

EFSUMB Guidelines on Interventional Ultrasound (INVUS), Part III

Abdominal Treatment Procedures (Short Version)

EFSUMB Leitlinien interventioneller Ultraschall (INVUS), Teil III Ultraschall-geführte therapeutische Interventionen (Kurzversion)

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Bibliography

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Abstract

The third part of the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) Guidelines on Interventional Ultrasound assesses the evidence for ultrasound-guided and assisted interventions in abdominal treatment procedures. Recommendations for clinical practice are presented covering indications, contraindications, safety and efficacy of the broad variety of these techniques. In particular, drainage of abscesses and fluid collections, interventional tumor ablation techniques, interventional treatment of symptomatic cysts and echinococcosis, percutaneous transhepatic cholangiography and drainage, percutaneous gastrostomy, urinary bladder drainage, and nephrostomy are addressed (short version; a long version is published online).

Introduction

This is the third of three guidelines (parts I – III) within the framework of the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) Guidelines on Interventional Ultrasound describing ultrasound (US)-guided percutaneous diagnostic and therapeutic interventions of the abdomen. Part III deals with the indications and clinical impact of US-guided therapeutic interventions and gives evidence-based recommendations for the safety and efficacy of these techniques using the available evidence at the time of manuscript preparation. It is complemented by guidelines on general aspects of US-guided interventions (part I) [1] and US-guided diagnostic interventions (part II) [2]. In addition, EFSUMB also will publish guidelines on the use of diagnostic and therapeutic endoscopic ultrasound [3, 4] and ultrasound-guided vascular interventions [5].

Zusammenfassung

Der dritte Teil der Leitlinien der European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) zur interventionellen Sonografie im Abdomen bewertet die Evidenz für transkutane sonografisch gestützte und assistierte therapeutische Interventionen im Abdomen. Auf der Grundlage publizierter Daten werden zu Indikationen, Kontraindikationen sowie zur sicheren und effizienten Durchführung Empfehlungen für die klinische Praxis gegeben. Berücksichtigung finden die sonografisch geführte Drainage von Abszessen und Flüssigkeitsansammlungen, Tumorablationstechniken, transkutane Zystensklerosierung symptomatischer Zysten und der Echinokokkose, die perkutane transhepatische Cholangiografie und Drainage, die perkutane Gastrostomie, die Harnblasenpunktion und Drainage sowie die Nephrostomie (Kurzversion; eine Langversion ist online publiziert).

Methods of guideline development are described in the introduction to the EFSUMB Guidelines on Interventional Ultrasound [6]. 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-based-medicine-levels-evidence-march-2009>].

Local ablative procedures

Introduction
Local ablative procedures play a key role in the management of patients with malignancies, primarily with hepatocellular carcinoma (HCC), but also with metastases [7 – 10].

Treatment intention

Local ablative procedures can be classified according to the treatment intention as curative or palliative [11, 12].

Curative intention

Tumor ablation is usually performed with curative intent. This applies mainly to small HCCs (≤ 5 cm), as well as to colorectal liver metastases [12–18]. The decision for local ablation over resection should take into account data such as the patient's age, co-morbidities, normal parenchymal reserve and tumor distribution inside the liver, as well as the risks for metachronous tumor growth, and all these should be weighed against the invasiveness of the procedure [11].

Recommendation 1

HCC ablation should be preferably performed with curative intent (LoE 1a, GoR A). Strong consensus (100%).

Palliative strategy

The main indication for palliative treatment of liver tumors is metastatic neuroendocrine tumor load. Other primary [19] and secondary liver tumors may also be treated [11, 20–27].

Combined treatment options

With multiple liver metastases (commonly colorectal) not suitable for surgical resection because of their number or location (e. g., proximity of vascular or biliary structures), a combined approach should be considered [28].

Ablation in conjunction with resection is increasingly used as a parenchyma-sparing curative strategy that combines effective ablative treatment of small tumors with resection of large tumors, for which ablation is less effective [29–36]. Similar concepts can be applied to hepatocellular carcinoma (HCC) in a cirrhotic liver, when extensive surgical sacrifice of the parenchyma must be avoided.

Recommendation 2

Ablation in conjunction with resection may be considered as a parenchyma-sparing curative strategy (LoE 2a, GoR B). Strong consensus (100%).

Hepatocellular carcinoma (HCC)

The treatment options for HCC in a cirrhotic liver are transplantation, surgical resection, local ablative therapies, transarterial chemoembolization (TACE), radioembolization with Yttrium90 loaded beads (transarterial radioembolization) (TARE), and, in cases of advanced disease, systemic therapy with sorafenib (Nexavar®). Image-guided percutaneous ablation therapies, such as radiofrequency ablation (RFA) [37–39], percutaneous ethanol injection (PEI) [40–42] and microwave ablation [43], have been performed mainly with small HCCs, according to the Milan criteria [44]. These are potentially curative, minimally invasive, and repeatable in case of recurrence [45].

Local ablative treatment techniques for HCC

Size of tumors

As a single RFA needle usually coagulates a region of about 2 cm in diameter, potentially non-spherical (depending on the RF sys-

tem) multiple sequential insertions may be required to achieve a safety margin.

To overcome this limitation, multi-needle systems have been introduced for simultaneous ablations and stereotactically guided RFA [46–49]. There is no accepted maximum tumor size that can be ablated in a single session but the size is generally in the 4 to 5 cm range. The ablated zone should encompass the treated tumor and a circumferential margin of 5–10 mm around the tumor [50].

Location of tumors

HCC tumors in a subcapsular location or adjacent to the gallbladder have a higher likelihood of incomplete ablation [51] or major complications [52–54].

To reduce the number of complications, attention must be paid to vulnerable structures close to the tumor or the ablation zone. This applies to the porta hepatis, gallbladder, stomach, small intestine and colon, all of which are particularly sensitive to thermal damage [55, 56]. In case of subdiaphragmatic lesions, pulmonary, pleural or cardiac heat damage might occur, usually with only minor clinical significance [57, 58].

Number of tumors

The maximum number of tumors that can be ablated in a single procedure is not clearly defined, but ranges from 3 to 5 in most centers [11]. Overall survival is best for patients with solitary tumors, intermediate for those with 2 to 3 tumors, and worst for those with ≥ 3 tumors [59].

