Findings of the UK National Audit Evaluating Image-guided or Image-assisted Liver Biopsy. Part I. Procedural Aspects, Diagnostic Adequacy, and Accuracy
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Findings of the UK National Audit Evaluating Image-guided or Image-assisted Liver Biopsy. Part II. Minor and Major Complications and Procedure-related Mortality
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Introduction

• Liver biopsy is a key investigation in diagnosis and management of patients with liver disease

• Core biopsy is of increased diagnostic value compared with FNAC

• Image-guidance or assistance is superior to blind palpation for optimisation of sample adequacy and minimizing procedural complications

• Ultrasound assessment is the modality of choice, although CT and MRI are used in some centres
Introduction

- To assess current techniques and practice of liver biopsy across the UK
- To document rates of sample adequacy and diagnostic accuracy and compare with literature
- To identify statistically significant factors which may be associated with increased or reduced sample adequacy or diagnostic accuracy

• Liver biopsy is an invasive technique and rates of procedure-related complications must be acceptably low
• Complications have been extensively studied and guidelines for practice introduced in the UK and USA
Materials and Methods

• All UK departmental audit leads invited to participate and asked to submit liver biopsy data to the RCR

• First 50 consecutive unique patients in each department who had image-guided/assisted liver biopsy from 1st January 2008 were identified retrospectively from department databases

• Adults (> 16 years) and paediatric patients included
Materials and Methods

- Inclusion criteria were:-
  - Availability of patient records
  - Radiology images/reports and histology
  - Image guided/assisted needle core biopsy only (percutaneous or transjugular)

- Transjugular biopsy recorded separately
- FNAC and surgical/laparoscopic biopsy not included
Materials and Methods ~ Data collection forms

- 4 separate questionnaires:-
  - A = Organisational – generic aspects e.g. operator characteristics and facilities
  - B = Clinical aspects of biopsy
  - C = Coagulation Data
  - D = Complications Data

Identity of respondents re teaching/district general hospital and UK region was known, in attempt to evaluate potential selection bias
Materials and Methods ~ Standards

- Literature search (1950 onwards) on Medline and NHS Evidence
- Review of all available, relevant literature by RCR Clinical Audit Committee
- Standards should be practical and achievable
Materials and Methods ~ Standards

1. Completed consent form = 100%
2. Documented post-procedural instructions = 100%
3. Sample adequacy (diagnostic histology report) = 98%
4. Diagnostic accuracy (sufficient, representative tissue) = 90%
Materials and Methods ~ Statistics

- **True positive** = initial malignant biopsy result with no subsequent amended benign diagnosis
- **True negative** = initial benign biopsy result (inflammation, normal liver) with no subsequent amended malignant diagnosis
- **False positive** = initial malignant biopsy result and subsequent amended benign histological diagnosis
- **False negative** = initial benign biopsy result and subsequent amended malignant histological diagnosis
Materials and Methods ~ Statistics

- Sensitivity, specificity, likelihood ratio and accuracy were calculated.
- Confidence intervals were computed using exact binomial confidence intervals where applicable.
- Exploratory analyses of pertinent variables in the organisational and clinical questionnaires.
- Chi square, Fisher exact, Mantel Haenszel and t-tests were used as appropriate to assess significance using SAS 9.2.
Materials and Methods ~ Standards

• Complications broadly classified as minor or major:
  
  • Minor Complications:
    - Minor pain
    - Severe pain
    - Hypotension (likely vasovagal)

• Major Complications:
  - Significant haemorrhage
  - Haemobilia
  - Puncture of another organ
  - Death
Materials and Methods ~ Standards

1. Minor pain (no analgesia) = 30%
2. Severe pain (analgesia < 3%)
3. Hypotension (likely vasovagal) = < 3%
4. Significant haemorrhage (Hb drop > 2d/dL) = < 0.5%
5. Haemobilia < 0.1%
6. Puncture of another organ < 0.1%
7. Death = < 0.1%
Factors affecting Complications

- Liver Biopsy
  - Biopsy technique & equipment
  - Image guided/assistance
  - Operator grade & experience
  - Patient, cooperative, habitus, ascites
  - Lesion
  - Clotting
Results

• 87/210 departments responded
• 3496 cases (1225 focal lesion, 2262, no focal lesion)
• 38 departments submitted 50 cases
• Coagulation questionnaire (C) was sent out shortly after A and B with responses from 76 departments
• Majority adult patients with data from 122 children
• Reasons for no participation included no liver biopsies, contact failure and lack of time/resources
Results

- **Sample adequacy** = 97.96%, standard = 98%
- *Focal lesion, inadequate biopsy* = 7.1% (82/1162)
- *No focal lesion, inadequate biopsy* = 1.7% (37/2155)
- **Diagnostic accuracy** = 98.55%, standard = 90%
  - *Diagnostic accuracy for focal lesion* = 96.43%, sensitivity = 96.39%, specificity = 96.69%
- All departments lie within control limits for accuracy, none differing significantly from one another
Results

• Large likelihood ratios for:
  • 16 and 18 gauge needles,
  • single passes
  • side-cutting needles

