi-critical items (objects that come into contact with mucous membranes or skin that is not intact). Direct transducer contact with critical medical products should be avoided during the procedure despite the use of sterile, disposable transducer covers. Critical medical products, which include ultrasound transducers that are used intraoperatively, or through which a needle will be introduced (e. g. for abscess drainage or PTCD) must be sterilized. After every examination, residual US gel should be carefully removed with a disposable towel and the transducer cord wiped with a towel moistened with cleanser, followed by disinfection with a virucidal agent [49, 50]. The sterilization process should always conform to standard operating procedures.

Decontamination of ultrasound accessories

Whenever available, the biopsy instruments such as cannulae, hollow needles, etc. should be disposable, single-use items [51]. Otherwise, the biopsy instruments should be submitted to machine decontamination (cleaning and disinfection) followed by sterilization. All steps require detailed standard operating instructions.

Recommendation 16

A hygiene plan should be established in every department. (LoE 5, GoR D). Strong consensus (100 %).

Recommendation 17

Hand hygiene is the most important measure for preventing infection. (LoE 2a, GoR B). Strong consensus (100 %).

Recommendation 18

A limited hygiene program is sufficient when there is a low risk of infection. (LoE 5, GoR D). Strong consensus (100 %).

Recommendation 19

A strict hygiene program is required for procedures with a high risk of infection. (LoE 5, GoR D). Broad agreement (93 %).

Recommendation 20

A sterile ultrasound transducer or a sterile disposable transducer cover must be utilized if in contact with a needle. (LoE 5, GoR D). Broad agreement (93 %).

Recommendation 21

The ultrasound transducer should be adequately cleaned after every examination and procedure. (LoE 4, GoR C). Strong consensus (97 %).

Puncture routes and accessing techniques

There is a lack of evidence in the literature in this area.

Choice of puncture route

One of the most important points for a successful US-guided intervention is choosing the best path for the target lesion. Although not always possible, the shortest route should be preferred. If any "risky" structure is present on the anticipated pathway, then a longer but still safe route may be chosen. The shortest route may not be possible for other reasons e. g. natural bony structures (costal cartilage, iliac bone, etc.), subcutaneous emphysema, overlying blood vessels or bowel gas, skin lesions or fixed cutaneous devices. The distance from the skin puncture site to the target should be measured using the US machine, so that the correct needle length can be selected. Furthermore, although not always practical, an estimate of the route angle may be calculated to aid puncture.

The stomach and small bowel can be traversed usually without any consequences, particularly with fine needles, but colon puncture should be avoided because of the infection risk. Transcolonic needle aspiration of an abscess might in rare cases be the only treatment option.

Puncture routes for specific procedures may vary. For biliary drainage, a right intercostal puncture is usually preferred. However, a subxiphoid puncture route is necessary for left biliary duct drainage. Nephrostomy is usually performed from a postero-caudal route, targeting a lower pole calyx. The renal pelvis should be outside the puncture route to avoid damage to the hilar vessels. When puncturing an abdominal hydatid cyst, needle entry into the cyst should traverse the organ parenchyma to prevent subcapsular cyst fluid leakage.

Penetrating organs in INVUS

Puncture should be rapid and during breath-hold so that the capsule (liver, kidney and spleen) is minimally traumatized and bleeding is potentially avoided.

Hazardous organs on INVUS

Traditionally the spleen has been considered a hazardous organ for puncture, primarily because of the risk of bleeding. However, there is evidence that the risk of splenic bleeding is not significantly higher than liver or kidney bleeding after puncture [52].

Recommendation 22

The safest access route with the best visibility on US should be used in interventional procedures. (LoE 5, GoR D). Strong consensus (97 %).

Avoidance of complications

Large retrospective surveys indicate that US-guided fine-needle biopsy (needle diameter up to 1.0 mm) has a complication rate ranging between 0.51 % and 0.81 %, including a major complication rate of between 0.06 and 0.095 % [53, 54]. The mortality rate ranges from 0.0011 to 0.018 % [54, 55]. Retrospective and prospective single-center studies of liver and abdominal organ biopsies with large numbers using a needle diameter > 1.0 mm have shown higher complication rates from 0.4 % to 2.5 % [56 – 60]. In a recent prospective German multicenter study, deaths occurred in 0.05 % of percutaneous US-guided intraabdominal interventions performed under continuous US guidance [61].

Minor complications like pain occur in 5 – 10 % of US-guided interventions [58, 62, 63]. However, in these retrospective studies, pain assessment is based on medical records. In a retrospective single-center analysis of 1923 diagnostic and therapeutic punctures in the liver and pancreas, postinterventional pain treatment was reported by 10.5 % patients [58]. Vasovagal reactions range from minor symptoms associated with pain in 0.13 % liver biopsies to severe vasovagal reactions in 2.8 % of patients undergoing prostatic biopsy [64 – 66].