Recommendation 3

The maximum recommended diameter of HCC lesions treatable with thermal ablation is generally considered below or equal to 5 cm, although optimal results are obtained in lesions < 3 cm (LoE 2b, GoR B). Strong consensus (100%).

Recommendation 4

The ablation zone should aim to extend at least 5 mm beyond the visible borders (LoE 3a, GoR B). Strong consensus (100%).

Recommendation 5

In lesions close to large vessels and heat-sensitive structures, alternative or additional techniques should be considered (LoE 3a, GoR B). Strong consensus (100%).

Recommendation 6

Three to five HCCs are the recommended maximum number of lesions in a single session that allows percutaneous ablation with curative intent (LoE 2a, GoR B). Strong consensus (100%).

RFA versus surgical resection in small HCCs

There is inconclusive evidence as to whether RFA is as effective as surgical resection as the first-line treatment for patients with small, solitary HCCs [50, 51, 53–56, 60–63]. A systematic review of 8000 patients [64] with a current Cochrane analysis [65] reported uncertainty regarding the question of the impact of RFA versus surgery. However, a more recent meta-analysis, published

after the Cochrane analysis [66], showed that there were differences in age and liver function between patients with early HCC submitted to either RFA or resection. When the analysis was corrected for these parameters, no survival differences were observed between RFA and surgery in single HCCs <2 cm or 2–3 HCC tumors <3 cm, whereas surgery resulted in a longer survival in the case of single HCCs measuring 2–5 cm [66]. Mortality and morbidity rates of RFA have been reported to be 0–1.5% and 0.9–7.9%, respectively [67–72].

Percutaneous ethanol injection (PEI)

PEI was the first ablative procedure, initially reported in the early 1980s [40, 41, 73].

The procedure is inexpensive and safe, with low mortality and morbidity (0–3.2% and 0–0.4%, respectively) [74–76]. Even though RFA has replaced PEI [38, 77, 78], PEI can be offered in small HCCs, mainly those for which RFA is not feasible due to tumor location.

RFA versus PEI

Randomized controlled trials comparing RFA with PEI demonstrate that RFA is superior to ethanol injection in terms of treatment response, number of sessions, recurrences, and overall survival [77–83] as further supported by meta-analyses [65, 82, 84]. The efficacy of the methods is similar for tumors ≤2 cm [38, 77, 78, 85]. Meta-analyses, including randomized controlled trials (RCTs), confirmed that treatment with RFA offers a survival benefit as compared to PEI in tumors >2 cm [82–84, 86, 87]. RFA has a slightly higher rate of major complications (4%; 95% CI, 1.8–6.4%) as compared to PEI (2.7%; 95% CI, 0.4–5.1%) [52, 79, 81, 87]. The best results obtained in series of HCC patients treated by RFA provided 5-year survival rates of 40–70% or higher in select groups of patients [47, 67, 88]. The best outcomes have been reported in Child–Pugh A patients with small (<2 cm) single tumors [70, 89]. Independent predictors of survival with RFA are initial complete response, Child–Pugh score, number or size of nodules, and baseline alpha-fetoprotein levels [90].

Other procedures

Percutaneous microwave ablation (MWA) was introduced into clinical practice in the 1990s [43, 91–97].

Selection of ablation technique

With PEI, local response is related to tumor size. PEI has yielded very favorable results for small encapsulated HCCs (<2 cm) [12, 73]. HCC encapsulation by a cirrhotic liver prevents satellite nodules from being reached, leading to higher rates of local recurrence in comparison to RFA [98–101]).

Recommendation 7

Percutaneous ethanol injection with curative intent is an alternative to thermal ablation in encapsulated HCCs <20 mm (LoE 2a, GoR B). Broad agreement (95%).

Recommendation 8

Percutaneous ethanol injection can be an alternative in case of contraindications to thermal ablation (LoE 3b, GoR B). Broad agreement (79%).

Selection of imaging modality (ultrasound, CT, MRI)

US is the first-line imaging modality for local ablative procedures in the liver. CT guidance can be an alternative, particularly when US guidance is not feasible anatomically or with US imaging of occult lesions [102, 103]. MRI guidance is possible but with limited availability and major costs. Local expertise and personal experience determine the modality of choice. Contrast-enhanced imaging must be available during the interventional procedure to confirm the completeness of necrosis. Fusion imaging is an alternative technique that can be used for the guidance of the procedure.

Planning and monitoring ablation treatment

Imaging plays an important role before, during and after ablation procedures. Assessment of tissue perfusion is crucial to differentiate necrotic areas from viable residual tumor. With US- and CT-guided RFA, this requires evaluation with contrast-enhanced imaging during and immediately after ablation. Contrast-enhanced ultrasound (CEUS) can provide important information for assessment during and immediately after ablation [104, 105]:

- ▶ assessment of the lesions to be treated by ablation (number, size, degree and homogeneity of lesion enhancement, presence of feeding vessels, to define the eligibility for treatment and the best ablation strategy)
- ▶ depiction of previously undetectable lesions with the support of fusion imaging, enabling needle/probe guidance to occult lesions
- ▶ detection of viable tumor persistence following loco-regional treatment [50]

CEUS is the most effective method to define local recurrence in a treated nodule because of its real-time capability, the intra-vascular characteristic of the contrast agent and the near-total differentiation between the displayed contrast and background information of current imaging methods [8]. CT and MRI provide better overviews of the liver and adjacent organs, which are necessary for pretreatment staging and useful to detect distant intra- and extra-hepatic tumor recurrence.

Complications

Studies have established that RFA is a low-risk procedure [106–109], with a mortality of 0.1–0.8% and few adverse events. Major complications occur in 2.2–11% of RFA-treated patients [72, 106, 110–112]. Bleeding, infection, arteriovenous fistula formation, bile duct damage, and tumor seeding are possible complications of local ablative therapy [11, 12, 18, 113].

Thermal track ablation can potentially reduce the likelihood of tumor seeding in HCC ablation to below 1% [114–117].

Recommendation 9

A multidisciplinary approach to assess patients with HCC in liver cirrhosis for possible transplantation is recommended prior to alternative treatments (LoE 5, GoR D). Strong consensus (100%).

