# 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%

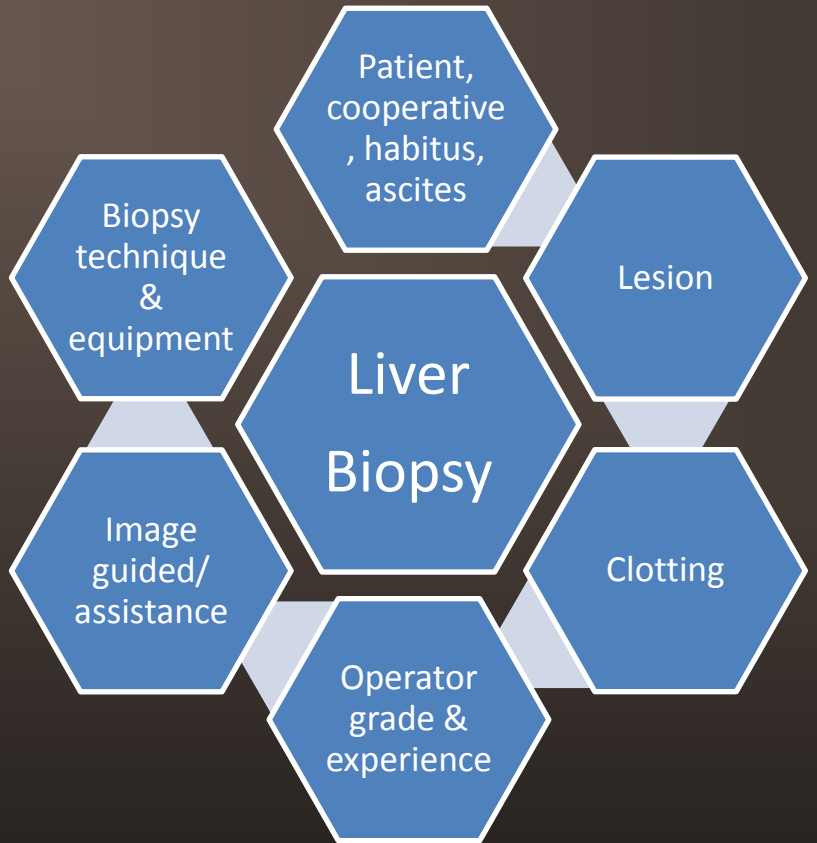
4, Significant haemorrhage (Hb drop > 2d/dL) = < 0.5%

5, Haemobilia < 0.1%

6, Puncture of another organ < 0.1%

7, Death = < 0.1%

# Factors affecting Complications



# 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