The relative frequency of organ-specific major complications (pancreatitis, pneumothorax, bile leakage) relates to the inclusion of various targeted sites in the statistical data. Retrospective and prospective single-center studies with large numbers reporting on liver and other abdominal organ biopsy with needle diameters > 1.0 mm have shown higher complication rates ranging from < 0.4 % to 2.5 % [57 – 60]. In the UK national audit evaluating liver biopsy including 3486 patients, the rate of major complications was 0.43 % and 4 hemorrhage-related deaths occurred (0.11 %) [67]. In a prospective study in France, 2082 liver biopsies were performed by senior physicians in 76 % of cases, by junior physicians in 24 % of cases, by hepato-gastroenterologists in 89 %, and by radiologists in 11 % [68]. In this study, the rate of severe complications was 0.57 % and increased with the number of needle passes and decreased with the experience of the operator, use of atropine, and US guidance. US guidance was used in 56 % of biopsies and sedation was given in 0.46 % of patients. In an Italian study of 203 percutaneous liver biopsies in hepatitis C patients, the rate of major bleeding was 0.4 % [69]. In the prospective German multicenter study including 8172 intraabdominal interventions, the rate of major bleeding was 0.43 % [61]. In both studies, the risk of major bleeding events was significantly higher in patients with a INR > 1,5 compared to a normal INR [61, 69].

Needle tract seeding

In three large surveys the range of needle tract seeding was 0.003 % (2/66 397 fine-needle biopsies), 0.0063 % (6/95 070 fine-needle biopsies), and 0.009 % (1/10 766) [54, 55, 70]. However, these data are likely to understate the true incidence as tumor seeding generally presents after a latency period of several months to as long as 25 months after needle biopsy [70 – 73]. More recent studies indicate a higher risk of malignant needle tract seeding after both diagnostic and therapeutic US-guided interventions for malignant tumors. The risk for tumor seeding differs between specific targets sites and tumor entities [74]. A significantly higher bleeding risk was shown for patients with an INR > 1,5.

Recommendation 23

Routine ultrasound examination after ultrasound-guided interventions is not necessary in asymptomatic patients. (LoE 5, GoR D). Strong consensus (97 %).

Recommendation 24

The rate of bleeding complications is increased in patients with an INR > 1.5. (LoE 1b, GoR A). Strong consensus (100 %).

Recommendation 25

The rate of bleeding complications is increased in patients with low platelets, although the threshold has not been definitively established (< 50,000 – 100,000/ ul). (LoE 2b, GoR B). Strong consensus (100 %).

Recommendation 26

The rate of bleeding complications is increased in patients taking non-acetylsalicylic acid antiplatelet drugs or anticoagulants. (LoE 5, GoR D). Strong consensus (100 %).

Recommendation 27

Acetylsalicylic acid prescribed for secondary prevention need not be stopped in low risk procedures. (LoE 2b, GoR B). Broad agreement (88 %).

Recommendation 28

In patients on antiplatelets and/or anticoagulants, a risk assessment balancing thromboembolic events versus bleeding should be performed prior to INVUS. (LoE 5, GoR D). Strong consensus (100 %).

Recommendation 29

Decision on suspension of antiplatelet drugs and/or anticoagulants or delay of the procedure should be made based on an individual risk assessment. (LoE 5, GoR D). Strong consensus (100 %).

Recommendation 30

Complications that arise in association with ultrasound-guided interventions should be documented. (LoE 5, GoR D). Strong consensus (100 %).

Organization of INVUS

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Training on biopsy phantoms and simulators

Technical improvements in image quality and haptic feedback have made digital simulators more realistic and relevant to achieve a level of competence in the course of performing INVUS. Studies indicate a shorter learning curve by adding simulator-based training to clinical practice [75 – 79]. Learning INVUS should always be based on knowledge with non-interventional US imaging of the area of interest. Competence training in INVUS should start on a phantom.

To practice and maintain skillfulness in complex and rarely performed procedures, the introduction of more sophisticated commercial phantoms (full procedure trainers) which mimic the anatomy may be a good investment [80].

Interventional phantoms used with real interventional needles have a limited life span, and computer simulations may be adequate in order to reach level 3. Another advantage of computer simulators is that training can be performed individually without occupying or having expensive clinical equipment at hand. The disadvantage is that the clinical equipment is not used in the simulation situation, and hands-on realism is not part of the training. Web-based teaching resources are also available, and have been shown to be as efficient as lectures in increasing competence in US-guided vascular access [81].

Recommendation 31

Ultrasound interventional procedures on phantoms improve skills and are useful before commencing clinical INVUS training. LoE 2b, GoR B. Strong consensus 100 %.

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