Recommendation 10

RFA with curative intent is an alternative, more cost-effective technique in comparison to surgery in early HCC BCLC-0 (HCC <2 cm) (LoE 2a, GoR B). Strong consensus (100%).

Recommendation 11

RFA with curative intent should be considered as a second-line treatment in single HCCs 2 – 5 cm in Child-Pugh A patients, after the patient has been evaluated for surgical resection (LoE 2b, GoR B). Strong consensus (100%).

Recommendation 12

RFA with curative intent should be considered as the first-line treatment in Child-Pugh B patients with single HCCs < 5 cm or in patients with 2 or 3 HCCs < 3 cm (LoE 2b, GoR B). Strong consensus (100%).

Recommendation 13

Solitary HCCs > 3 cm not suitable for surgery should be considered for combined loco-regional treatments (LoE 4, GoR C). Broad agreement (95%).

Colorectal cancer liver metastases

It is estimated that 50–60% of patients with colorectal cancer (CRC) will develop liver metastases [118]. The most successful treatment for hepatic metastases is surgical resection [9, 10, 31, 59, 119–125]. However, approximately 50–70% of these patients will develop recurrence [126].

Local ablative procedures with curative intent have a role in the management of CRC liver metastases [9, 10]. Depending on the size of the lesions, RFA may be performed alone or combined with resection [127]. Several studies have demonstrated that RFA achieved permanent local ablation of liver metastases and a 5-year survival of 24% to 43% [128–132]. These results are comparable to surgery [31, 59, 119–125]. Local recurrence occurs more frequently after ablation than with resection [9, 10, 133].

Two meta-analyses confirmed that surgery is superior to RFA with regard to survival outcomes in patients with resectable CRC liver metastases [134, 135]. The first RCT on the efficacy of RFA combined with chemotherapy versus chemotherapy alone was underpowered; RFA plus systemic treatment resulted in significantly longer progression-free survival (PFS) compared with chemotherapy alone [136].

Recommendation 14

Percutaneous thermal ablation with curative intent is a second-line alternative to surgery in patients with colorectal liver metastases (LoE 2a, GoR B). Strong consensus (100%).

Recommendation 15

The maximum diameter of metastatic lesions treatable with thermal ablation is generally considered ≤ 4 cm, although better results are obtained in lesions < 3 cm (LoE 5, GoR D). Strong consensus (100%).

Recommendation 16

The ablation zone should aim to extend at least 10 mm beyond the visible borders (LoE 5, GoR D). Broad agreement (94%).

Other liver metastases

Percutaneous thermal ablation or PEI may be a therapeutic option for neuroendocrine liver metastases [23, 24].

Renal malignancies treated with local ablative therapy
Introduction

Possible treatment options for renal cell carcinoma (RCC) are [137]:

- ▶ Surgery, either nephrectomy or nephron-sparing (open or laparoscopic)
- ▶ Local ablative procedures (percutaneous or laparoscopic)
 - ▶ cryoablation
 - ▶ RFA
 - ▶ MWA
- ▶ Active surveillance

Small masses

Standard therapy for small RCCs is nephron-sparing surgery. Local ablative techniques have evolved into alternative procedures, showing excellent results [138].

Tumors < 4 cm in diameter are ideal candidates for ablative techniques. The volume to be treated should include a 5–10 mm safety margin [139]. Most tumors < 3 cm can be treated in a single ablation session. Tumors between 3–4 cm in diameter can also be successfully treated, although multiple ablation sessions may be required [140–148].

Recommendation 17

Patients with RCCs < 3 cm with significant surgical risk or requirement for nephron-sparing strategy should be considered for local ablative therapy (LoE 2b, GoR B). Strong consensus (100%).

RCTs comparing surgery and local ablative therapy have not been performed [137, 149]. Cancer-specific survival is similar for both methods [150, 151]. The European and American Urological Associations recommend thermal ablation as a treatment option for patients with a T1 renal mass [152].

Local recurrence-free survival following image-guided tumor ablation is 87% [153]. The local recurrence of percutaneously performed RFA is estimated at 2.5–14% [154]. Cancer-specific survival of patients treated with RFA is comparable to patients treated with surgery [142, 152, 155]. Both cryotherapy and RFA had a higher risk of recurrence compared to partial nephrectomy [156], but re-intervention is straightforward [142].

The rate of major complications for cryotherapy is 5%, which is lower than for surgery [152], the most common complication being hemorrhage [213] with 2% developing distant metastases [152, 155]. Post-procedural ureteric strictures have also been documented [152]. Cryotherapy is preferred over RFA in central tumors in contact with the renal hilum or the ureter [157].

Recommendation 18

RCC histology should be obtained prior to ablation (LoE 4, GoR C). Broad agreement (81%).

CEUS can be used for surveillance after RFA of RCCs in order to detect local recurrence and to assess for liver metastases [158]. CT of the thorax and abdomen is necessary to exclude metachronous extrahepatic metastases. No RCTs have been performed [159–161].

Recommendation 19

Contrast-enhanced ultrasound or CT or MRI should be performed in the follow-up after RCC ablation, unless contraindicated (LoE 4, GoR C). Strong consensus (100%).

Abscess drainage

US-guided percutaneous drainage of abdominal abscesses is a well-established interventional procedure first described in 1974 [162] and is currently the first-line treatment approach for abdominal abscesses.

Definition and classification

Differentiation between phlegmonous inflammation and abscesses is of importance for treatment guidance. An abscess is a pus-containing confined collection, most often caused by bacteria. To be termed an abscess, the fluid has to be viscous and surrounded by an inflammatory wall that develops as a result of effective host defense [163].

Recommendation 20

Phlegmonous infections and small abscesses should be treated with antibiotics and require no drainage (LoE 5, GoR D). Strong consensus (100%).

Postoperative fluid collection

Fluid collections present on postoperative imaging, localized or generalized ("free fluid"), are common and nonspecific which may represent different pathological entities such as hematoma, exudate, seroma, biloma, lymphocele or an abscess. Fluid seen on imaging is often not characteristic; any patient with a clinical suspicion of an abdominal abscess should have a diagnostic aspiration to guide further management. Sterile fluid collections can become infected postoperatively, requiring diagnostic aspiration and eventually therapeutic drainage.

