

# ULTRASOUND GUIDED PARENCHYMAL LIVER BIOPSIES: AUDIT OF COMPLICATIONS

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## ABSTRACT

**INTRODUCTION:** Hepatic biopsy is as an invasive procedure which has inherent risk of complications requiring caution in patients selection as well as technical aspects of biopsy. The purpose of this audit was to evaluate the incidence of complications associated with parenchymal liver biopsy and to compare with the standards set by Royal College of Radiologists advisory committee. **METHODS:** This audit was performed in Radiology department of Jinnah hospital, Lahore. Thirty consecutive patients who fulfilled inclusion and exclusion criteria were audited for the incidence of complications, followed by re-audit to look for improvement in local practice. **RESULTS:** In the 1<sup>st</sup> audit, 13 out of 30 patients (43%) complained of pain. Eleven out of 30 (36.6%) complained of minor pain that did not require medication against the target of < 30% and 3 out of 30 (10%) required analgesia against the target of < 3%. Rests of the standards were met. The re-audit performed after implementation of changes following there commendations made after 1<sup>st</sup> audit showed good compliance with standards. **CONCLUSION:** The operator expertise, emphasis on consenting/ proper counseling and use of premedication were found to improve outcome that resulted in meeting the standards.

**Key Words:** Parenchymal liver biopsy, royal college of radiologists, medical audit, recommendations, re-audit

## Descriptor

An audit of local practice to evaluate the incidence of complications associated with Ultrasound guided Parenchymal liver biopsies.

## Introduction

Liver can be biopsied for either diffuse parenchymal abnormality or for characterization of a focal lesion. The histological evaluation of the specimen obtained from liver plays a central role in the diagnosis of many local and systemic pathologies. Results of the biopsy help grade the disease, facilitating prognostication, which helps in planning specific treatment strategies.<sup>1</sup>

Liver can be biopsied with and without image guidance. However, image guided procedures are now preferred universally. There are various imaging modalities that can offer guidance including ultrasound, CT, MRI and fluoroscopy. Out of these, ultrasound remains the modality of choice for this procedure owing to ease of performance, lack of radiation, easy availability and less time consumption. Whatever the method may be, there is associated risk of complications due to invasive nature of the procedure. There has been a lot of research to define best technique for the procedure and the factors affecting various complications. Trucut biopsy of liver is superior to FNAC in terms of specimen yield but obviously imparts greater risk of complications. So the important aspect of parenchymal liver biopsies is to obtain diagnostically adequate specimen while keeping the complication rate to the minimum.

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Detailed documentation of the procedure as well as any incurred complications is as important as the procedure itself so as to improve the technique in terms of avoiding hazards in future. Documentation is also very important for research, audit and future reference for the patient and the healthcare provider. The purpose of this audit was to evaluate the rate of various complications from parenchymal liver biopsies performed under ultrasound guidance in the radiology department of Jinnah hospital Lahore and complete the audit cycle so as to bring positive change in local practices if required.

#### **STANDARD:**

- All patients should have written informed consent.
- Clotting parameters and full blood count should be checked and documented.
- The procedure itself should be adequately documented:
  - o Needle gauge
  - o Number of passes
  - o Skill of the personnel
- Every complication (major or minor) should be documented
- Management plan for each complication should be documented
- Complication rates should be in line with published literature.

#### **TARGETS:**

The targets were set as follows:<sup>2</sup>

#### **Minor complications:**

- Mild pain requiring no analgesia - target < 30%
- Mild pain requiring analgesia - target < 3%
- Hypotension requiring no fluids - target < 3%
- Non expanding hematoma - target < 30%

#### **Major complications:**

- Severe pain with hypotension (likely vasovagal) needing IV fluids - target < 3%
- Significant bleed (Hb drop of > 2g/dl) - target < 0.5%.
- Haemobilia - target < 0.1%
- Puncture of kidney, bowel, lung or gall bladder -target < 0.1%
- Death - 0%

## **Materials and Methods**

This audit was performed in Radiology department of Jinnah hospital from 01-02-2014 to 30-09-2015 and was exempted from the need for review by the responsible ethical review board.