• Positive likelihood for focal lesions > 10 cm is small, biopsy is less good in this context (\(?\) Necrosis)
  • Fewer passes are associated with lower odds of non-diagnostic sampling (\(?\) necrosis-related)
Results

- **Liver metastases**
  - Diagnostic accuracy/sensitivity = 97.58% (886 true positive and 22 false negative)

- **Hepatoma**
  - Diagnostic accuracy/sensitivity = 86.77% (59 true positive, 9 false negative)
Results

- 376 patients had a minor complication
- 22 patients had 1 or more non-fatal major complication
- 4 deaths due to haemorrhage post Bx
- No patients undergoing transjugular or plugged biopsy had a major complication, 7 patients had minor complications
- No paediatric patients experienced a minor or major complication
Results ~ Needle gauge

Minor complication rates:

- 14G = 4/45 (8.9%)
- 16G = 58/391 (14.8%)
- 18G = 247/2541 (9.7%)
- 20G = 5/72 (6.9%)
- Other = 18/115 (15.7%)
Results ~ Deaths & major complications

• 4 patients died and 15 had one or more major non-fatal complication

• The 4 patients who died all underwent ultrasound-guided biopsy for a focal lesion (2 metastasis, 1 lymphoma, 1 HCC)

• Biopsy-related haemorrhage was the cause of death in all 4 cases, with no other organs punctured

• 2 received blood transfusion and 1 underwent embolisation
Results ~ Deaths & major complications

- 18G needles employed in all 16 cases
- Tru-cut biopsy device with 1 pass in 7 cases, 2 passes in 7 cases, 3 passes in 1 case & > 3 passes in 1 case
- For patients who died/had major complication, completed consent form present in patients notes in 14/19 cases and post-procedural instructions in 11/19 cases
- Association with INR>1.5 and platelet count<60 confirmed
- Association between no coagulation results and results>1 week old also
Results ~ Children

- 122 paediatric patients
- 18 gauge needles used most frequently (n = 42, 22 patients = 16G, 8 =14 G, only 72 responses overall) with 1 or 2 passes in majority (n = 111)
- Higher incidence of general anaesthesia than in adults (63/120 vs. 5/3181)
- USS was only modality for guidance (n = 77) or assistance (n = 44)
- 55 performed by consultant radiologists, remainder performed by interns in radiology or internal medicine
Discussion

• This study represents the largest biopsy series looking at modern image guided/assisted biopsy practice
• Move towards image guidance/assistance
• The vast majority of departments utilise ultrasound
• Blind biopsies do still occur (9/80, 11% departments)
Discussion

• USS guidance rather than assistance was used in the majority of cases (1665) where no focal lesion present

• USS assistance only was used in a small number (33) of focal lesion biopsies

• MR biopsy not utilised at all, CT biopsy in a minority

• 57% (46/81) departments offer transjugular liver biopsy

• 54% (43/79) departments offer plugged biopsy
Discussion

• **Operator**

  - American Association for the Study of Liver Diseases recommends a minimum of 40 supervised biopsies
  
  - In this study there was a range in number of biopsies per operator in a year from minimum of 1 to maximum = 134
  
  - No statistically significant link between no. of biopsies and sampling or complication rates
Discussion

- **Consent, Post-procedural Instructions**
  - 10% (334/3368) completed consent form absent
  - 4.5% of patients had no INR or platelet data pre biopsy
  - 23% (775/3325) no post-procedural instructions
Discussion

• **Needle Gauge**

  - Increasing needle gauge and number of passes are important factors for sample adequacy and accuracy.
  - North American guidelines suggest a 16 gauge needle, 3 cm long specimen, to maximize portal tract yield.
  - Majority of biopsies were 18G with 1 or 2 passes and side-cutting (Tru-cut needles), but with 98% adequacy, suggests that 18G needle is sufficient.
Discussion

- 71 patients had an initial inadequate biopsy (insufficient tissue) and some went on to have a further diagnostic biopsy

- Statistically significant factors relating to inadequate biopsy include:
  - Smaller number of biopsies performed in department
  - Focal lesion
  - Increasing number of passes
Discussion

- Limitations

- Retrospective data collection, relying on accuracy, availability and completeness of documentation

- Data from some centres was incomplete

- 41% response rate, ? response bias, although only small percentage difference between teaching and district general hospital responders and non-responders and also when assessing geography of response rates
Conclusion: Complications

- Majority of audit standards met, although procedural documentation was sub-optimal
- The expected target of < 0.1% mortality rate was not reached, although practice figure of 0.11% (4/3486) in keeping with published data
- Serious complications e.g. puncture of adjacent organ/vascular structure largely avoidable with use of imaging
Conclusion

- This study provides data for a large number of image-guided and assisted biopsies of focal and diffuse liver lesions and gives an indication of current UK radiological practice.
- To our knowledge it is the largest of its kind in available current literature.
Conclusion

- Majority of liver biopsies performed by radiologists using image guidance/assistance, usually USS
- Biopsies were performed to a high degree of diagnostic accuracy, however some post-procedural aspects failed to meet required standards