Ultrasound (US)

US imaging is often the initial modality used in abscess delineation as it allows dynamic evaluation and real-time guidance of needling. Depending on the contents, an abscess can be anechoic, hypoechoic and even hyperechoic. CEUS can be helpful in differentiating vascularized from avascular areas [164, 165]. CT is indicated in technically limited US examinations or inconclusive results.

Diagnostic aspiration

A US-guided diagnostic puncture of a fluid collection with a fine needle or a larger needle (depending on the viscosity) can distinguish an abscess from a non-infected fluid collection.

Recommendation 21

Diagnostic aspiration of a suspected infected fluid collection is recommended (LoE 5, GoR D). Strong consensus (100%).

Puncture and drainage**Catheter drainage versus needle aspiration**

A meta-analysis of 5 RCTs comparing catheter drainage and repeated needle aspirations of liver abscesses demonstrated catheter drainage to be more effective, with higher success and shorter time to achieve clinical improvement [166]. Studies of abdominal abscesses of various etiologies have shown good results with repeated needle aspiration in simple abscesses < 5 cm. In larger abscesses catheter drainage performed better than repeat needle aspiration [167 – 171].

Recommendation 22

Abscesses less than 5 cm in diameter can be treated with needle aspiration (LoE 2b; GoR B). Strong consensus (100%).

Recommendation 23

Catheter drainage is more effective than needle aspiration in abscesses larger than 5 cm in diameter (LoE 1a, GoR A). Broad agreement (89%).

Small or large catheters

No difference in outcome was seen in a study of intra-abdominal abscesses treated with 7F pigtail catheters and 14F sump drain catheters [172]. Currently large catheters (> 10F) should be reserved for complex abscesses containing thick pus and debris.

Recommendation 24

Catheters of 7 – 10F in size are recommended for the treatment of most abscesses, regardless of abscess dimensions (LoE 4, GoR C). Broad agreement (90%).

Recommendation 25

Large catheters (> 10F) should be reserved for complex abscesses with thick contents (LoE 5, GoR D). Broad agreement (90%).

Catheter introduction techniques: Trocar versus Seldinger

Two techniques are used for the insertion of a drainage catheter: the trocar (one-step) technique and the Seldinger (two-step) technique. Both have advantages and disadvantages and can be performed with either a free-hand or needle-guided technique, depending on the preference and experience of the operator.

Recommendation 26

The trocar technique is suitable in most circumstances using catheters ≤ 10 F (LoE 5, GoR D). Broad agreement (93%).

Recommendation 27

The Seldinger technique is recommended when access is difficult, for large catheters, and for catheter replacement (LoE 5, GoR D). Broad agreement (86%).

Single versus double lumen

Double lumen catheters are not recommended since they combine the negative features of large diameters and relatively small lumens.

Recommendation 28

Double lumen catheters are not recommended (LoE 5, GoR D). Broad agreement (94%).

Abscess cavity extension and complexity, fistula, and contrast injection (X-ray, CEUS)

Treatment planning requires careful assessment of the size, shape, content and extent of the abscess, including identification of associated fistulas. Fistulography (or abscessography, sinography) with intracavitary injection of iodinated contrast media under CT or fluoroscopic guidance has been the recommended technique. Direct injection of US contrast agent through the needle or catheter has been reported to facilitate confirmation of correct needle or catheter position and allows evaluation of any communication between cavities in complex abscesses at the bedside [173–175].

Recommendation 29

Intracavitary CEUS may add value regarding needle and catheter position, cavity morphology and presence of fistulas (LoE 4, GoR C). Strong consensus (100%).

Specific organs and locations

Liver abscess

Pyogenic liver abscesses are often the result of biliary obstruction caused by benign or malignant diseases with consequent cholangitis. For percutaneous drainage, a transhepatic access route is preferred for direct puncture to avoid spillage of pus into the peritoneal cavity. Small amebic abscesses generally respond to conservative treatment and do not require drainage, but large amebic abscesses may need drainage [176].

Recommendation 30

The origin of liver abscesses should be investigated to search for an underlying cause (LoE 5, GoR D). Strong consensus (100%).

Recommendation 31

A transhepatic access route is recommended for the percutaneous drainage of hepatic abscesses (LoE 5, GoR D). Strong consensus (100%).

Splenic abscess

Splenic abscesses are rare, except in immunocompromised patients. Splenic puncture or biopsy is relatively safe as documented in a meta-analysis [177].

Recommendation 32

Percutaneous splenic abscess drainage should be the first-line treatment and surgery should be performed in the case of treatment failure (LoE 4, GoR C). Broad agreement (89%).

Pancreatic abscess

Percutaneous drainage of pancreatic abscesses is often prolonged and may require multiple catheters. The percutaneous approach offers quick access for severely ill patients. As a second stage procedure, conversion to internal drainage with an endosonographic approach should be considered.

Recommendation 33

Pancreatic abscess management is complex and often prolonged. Drainage procedures guided by transcutaneous or endoscopic ultrasound (EUS) should be considered (LoE 4, GoR C). Broad agreement (89%).

Enteric abscess

Abscesses are frequent complications of Crohn's disease, diverticulitis and appendicitis. In Crohn's disease, there is no study comparing percutaneous and surgical drainage of abscesses. Percutaneous drainage of Crohn's-related abscesses has a high success rate, demonstrated in several studies and is the first-line treatment [178, 179]. With early percutaneous drainage, (non-elective) surgery can often be avoided (14–85% of patients) [179–183].

Abscesses can be detected in 15% of patients with acute diverticulitis [184, 185]. Antibiotics successfully treat smaller abscesses (< 3 cm) [184, 186, 187], but larger abscesses (> 3 cm) require percutaneous drainage [188, 189]. Peri-appendicular abscesses can occur either as a result of rupture of an infected appendix or post-operatively.

It is generally accepted that a peri-appendicular abscess will respond to percutaneous drainage. Leakage of enteric contents at an anastomosis may lead to abscess formation, which most often requires reconstructive surgery. Sometimes, a non-surgical approach is preferred with usage of long-term percutaneous drainage with large catheters.

Recommendation 34

Abscesses in Crohn's disease, diverticulitis and appendicitis may benefit from percutaneous drainage as the first-line strategy (LoE 4, GoR C). Broad agreement (89%).

