# A REVIEW OF COMPLICATIONS OF INTERVENTIONAL ULTRASOUND PROCEDURES IN THE ABDOMEN

The Professional and Educational Standards Committee of EFSUMB committee plans to publish a series of guidelines for ultrasound guided interventional procedures. We have already published evidence based guidelines on amniocenteses and chorionic villus sampling. As part of our work on such guidelines the committee publishes below a review of complications of interventional ultrasound guided procedures in the abdomen written by Dr Elisabetta Buscarini. At the end of this document you will find a few guidelines (needles and guidance, and precautions to be taken). We hope that our readers will find this publication useful in their clinical work and the committee thoroughly thanks Dr Buscarini for her contribution.
Any comments on the review are welcomed and can be sent to EFSUMB's General Secretary Mrs Gianna Stanford (e-mail: efsumb@efsumb.org).

**Lil Valentin**
**EFSUMB's Educational and Professional Standards Committee Chairperson**

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# REVIEW OF INTERVENTIONAL ULTRASOUND IN THE ABDOMEN

## *"safety first"*

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Interventional ultrasound (US) includes invasive procedures carried out under US guidance for diagnosis and therapy. Diagnostic procedures are undertaken for cytology or tissue sampling, generally performed with a fine needle (FN), which has a calibre less than 1 mm. Therapeutic procedures performed under US guidance are for drainage of fluid collections, or of obstructed collecting systems (typically US guided nephrostomy), or of hollow organs for nutritional purpose. Tumour ablation either by injection of chemicals (mainly ethanol) or by deposition of thermal energy with radiofrequency electrode needles or laser fibers is another therapeutic area.
The small calibre of biopsy needles and the safety offered by US guidance has made interventional US a minimally invasive procedure; nevertheless fatal and major complications are reported, generally caused by abdominal interventional procedures. Therefore, physicians performing interventional US should have a thorough knowledge of the relevant literature and of reported complications to improve their technical choices, to reduce the risk of complications, and to minimise the consequences of complications when they occur. It is important to learn how to prevent and how to correct complications.

### *Definition*

One problem when discussing complications is to ensure that everyone is speaking about the same thing. Complications range from trivial incidents to major life-threatening crises, and without any generally agreed definitions it is difficult to make sense of overall figures.
**A complication can be defined as an unfavourable event, unexpected even if predictable, occurring because of the invasive procedure, in spite of technical accuracy of the procedure.**
Depending on their clinical and biological impact complications are classified as:

- **Minimal**, when they cause transient inconvenience, they do not imply a significant worsening of the patient's condition, they resolve spontaneously or with minimal care, even if they may require a short period of intensive check-up of some parameters (e.g., blood pressure)
- **Major**, when they induce a significant worsening of the clinical condition of the patient and require substantial care (e.g., blood transfusion, resuscitation, surgery) with delayed hospital discharge or renewed hospitalization
- **Fatal**

According to the timing of appearance complications are divided into **early** and **late.**

### *Complications of diagnostic US-guided procedures*

Mortality rate due to abdominal biopsies ranges from 0.001% to 0.038% as described in major studies, including questionnaire surveys obtained by multicentre and single institution series (1-8, Table I). Mortality and major complication rates are greatest for hepatic and pancreatic biopsies. However, cases of death have been described after biopsy of every abdominal organ. Two deaths out of 6,261 biopsied patients (0.03%) occurred after hepatic biopsy. Both fatalities were due to massive haemorrhage. They occurred in one patient with hepatocellular carcinoma (HCC) out of 2,293 patients who underwent biopsy for the diagnosis of HCC, and in one patient with liver haemangioma out of 157 patients who underwent biopsy for the diagnosis of liver haemangioma (9). Another three cases of death after puncture of liver haemangioma have been observed in a series from a single institution (8). These data suggest a significant risk of bleeding after biopsy of liver haemangioma. Therefore diagnostic work-up of liver haemangioma should be completed whenever possible by using imaging techniques. The risk of bleeding is very important in case of biopsy of angiosarcoma. In spite of the rarity of this tumor, fatalities have been reported after biopsy of angiosarcoma either in the liver (4, 10) or in the adrenal gland (2). Fatal complications after pancreatic biopsy are mainly due to severe pancreatitis, after puncture of a normal gland in the wrong assumption of a pancreatic mass (11,12).