The data for audit was collected prospectively from 30 consecutive patients in whom ultrasound guided biopsy of liver parenchyma was performed and who fulfilled inclusion and exclusion criteria. Inclusion criteria was age of patient 15-60 years of either gender having chronic hepatitis B or C infection. Those who had INR > 1.2, severe thrombocytopenia of < 50,000/ml, blood pressure of < 100/70 and pulse rate either < 60 or > 100 were excluded due to increased risk of complications and difficulty in defining development of complications. Prior to the biopsy, the stability of vitals was assured. Written informed consent was acquired and aseptic measures adopted. The trucut biopsy was performed with simple technique using Stericut 18G needle through subcostal/intercostal approach with patient lying in oblique left lateral position. Two passes were made in each case and hence two cores of tissue sent for histological analysis in formalin container every time. Post procedure the patient was initially assessed immediately for presence of pain and asked to grade the pain from a scale of 0 to 10 using NRS scale where 0 represented no pain and 10 the most severe pain. Score of 1-3 was taken to represent mild pain, 4-6 moderate pain and 7-10 severe pain. Pulse and blood pressure was measured and recorded. The check ultrasound scan was performed to look for hemorrhage or other organ injury. Each patient was kept in observation for four hours and all these parameters were checked repeatedly. Vitals were monitored every 15 mins for one hour and every 30 mins afterwards. Repeat check ultrasound scan was performed before discharge. Any minor/ major complication following procedure and special management for the complications was recorded on specially designed Performa (Annexure 1) and percentages calculated.

#### **ASSESSMENT OF PERFORMANCE AGAINST STANDARDS:**

The collected data was compared with the standards described by Royal college of Radiologists clinical audit committee.<sup>2</sup>

### DEMOGRAPHICS

Name	Age
Gender	MR No.
Date	Referred by

### TECHNIQUE

Needle Brand	Gauge
No. of Passes	Throw in cm

### COMPLICATIONS

#### Minor:

Name	Yes	No
Mild pain (No Analgesia)		
Moderate pain (With Analgesia)		
Hypotension (No Fluids)		
Non expanding hematoma (< 2%)		

#### Major:

Name	Yes	No
Severe pain with hypotension (requiring IV fluids)		
Hemorrhage (Hb < 2d/dl)		
Hemobilia		
Injury to other structures		
Death		

Annexure 1: Liver Biopsy Audit Performa

The complications were divided into minor and major ones. The minor complications included pain that may or may not require pain killers, hypotension not requiring transfusion and post procedural non expanding hematoma at the puncture site or in the liver parenchyma from the sampling site.

The major complications included severe pain with resultant vaso-vagal hypotension requiring IV fluids, significant bleed with hemoglobin drop of > 2g/dl or that resulted in instability of vitals with radiological evidence of bleed that required transfusion or further intervention, haemobilia, other organ injury including lung, kidney, bowel and gallbladder or death.

## Results

Out of the total number of 30 patients, 12 were males and 18 females. Ages ranged from 15-58 yrs. Among the minor complications, pain was found to be the most prevalent. Thirteen out of 30 patients (43%) complained of pain. Analgesia was given from 5-7

scale and no analgesia was given for pain less than 5. Results in (Tab. 1) & (Fig. 1) show that 11 out of 30 (36.6%) complained of minor pain that did not require medication against the target of < 30% and 3 out of 30 (10%) required analgesia against the target of < 3%. These clearly did not meet the target. One patient each suffered from hypotension requiring fluid management and hypotension requiring no fluids. Target was < 3% each. So our results showed that we just met the target.

Non expanding hematoma developed in 8 patients (26.6%) which was well within the target.

None of the patients suffered from severe hemorrhage, injury to other organs or died thus easily meeting the target.

Complications	%age of patients (n=30)	Target
<b>Minor Complications</b>		
Mild pain (No analgesia)	11(36.6%)	<30%
Mild pain (With analgesia)	3(10%)	<3%
Hypotension (No fluids)	1(3%)	<3%
Non expanding hematoma < 2cm	8(26.6%)	<30%
<b>Major Complications</b>		
Severe pain with hypotension (requiring IV fluids)	1(3%)	<3%
Hemorrhage (Hb< 2d/dl)	0	<0.5%
Hemobilia	0	<0.1%
Injury to other structures	0	<0.1%
Death	0	0%

Table 1: 1<sup>st</sup> Audit: Results show poor compliance with standards in incidence of Pain

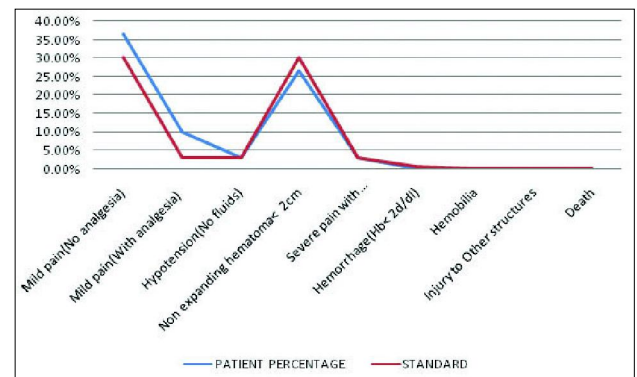


Figure 1: 1<sup>st</sup> Audit

## IDENTIFICATION OF CHANGES & RECOMMENDATIONS:

Following set of recommendations was made in the

departmental meeting so as to reduce the incidence of pain so as to meet the target:

- Only Final Year residents or consultants would perform the parenchymal liver biopsy.
- The quality of available local anaesthetic in the hospital pharmacy needs to be rechecked.
- The amount of anaesthetic used should be optimum and liver peritoneal surface needs to be anesthetized.
- For anxious patient, pre-biopsy IV midazolam will be given.
- While taking consent, patient would be told the procedure and complications in detail in a very considerate manner.
- Pre-biopsy preparation should rule out other possible causes of pain due to disease or degeneration related problems arising from other organs.
- Re audit after 3 months.

These recommendations were conveyed to whole staff of Radiology department through meetings. The print outs were displayed on the notice board in the procedure room.

**RE-EVALUATION:**

This was followed by re-audit from 01-01-2015 to 31-08-2015 in the same department after implementing the changes recommended from the results of previous audit. Thirty-Four consecutive patients with chronic hepatitis were included in the study who met the same inclusion and exclusion criteria. All procedures were performed by either experienced consultants or R4 trainees. The consenting was given special emphasis i.e., consent was taken by the doctor who was supposed to perform the procedure himself. Other causes of systemic and local pain e.g. degenerative bone pains, metabolic disorders, and costochondritis were ruled out prior to biopsy. Every patient was dealt with in a very considerate manner so as to alleviate anxiety and thus increase the confidence of patient on care giver. In 1 very anxious patient 1mg IV midazolam was given prior to biopsy.

**RESULTS OF 2<sup>ND</sup> AUDIT:**

In the 2<sup>nd</sup> audit total number of patients was 34 (22 males, 12 females). Ages ranged from 20-60 yrs. There had been considerable improvement in the results with good adherence to standards. Nine out

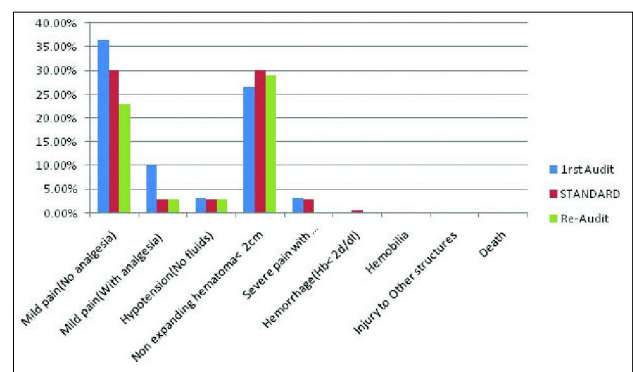
of 34 (26.4%) patients complained of minor pain that did not require medication in 8 (23%) and was managed with analgesics in 1 (2.9%) patient.

Non expanding hematoma (Up to 2 cm) developed in 10 (29%) patients.

No Patient suffered from severe hypotension, intra-peritoneal bleed, hemobilia, other organ injury or death. One patient (2.9%) developed vasovagal hypotension that however, did not require IV fluids. (Tab. 2), (Fig. 2)

Complications	%age of patients (n=34)	Target
<b>Minor Complications</b>		
Mild pain (No analgesia)	8(23%)	<30%
Mild pain (With analgesia)	1(2.9%)	<3%
Hypotension (No fluids)	1(2.9%)	<3%
Non expanding hematoma < 2cm	10(29%)	<30%
<b>Major Complications</b>		
Severe pain with hypotension (requiring IV fluids)	0	<3%
Hemorrhage (Hb< 2d/dl)	0	<0.5%
Hemobilia	0	<0.1%
Injury to other structures	0	<0.1%
Death	0	0%

**Table 2:** Re-Audit: Good compliance with the standards



**Figure 2:** Interval improvement

**Discussion**

This audit cycle was performed in the Radiology department of Jinnah hospital which is a large tertiary care hospital with a busy radiology department. Ultrasound guided liver biopsies are performed frequently and the purpose of this audit was to evaluate the safety of this invasive procedure.

Liver biopsy and histological assessment of the liver has now taken on an important role in clinical management, therefore, as of 2009, liver biopsy currently has three major roles: (1) for diagnosis, (2) for assessment of prognosis (disease staging), and/or (3) to assist in making therapeutic management decisions.<sup>3</sup> The area to be biopsied is either focal lesion or liver parenchyma. A large number of parenchymal liver biopsies are still performed with the primary intent of diagnosing specific hepatic diseases, including acute and chronic hepatitis, hepatic steatosis, disorders of cholestasis, infection and granulomatous disease, infiltrative liver disease, and hepatic storage disorders.<sup>1</sup> In this audit all 30 patients were referred for liver biopsy with history of chronic hepatitis.