Abscess in the lower abdomen and pelvis

For deep pelvic abscesses, alternative puncture routes are available. Transrectal, transvaginal, transperineal and transgluteal accesses have all been shown to be useful and safe [169, 190–192].

Recommendation 35

US-guided drainage by transrectal, transperineal or transvaginal access is associated with a low risk of complications and should be considered for deep pelvic abscesses (LoE 4, GoR C). Strong consensus (100%).

Recommendation 36

Use of intracavitary fibrinolytics is not routinely recommended (LoE 5, GoR D). Broad agreement (94%).

Ultrasound-guided paracentesis



Background

Paracentesis is performed either as a diagnostic or as a therapeutic procedure, in the presence of ascites or suspected bacterial peritonitis. Therapeutic paracentesis provides almost immediate symptomatic relief and is usually well tolerated.

Technical issues

Ascites drainage is usually easily and safely performed by inserting a 14–18 gauge needle (including paracentesis-specific devices) or as a one-step catheter under US guidance. Catheters can be pig-tail, they can have an internal string for internal loop fixation, or an internal balloon fixation can be used. A small bore catheter (between 5F and 7F) is usually adequate.

US guidance offers real-time imaging of the needle tip and surroundings during the procedure, making it safe and effective. In most instances, US assistance (i.e., US utilized to select the best access point prior to blind needle insertion) is as safe as US guidance [193].

Complications

Paracentesis is considered a safe procedure, carrying a 1% risk of overall complications, which include leakage of ascitic fluid, local infection, abdominal wall hematomas, intraperitoneal hemorrhage, and intestinal perforation [194]. It is recommended to follow strict antiseptic practices in all patients [195]. Ultrasound guidance can reduce the risk of complications after paracentesis [193, 196].

Recommendation 37

Ultrasound-guided or assisted paracentesis is a low-risk and effective procedure (LoE 4, GoR C). Strong consensus (100%).

Specific considerations

Cirrhosis

Ascites is the most common complication of cirrhosis leading to hospital admission.

Albumin administration

Large-volume paracentesis (>5 L) is generally an effective and safe procedure, but it does carry a risk of “postparacentesis circulatory dysfunction” (PCD).

Recommendation 38

Administration of albumin is mandatory in large-volume (>5 liters) paracentesis (LoE 1a, GoR A). Strong consensus (100%).

Recommendation 39

There are no established preprocedural threshold coagulation levels that preclude paracentesis (LoE 5, GoR D). Broad agreement (94%).

Palliative paracentesis for malignant ascites

Malignant ascites accounts for around 10% of cases and occurs with a variety of neoplasms [197]. Large amounts of ascites can cause increased abdominal pressure with pain, dyspnea, loss of ap-

petite, nausea, and reduced mobility. Long-term paracentesis is indicated for patients with symptoms of increased intraabdominal pressure caused by recurring malignant ascites despite repeated paracentesis.

Recommendation 40

Permanent catheter drainage should be considered for terminally ill patients with refractory ascites (LoE 4, GoR C). Broad agreement (94%).

Sclerotherapy of non-parasitic cysts



Hepatic cysts

Hepatic cysts have a prevalence of 2.5–7%. Most are asymptomatic and do not need treatment [198]. Percutaneous treatment, consisting of aspiration of cystic fluid followed by injection of a sclerosing agent, is usually performed with US guidance, as a minimally invasive option for large or symptomatic cysts.

Indications

Large cysts (>6–10 cm), which are symptomatic (pain or infected) or causing space-occupying effects (abdominal distension, obstructive jaundice or both), require treatment. Other less established indications include symptomatic small sub-capsular cysts located at sites exposed to mechanical stress (beneath the ribs or sternum) [199]. In polycystic liver disease, any cysts may be treated if causing symptoms or to avoid complications (e.g., rupture, bleeding, infection) [200–205].

Recommendation 41

With symptomatic or compressive hepatic cysts, percutaneous sclerotherapy or surgery should be considered (LoE 4, GoR C). Strong consensus (96%).

Contraindications

Caution is required when treating hydatid cysts; the nature of a cyst may not be known prior to aspiration [199]. A relative contraindication is hemorrhagic cysts [206] although they can be treated with similar results once infection or malignancy has been excluded [202]. Ascites and planned liver transplantation are other relative contraindications.

Multidisciplinary decision making

Multidisciplinary decision (gastroenterologists, surgeons, interventional radiologists) for the procedure is mandatory as other options include open surgery and laparoscopic deroofing which are effective treatments. These treatments are associated with substantial morbidity and mortality and require expertise [207, 208]. Percutaneous treatments have similar efficacy, allowing surgery to be reserved for complicated cases or if percutaneous sclerotherapy fails [201, 209].

Sclerotherapy versus surgery (fenestration)

No randomized prospective study comparing fenestration and sclerotherapy has been published. In most centers, sclerotherapy is attempted first as a noninvasive option, and laparoscopic fenestration is indicated in refractory cases [209].

Recommendation 42

Percutaneous ethanol sclerotherapy is a good alternative to laparoscopic deroofing with similar efficacy and lower complication rates (LoE 4, GoR C). Strong consensus (96 %).

Prognosis

The majority of patients who undergo percutaneous sclerotherapy are symptomatically improved immediately following the procedure, but only 20 % will have partial or full regression of the dominant and symptomatic cyst [208]. In polycystic liver disease both sclerotherapy and surgery are disappointing (77–100 % recurrence rate) [9].

Materials and technical issues

The treatment consists of evacuation of the cystic contents (either by aspiration or drainage via a catheter) followed by sclerotherapy of the inner epithelium using standard agents (ethanol, polidocanol, tetracycline chloride, minocycline chloride, hypertonic saline solution and ethanolamine oleate) [210–214]. A radiopaque contrast medium or US contrast agent should be instilled into the cyst to exclude a connection with the biliary tree [215]. If contrast medium enters the bile ducts, sclerotherapy is contraindicated.

Ethanol sclerotherapy

Ethanol (95–98 % concentration) is most commonly used for sclerotherapy of hepatic cysts [216–218]. Single or multiple sessions may be needed with evacuation of the fluid content performed using 6–8F catheters or a Chiba needle (18–20 gauge) [216–218]. After ethanol sclerotherapy, an 80–100 % reduction of cyst volume may be achieved [198, 201, 210, 216, 218, 219]. The main complications during ethanol sclerotherapy are pain, ethanol-induced fever or hyperthermia, intoxication, intra-cystic bleeding and iatrogenic pleurisy or peritonitis [202, 211].