The rate of major complications after ultrasound guided biopsy is shown in table I. In a multicentre survey of haemorrhagic complications after liver fine needle biopsy (FNB) the rate was 0.13%. It did not seem related either to the needle type (aspiration or cutting needle) or to blood clotting function. The risk of liver haemangioma puncture was confirmed, because in two cases out of 157 hemorrhagic complications occurred (9). Even if spleen biopsy is a commonly feared procedure the related series showed no fatalities, but major complication rate was as high as 1.3% (10).

| Authors | Number of procedures or patients | Death % | Major complications % | Tumor seeding % |
|---|---|---|---|---|
| Livraghi et al (1) | 11,700 | 0.008 | 0.05 | 0.017 |
| Smith (2) | 63,108 | 0.006 | NR | 0.005 |
| Weiss et al (3) | 66,379 | 0.007 | 0.05 | 0.003 |
| Smith (4) | 16,381 | 0.031 | NR | 0.006 |
| Fornari et al (5) | 10,766 | 0.018 | 0.18 | 0.009 |
| Weiss et al (6) | 95,070 | 0.001 | 0.09 | 0.006 |
| Nolsoe et al (7) | 8,000 | 0.038 | 0.18 | 0 |
| Livraghi et al (8) | 2,708 | 0.037 | 0.23 | 0.036 |

Table I – Deaths, major complications, and tumor seeding observed after diagnostic or diagnostic and therapeutic interventional procedures (series 3, 6 and 7) guided by ultrasound.
NR = not reported

An intriguing complication is tumor seeding, which implies the dragging of a critical number of tumour cells along the needle track, their deposition in a favorable microenvironment and subsequent tumour growth. The time elapsing between the procedure and tumour seeding generally corresponds to a few months, even if in some instances it is as long as two years or more. The incidence generally varies between 0.003% and 0.036% but the exact incidence is difficult to determine, because only in a proportion of the patients is follow up complete. Tumour seeding correlates with needle calibre, number of biopsy passes into the tumor, and location of the tumor. Seeding is probably easier after a puncture of superficial tumours while it seems to be independent of tumour histology (14). However a high incidence of tumour seeding after pancreas tumour biopsy is frequently reported, even if in one large series of pancreas biopsies no case of seeding occurred (15). Another analysis of 33 reported series of pancreatic biopsies, including 2533 patients altogether, revealed 1 (0.039%) case of seeding (16). According to some authors biopsy should be avoided in patients who are candidates for surgery to avoid the risk of tumour seeding. The high diagnostic accuracy of imaging techniques strongly supports this point of view. The matter is still debated, even though the trend is to reduce invasive procedures. Irregularities of the needle surface to improve needle US visualization (the so-called echo-marker) may potentially increase the seeding. An in-vitro study has shown these irregularities to induce greater cell dragging after biopsy. Therefore echo-marker should be avoided (17). Tumour seeding seems to rarely have a clinical impact, and it generally does not affect the patient outcome.

***Complications of therapeutic US-guided procedures***

Drainage of abdominal collections is followed by a variable number of major complications and deaths. In a large series (886 patients) of abdominal drainages no death related to the procedure was reported, but major complications were observed in 77 patients (8.6%) (18).

Complications of percutaneous ethanol injection (PEI) in the treatment of HCC have been studied in a multicentre series of 1066 patients (19). Mortality rate was 0.09% (one death due to haemoperitoneum). Major complication rate was 3.2%. The complications comprised haemorrhage (9 cases), pleural effusion, hepatic or portal vein thrombosis, hepatic infarct, and liver abscess. Forty cases of severe pain with interruption of the procedure were described but not included in the major complications. Tumour seeding along the needle track was observed in 7 patients (0.6%). In another paper (20) tumour dissemination was found in 4 out of 348 patients (1.1%). An emerging percutaneous therapeutic option used either for small HCC or for liver metastases is radio-frequency (RF) thermal ablation. There are two different technologies: the expandable needle electrode and the cooled tip needle electrode. Complications of the cooled system have been described in a multicentre report (21), while those of the expandable system are being reported in a series from a single institution (22). It is certainly interesting to compare adverse effects of PEI and RF thermal ablation (Table II). However an "a priori" definition of complication is missing in the paper on PEI (19), and the definition of major complications in the RF cooled system series (21) differs from that used in the RF expandable system series (22).