Percutaneous liver biopsy has a small but inherent risk even in the most experienced hands, and it should therefore only be performed when the benefits of knowing the histology outweigh the risks to the patient (in terms of altering treatment or defining disease outcome).<sup>4</sup> The complications of this procedure are broadly classified into minor and major ones.

Pain is considered to be the most prevalent complication of liver biopsy. The percutaneous liver biopsies are shown to carry 84% risk of pain<sup>5</sup> however the risk seems to have reduced with ultrasound guidance.<sup>6</sup> Our audit showed that 43% of the patients undergoing biopsy complained of pain and 10% had pain of the degree requiring analgesic medication i.e, ranging from 5-7 on scale of 1-10 with 10 showing maximum severity. The target set by Royal college of radiologists advisory committee was less than 30% for minor pain and 3% moderate pain requiring analgesia. We clearly did not meet the target in this regard. Multiple factors were analyzed and thus recommendations made for the department. Factors affecting the pain associated with percutaneous liver biopsies are summarized in (Tab. 3).

1. Experience of operator
2. Choice of analgesia
3. Inadequate infiltration
4. Choice of technique
5. Needle gauge
6. Number of passes
7. Pain from other causes
8. Hypersensitive patient
9. Premedication

**Table 3:** Factors affecting pain during and after parenchymal liver biopsy

The mechanism of pain following percutaneous liver biopsy is considered to be related to bleeding or injury to surrounding organs and the role of other factors is rather controversial.<sup>7</sup> Bleeding on the surface of liver following biopsy is a universal phenomenon and oozing begins soon after the needle is withdrawn.<sup>7</sup> The amount of blood is usually only 30-50 ml as estimated by gross inspection; however, it seems likely that this hemodynamically inconsequential amount of blood is the source of most post-biopsy pain because of irritation of the capsule and peritoneum.<sup>7</sup>

There are several other factors affecting the pain. Among these the site of biopsy (intercostal or sub-costal) is proven by Tan et al to have no effect on pain.<sup>8</sup> Similarly no change in pain incidence is noted from choice of either right or left liver lobe for biopsy.<sup>8</sup> However the use of US guidance, premedication with midazolam and fentanyl and self delivering of mixture of N<sub>2</sub>O and oxygen via mask decreased significantly the incidence of post biopsy pain and anxiety.<sup>9</sup> The incidence of minor and major complications is further increased with number of passes and reduced with expertise of operator.<sup>10</sup> The use of automatic cutting needles is associated with a low incidence of post-biopsy pain with a reported incidence 31.4 to 34.3% in comparison to hand held needles (40.6 to 52.6%).<sup>11</sup> Other controversial factors associated with more pain are larger needle, hepatitis C infection, younger age and history of intravenous drug abuse.<sup>9</sup> Besides these, the patient factors including pre-procedure anxiety and particularly female gender has some effect on incidence and severity of pain.<sup>10,12</sup>

Based on this literature search, we derived a set of recommendations to be implemented in the department after discussing the results of this audit in a departmental meeting.

The rests of the minor as well as major complications in this patient data remained within the desired range except for hypotension. The audit results showed that one patient (3%) developed minor hypotension that did not require fluid management and one patient (3%) suffered from severe hypotension that required IV fluid management. The required standard for any severity of hypotension was less than 3%. However, the fact that the number of biopsies audited was small (n=30) this small difference can be neglected in pre-



sent audit in terms of devising recommendations. The results of the 2<sup>nd</sup> audit met standards in all areas. The basic difference made in local practice was to involve more senior members of faculty in the procedure and particular emphasis on patient counseling. We believe that pain is very much related to the anxiety level and apprehensive status of the patient. These maneuvers help build up patient's trust on the health provider and this bonding produces a placebo effect. 2<sup>nd</sup> important factor is the expertise of the operator which affects the technical aspects of procedure. One patient was given IV Midazolam prior to biopsy in whom we suspected poor cooperation due to severe anxiety and alertness. So we stress that special importance should be given to patient counseling, operator expertise and possible premedication in every setup where ultrasound guided liver biopsies are being performed.

## Conclusion

Liver parenchymal biopsy is an invasive procedure having small but important inherent risk of complications. Pain which is one of the commonest complications can have reduced incidence if the factors like patient counseling, operator expertise and analgesic premedication (if required) are given due focus.

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