Recommendation 43

With percutaneous ethanol sclerotherapy of large liver cysts, the use of small catheters instead of needles should be considered to achieve a longer ethanol exposure time (LoE 4, GoR C). Broad agreement (95 %).

Sclerotherapy using other substances

Several other substances with better safety profiles, ease of use and low cost have been tested with good results and few complications [210–214]. Polidocanol 1–3 % (aethoxysklerol) may be preferred for its local anesthetic properties (it is less painful than alcohol) and its slight bactericidal activity [199].

Recommendation 44

Percutaneous sclerotherapy using other substances is an alternative to ethanol (LoE 4, GoR C). Broad agreement (90 %).

Ultrasonographic follow-up

In polidocanol therapy maximum volume reduction occurred 1 year after the procedure [215]. Follow-up examinations may only be necessary in symptomatic patients.

Renal cysts**Indications**

Simple renal cysts are mostly asymptomatic and do not require treatment. In 2–4 % the cyst may become symptomatic because it enlarges or develops complications such as hemorrhage, infection, rupture or compression [220]. Cysts that develop adjacent to the renal hilum may obstruct the urinary tract [221]. US-guided cyst aspiration with or without sclerosing therapy is a minimally invasive, simple, safe and low-cost procedure [221].

Recommendation 45

Symptomatic simple renal cysts should be considered for treatment. (LoE 4, GoR C). Broad agreement (94 %).

Multidisciplinary decision making

A multidisciplinary decision regarding procedure choice is recommended as surgical excision via open, percutaneous, laparoscopic or robotic surgery is effective but more invasive. Laparoscopic deroofing achieves better results than percutaneous sclerotherapy (PS) [220, 221].

Recommendation 46

The decision on treatment modality should consider that percutaneous sclerotherapy is less invasive and associated with lower risks than laparoscopic deroofing, but has lower efficacy (LoE 2b, GoR B). Broad agreement (88 %).

Materials and technical aspects

A variety of substances are used for sclerotherapy of the cystic wall [214, 222–231] as described for liver cysts.

Simple cyst drainage without sclerotherapy

After simple aspiration, the recurrence ranges from 30–80 % [171, 232].

Recommendation 47

Simple aspiration should not be used in the treatment of renal cysts because recurrence is frequent (LoE 4, GoR C). Broad agreement (93 %).

Ethanol sclerotherapy

The most common sclerotherapy agent for renal cysts is ethanol [227–231]. A concentration of 95–99 % destroys the secreting cells of the cyst wall without affecting the renal parenchyma [220]. Single or multiple sessions have been used, with better results but with higher complications for multiple sessions [221, 228–233].

The main complications that may occur during ethanol sclerotherapy are pain, fever, and systemic reactions [220].

Recommendation 48

Multiple sessions and/or prolonged drainage should be used to reduce recurrence in symptomatic large renal cysts treated with ethanol sclerotherapy (LoE 4, GoR B). Broad agreement (87 %).

Ultrasonographic follow-up

Follow-up examinations may only be necessary in symptomatic patients.

Abdominal echinococcal cysts, puncture, aspiration, injection and re-aspiration (PAIR)

Introduction

Echinococcosis is a chronic, complex and neglected zoonosis with widespread global distribution. 70% of cases of cystic echinococcosis (CE) are located in the liver [234]. US has an important role in the diagnosis, treatment and follow-up of abdominal CE and is established in the interventional treatment of abdominal CE [235, 236].

Classification

The WHO echinococcal cyst classification [237, 238] is US-based and was introduced to guide treatment options and to predict prognosis [239]. Type CE1 and CE2 are the typical active cysts. Type CE1 is unilocular, whereas CE2 is multilocular with daughter cysts. The Gharbi classification is still widely used [240].

Diagnosis and differential diagnosis

Imaging

US is the imaging modality most appropriate for diagnosis and differential diagnosis [238], while US guidance is usually used for intervention [241, 242].

Serological tests

Serological tests for echinococcosis should be obtained, where available, before the procedure [243, 244].

PAIR indication

PAIR is most appropriate for CE1 and CE3a according to the WHO classification (Gharbi type I and II cysts) [244, 245].

Relative contraindications

Hydatid cysts with multiple daughter cysts and solid components (Gharbi Type III-IV and WHO CE2-CE3b) are not suitable for PAIR [236, 245, 246]. It is reported that aggressive percutaneous evacuation for these complex cysts is useful, but not widely accepted.

Pretreatment procedures

As with any interventional procedure, the patient should be carefully evaluated before the PAIR procedure. Albendazole should be started one week (or at least one day) prior to the procedure for prophylaxis against abdominal contamination [247], and thereafter continued for at least one month [236, 248].

Procedure, puncture and drainage

The procedure consists of puncture, aspiration, injection and re-aspiration [239, 249, 250] using a 20-gauge fine needle [251, 252].

Outcome

RCTs showed PAIR to be superior to albendazole alone [253] and to surgical treatment [239, 254]. PAIR combined with albendazole was more effective than surgery and was associated with a lower rate of adverse events and a shorter hospital stay. Retro-

spective studies favor PAIR over surgery in Gharbi type I and II cysts and found surgical treatment most appropriate in the other Gharbi types [249, 255].

A meta-analysis reported severe adverse events (anaphylaxis, cyst infection, abscess, sepsis, biliary fistula) in 7.9% of patients treated with PAIR plus albendazole [256].

Recommendation 49

US-guided PAIR is the most appropriate treatment for WHO CE1 and CE3a abdominal hydatid cysts (LoE 2b, GoR B). Strong consensus (100%).

Recommendation 50

PAIR should always be accompanied by measures to manage possible anaphylaxis (LoE 5, GoR D). Broad agreement (93%).

Recommendation 51

Albendazole should be started prior to PAIR (LoE 2b, GoR B). Strong consensus (100%).