| | Percutaneous Ethanol Injection (19) | RF cooled system (21) | RF expandable system (22) |
|---|---|---|---|
| **Number of patients** | 1066 | 2320 | 166 |
| | | | |
| **Death** | 1 (0.09%) | 6 (0.3%) | 0 |
| | | | |
| **Major complications** | | | |
| Severe pain (session stop) | 40 | NR | 3 |
| Capsular necrosis | | | 1 |
| Abdominal wall necrosis | -- | -- | 1 |
| Cutaneous burn | -- | 5 | 1 |
| Peritoneal haemorrhage | 5 | 6 | 1 |
| Haemobilia | 2 | -- | -- |
| Subcapsular haematoma | 1 | -- | -- |
| Parietal haematoma | 1 | -- | -- |

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|---|---|---|---|
| Haemothorax | -- | 3 | -- |
| Pneumothorax | 2 | 1 | -- |
| Hepatic abscesses | 2 | 6 | -- |
| Intestinal perforation | 1 | 5 | -- |
| Acute cholecystitis | -- | 1 | -- |
| Acute cholangitis | 1 | -- | -- |
| Portal vein thrombosis | 3 | 1 | -- |
| Caval vein thrombosis | 1 | -- | -- |
| Hepatic infarct | 3 | 1 | -- |
| Rapid hepatic decompensation | -- | 2 | -- |
| Large biloma | -- | 1 | -- |
| Right pleural effusion | 5 | -- | -- |
| Tumour seeding | 7 | 12 | 1 |
| Pulmonary embolism | -- | 1 | -- |
| Diaphragmatic paresis | -- | 1 | -- |
| Severe bradycardia | -- | 1 | -- |
| Sepsis | -- | 1 | -- |
| Common bile duct stenosis | -- | 1 | -- |
| **Major compl. number (rate)** | **74 (6.9%)** | **50 (2.2%)** | **8 (4.8%)** |

Table II – Complications after percutaneous ethanol injection (16), the radiofrequencies cooled system port (21) and the radiofrequencies expandable system (22).

The reported data confirm that RF thermal ablation can be considered at least as safe as PEI for the treatment of liver tumors.

***Needles and guidance***

a. Fine and large (>1 mm) needles (aspiration and cutting), catheters, needle-electrodes
b. Ultrasound guidance is sometimes difficult and may be replaced by computed tomography (CT).

***Comments***

a. Experimental and multicentre studies on fine needles show no effect of needle calibre (23) nor between aspiration and cutting needles on procedure related bleeding , whereas the use of large needles has been shown to be associated with an increased complication rate when compared to fine needles (1-9).
b. In most of the series reporting percutaneous biopsies or therapeutic procedures the guidance of choice has been US, even if some difficulties in targeting the lesion (i.e.because of meteorism or obesity) may indicate the need to use CT guidance. Literature survey does not indicate any connection between complication rate and type of guidance (16).

***Precautions to be taken***

a. Careful patient history, check coagulation tests
b. Choose a safe needle track
c. Use fine needles whenever possible
d. Reduce the number of needle passes
e. Experienced operator

***Comments***

a. A detailed clinical history can sometimes reveal a haemostatic defect even in the presence of normal routine coagulation tests. Coagulation tests which should routinely be evaluated before a percutaneous procedure on deeply located organs include: prothrombin time, partial prothrombin time, platelet count. The following values are generally considered safe: prothrombin time >40 per cent, partial prothrombin time < 5 sec above the upper limit, platelet count > 50,000/$mm^3$ (9). Discontinuation of aspirin and anticoagulants (possibly replace by heparin) is advisable before a biopsy, but it has to be weighed against the thrombotic risk (24).
b. When deciding the needle track any interposed structure between the abdominal wall and the target lesion or parenchyma has to be carefully evaluated so as to avoid passage through main blood vessels, gallbladder, or colon (16). Systematic check of the needle track with Doppler US can easily identify interposed vessels or vascular lesions misinterpreted as cysts or tumors (7).
c. See above, Needles, section a.
d. It has been shown that the diagnostic accuracy of cytology significantly increases if two passes are made instead of one, but that it does not increase if three or more passes are made. It is therefore recommended to check immediately the adequacy of every specimen by a rapid staining. This can reduce risks of complication by saving an average of one pass per biopsy (25).
e. Experience of the operator and number of performed procedures are certainly important factors affecting the complication rate of percutaneous biopsies (26). Personal opinion and experience suggests that a number of 50 annual liver biopsies is needed for biopsy to be safe.

***Concluding remarks***

An ultrasound guided diagnostic procedure, even if it is considered a minimally invasive one, should only be performed if it is judged to be of benefit to the patient. It should not be performed if it can be replaced by a less invasive procedure.

An US guided therapeutic procedure should only be performed if it can be expected to give a result equal to or better than that obtainable by a more invasive procedure (e.g.,a surgical intervention).

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