Percutaneous transhepatic cholangiodrainage (PTCD)

Introduction

Percutaneous transhepatic cholangiography and drainage (PTCD) is a commonly used procedure for the diagnosis and treatment of benign and malignant biliary diseases [257, 258]. PTCD also allows therapeutic interventions, such as placement of a stent across a malignant stricture, dilatation of benign biliary strictures and extraction of biliary tract stones [259].

Endoscopic retrograde cholangiography versus PTCD versus endoscopic ultrasound-guided cholangiodrainage

Endoscopic retrograde cholangiography (ERC) is the method of choice for patients with indications for (therapeutic) biliary access [260, 261]. The following surgically altered anatomical situations have a high likelihood for ERC failure: Roux-en-Y with gastric bypass, Kausch-Whipple resection, pylorus-preserving Whipple resection, Roux-en-Y with hepaticojejunostomy, choledochojejunostomy, and pancreaticojejunostomy [262].

Alternative methods are PTCD, EUS-guided interventions (EUS cholangiodrainage, EUS-CD) [192] and balloon-assisted enteroscopy (BAE).

Special problems

Ultrasound guidance versus fluoroscopic guidance

A blind percutaneous puncture of peripherally located intrahepatic bile ducts has limitations especially with non-dilated bile ducts [263, 264]. Real-time imaging with US is useful for the guidance of PTCD (US-PTCD), especially in patients with non-dilated ducts and for left-sided PTCD [265 – 267]. Fluoroscopy delivers significant irradiation both to the patient and to the interventional team. The “As Low As Reasonably Achievable” (ALARA) principle should be applied [268].

Recommendation 52

For initial puncture in PTCd ultrasound guidance should be considered (LoE 4, GoR C). Strong consensus (100%).

Percutaneous cholecystostomy**Introduction**

Acute calculous cholecystitis (ACC) is a common cause of acute surgical admission. Early cholecystectomy (CCE) is a widely accepted method of treatment [269]. Laparoscopic cholecystectomy (LCCE) in acute cases has minimal morbidity [270]. In high-risk patients morbidity and mortality increase to 14–46% [271]. Alternatively, percutaneous cholecystostomy (PC) is a bridging process, especially in otherwise healthy patients (e.g. ASA I and II) who are severely septic and may become fit in due course for semi-elective surgery [272].

Clinical efficacy

A meta-analysis of 53 studies (n = 1918 patients) reported successful PC for 85.6% of patients. The procedure-related mortality rate of PC was 0.4% [273].

Evaluation of US-guided percutaneous cholecystostomy (USPC) for patients with acute acalculous cholecystitis (AAC) is more difficult because it is normally a complication of serious medical and surgical illnesses [274, 275]. A study compared clinical efficacy and adverse events of PC and CCE in a large group of severely ill patients with AAC and showed PC to be a safe and cost-effective bridging treatment strategy, with perioperative outcomes superior to those of open CCE. Compared with open or laparoscopic CCE (n = 1021), PC (n = 704) was superior in terms of morbidity, intensive-care unit admissions, length of hospital stay, and costs [276]. Two studies showed that in seriously ill patients with AAC, PC is an effective procedure and may be regarded as a definite treatment option in the majority of patients [277, 278].

Data is limited with respect to the duration of gallbladder drainage. Before removal of the drain, laboratory and clinical data should confirm resolution of sepsis [279]. Patients should be re-evaluated following recovery to assess fitness for elective surgery. Cholecystitis recurrence of 10–30% is reported, and should be weighed against the mortality and morbidity risk in the individual patient.

Recommendation 53

Percutaneous ultrasound-guided gallbladder drainage may be considered in patients with acute calculous cholecystitis assessed to be unfit for surgery (LoE 3b, GoR B). Strong consensus (100%).

Recommendation 54

In patients with acute acalculous cholecystitis unfit for surgery, percutaneous ultrasound-guided gallbladder drainage should be considered after diagnostic puncture (LoE 2c, GoR B). Strong consensus (100%).

Drainage route

The transhepatic route has advantages regarding tract formation and the avoiding of peritonitis [280, 281]. The transperitoneal approach has been reported to be similar in relation to complica-

tions, but formation of a mature tract without leakage as a precondition for catheter removal is significantly delayed compared with the transhepatic approach [280, 282, 283]. EUS-guided transmural gallbladder drainage may be performed as an alternative to USPC [192].

Recommendation 55

Ultrasound-guided percutaneous gallbladder drainage should be performed transhepatically (LoE 2b, GoR B). Strong consensus (100%).

Percutaneous gastrostomy**Introduction**

Gastrostomy can be offered when oral food uptake is temporarily or permanently compromised. Gastrostomy may be used in patients with neurological disorders (e.g., neurological degeneration) and advanced (oncological) diseases, e.g. in gastrointestinal stenosis with intractable vomiting where surgical treatment is not feasible or is declined. The endoscopic approach (percutaneous endoscopic gastrostomy, PEG) with the “pull” technique is the most common technique.

Image-guided percutaneous gastrostomy (without endoscopic access)

The percutaneous approach (image-guided percutaneous gastrostomy, PG) can be performed under fluoroscopy (radiologically inserted gastrostomy, RIG) or US guidance (USPG).

US guidance in experienced hands allows the identification of the position of (a) the stomach, (b) the liver, and (c) in most instances, the transverse colon. Usually the stomach is filled with water by a nasogastric tube, but if US is used to assist endoscopy, air distension is sufficient.

US may be used in the following situations:

- ▶ In cases of anticipated difficulty locating the stomach (scars, advanced gastric cancer, obesity, surgically altered stomach anatomy).
- ▶ In endoscopic approach when trans-illumination fails.
- ▶ In cases without access to the upper gastrointestinal tract (complete esophageal obstruction).

Recommendation 56

In cases in which conventional endoscopically guided gastric puncture fails, ultrasound-assisted gastric puncture may make it possible to accomplish percutaneous gastrostomy (LoE 4, GoR C). Broad agreement (76%).

Recommendation 57

When placing of a nasogastric tube is not possible, the stomach can be punctured under ultrasound guidance and distended with air or water to facilitate percutaneous image-guided gastrostomy (LoE 4, GoR C). Broad agreement (86%).

Antibiotic prophylaxis is mandatory for PEG using the pull technique for prevention of peristomal infection. For introducer techniques, antibiotic prophylaxis is not necessary. The database for antibiotic prophylaxis in PEG is comprehensive [284]. There is data for RIG showing no wound infections [285].

Percutaneous nephrostomy



Introduction

Percutaneous nephrostomy (PCN) remains the procedure of choice for temporary drainage of the obstructed collecting system when the transureteral (or retrograde) approach is not indicated or feasible [286, 287]. PCN is also used for urinary diversion and to gain access to the urinary tract for subsequent interventional urologic procedures. PCN can be successfully performed in 95–98% of patients who have a dilated renal collecting system [250].

Indications and contraindications

Indications

PCN may be performed for diagnostic or therapeutic purposes [288, 289].

- ▶ Relief of urinary obstruction related to malignancy, urinary stones or iatrogenic causes [289].
- ▶ Pyonephrosis and obstructive acute pyelonephritis.
- ▶ Urinary diversion in patients with urinary fistula, leakage or hemorrhagic cystitis [290, 291].
- ▶ Access for endourologic procedures, such as nephrolithotomy and removal of urinary stones, dilation or stenting of a ureteral stricture [288].
- ▶ Diagnostic testing, such as antegrade pyelography, ureteral perfusion (Whitaker test) [290].
- ▶ Specific situations, e. g., uroenteric diversion.
- ▶ Treatment of urolithiasis in transplanted kidneys and external malignant obstruction [292–295].

Contraindications

There is no absolute contraindication for PCN, but the benefits and risks must be weighed for each individual [288, 289]. Relative contraindications are:

- ▶ Renal vascular malformations such as an arterial aneurysm [290].
- ▶ Severe life-threatening electrolyte imbalances such as hyperkalemia, or severe metabolic acidosis [288].
- ▶ Severe coagulopathy [296].

Imaging modalities

The optimal imaging methods to guide PCN vary at individual centers. The procedure can be performed with the guidance of fluoroscopy, US, CT, and various combinations of those techniques [297–299].

Ultrasound guidance

US-guided puncture of the collecting system with subsequent placement of the drainage tube under fluoroscopic control is regarded as the standard technique for PCN [290, 300, 301]. US is helpful to identify the most appropriate calyx for puncture and the presence of stones or blood clots or other intraluminal filling defects and to avoid damage to surrounding organs [302]. In addition, it is an ideal method for patient follow-up [302].

Recommendation 58

Percutaneous nephrostomy can be effectively performed under ultrasound guidance (LoE 2b, GoR B). Strong consensus (100%).

Injection of US contrast agents via a needle or catheter can also confirm whether the needle or PCN catheter have been correctly inserted in the renal pelvis, with reduction in radiation exposure

which may be especially important in the first trimester of pregnancy [303]. Fluoroscopy is recommended to determine the position of the needle and guidewire. The catheter can be visualized by injecting diluted US contrast agent.

Technical aspects and indications

Methods

Positioning

The risk of adjacent organ injury during percutaneous nephrostomy is minimized when the nephrostomy is inserted below the 12th rib. Attempts should be made to achieve catheter placement through a calyx, particularly if percutaneous nephrolithotomy or other large-bore catheter placement is considered [290].

Seldinger or trocar technique

US-guided PCN tube placement has a success rate of 92–94% [304, 305]. The trocar and Seldinger techniques are equally effective [306].

Size

A 6–10F catheter is recommended for PCN. If the collecting system is punctured for further procedures (e. g., tumor or stone removal), a larger catheter may be considered (14–22F).

Recommendation 59

In percutaneous nephrostomy, access via the posterior-inferior calyces should be attempted to reduce the risk of pleural and vascular injury (LoE 5, GoR D). Strong consensus (100%).

Post-procedure catheter management and patient care

Vital signs should be monitored during initial recovery (>24 hours) [288]. Urinary output should be charted. Urine will be blood-tinged initially but prolonged hematuria (>24–48 hours) should serve as an alert to persistent bleeding from vascular injury [288, 307]. Long-term indwelling catheters should be changed every 4–6 weeks [250].

Complications

The incidence of major complications ranges from 0–8% [286, 299, 308, 309]. Minor complications occur in 2–38% [286, 299, 308, 309].

Suprapubic puncture of the bladder



Introduction

Suprapubic puncture of the bladder is a safe and reliable method to drain the bladder, while avoiding urethral catheterization [310]. US guidance improves the success rate [311–314].

US is recommended to assess the position and volume of the bladder, and to avoid the inadvertent puncture of other structures [315, 316].

Recommendation 60

Puncture and drainage of the urinary bladder should be performed under ultrasound guidance (LoE 1b, GoR B). Strong consensus (100%).

Main indications

Suprapubic puncture of the bladder is indicated in pathological conditions of the bladder, prostate or urethra that require temporary or permanent drainage of the bladder when urethral catheterization is not possible or is contraindicated.

Contraindications to the percutaneous US-guided procedure

- ▶ Absence of visualization of the bladder on US.
- ▶ Uncorrected coagulopathy.
- ▶ Other relative contraindications are those secondary to complex anatomy due to congenital disorders, habitus, previous surgery or infiltrative pelvic cancer.

Materials and technical problems

The procedure is performed under sterile conditions after the administration of local anesthesia. Sedation may be useful in select cases. The position and volume of the bladder are identified by US and US is used for real-time guidance of the percutaneous puncture [315, 316]. Catheters are placed by either the Seldinger or the trocar technique, with dilation of the percutaneous track when necessary. Catheters of 10F are large enough to relieve acute urinary retention. Large catheters (> 16F) are recommended in patients who require prolonged drainage of the bladder in circumstances such as bladder rupture or complicated urethral stricture [310].

Complications

US guidance can decrease the complication rate of suprapubic puncture [310, 314, 317]. Major complications are rare and include perforation of intestinal loops [318]. Minor complications include pain, infection, hemorrhage, blockage, hematuria and catheter misplacement, all of which are less common when US guidance is performed [314, 317, 319].

Palliative care

Palliative care patients often have alterations in locoregional anatomy, vascular patterns and coagulation factors. Therefore, for any invasive procedure it is recommended to consider US guidance to improve safety and help minimize complications and patient discomfort. There are no contraindications of US-guided procedures in palliative care [320]. The management of cancer complications indicates potential roles for home-performed US and US-guided procedures at the end of life [321].

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