A PROSPECTIVE STUDY IN THE INCIDENCE OF IMMEDIATE COMPLICATIONS OF IMAGE GUIDED FNAC AND BIOPSY AT BLACK LION HOSPITAL, ADDIS ABABA UNIVERSITY, ADDIS ABABA, ETHIOPIA.
FROM AUGUST 2013 UPTO AUGUST 2014.

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RESEARCH SUBMITTED TO THE DEPARTMENT OF RADIOLOGY, AAU, FOR PARTIAL FULFILMENT OF THE REQUERMENTS OF CERTIFICATE OF SPECIALITY IN RADIOLOGY

October, 2014

ACKNOWLEDGEMENT

I would like to acknowledge to my advisor Dr. TesfayeKebede for his assistance in the title selection and also his unreserved helpful suggestions and comments from the very beginning proposal preparation and data collection till finalizing this research.

I would like also to express my appreciation to Sr. Roman and Sr. Seadaas well as the final year radiology residents for their assistance in the process of collecting data.

Lastly I would like to extend my gratitude to the Radiology department for its permission and cooperation of the staffs during data collection.

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ACRONYMS

AAU-Addis Ababa University

BLH-black lion hospital

CNB-core needle biopsy

CT-computed tomography

Dr.-doctor

FNAB-fine needle aspiration biopsy

FNAC-fine needle aspiration cytology

Fig-figure

IRB-Institutional Review Board

MD-medical doctor

MRI-magnetic resonance imaging

SPSS-statistical package for social sciences

USA-unites states of America

US-ultrasound

1. INTRODUCTION

Image-guided percutaneous biopsy or FNAC is defined as placement of a needle or needles into a suspected abnormal target site for the purpose of obtaining tissue or cells for diagnosis **(1).** Radiology plays an important role in guiding tissue biopsy. Even if all US, CT and MRI can theoretically be used as a guidance because of its wide availability and low cost ultrasound is the preferred guidance modality all over the world (**2).**The basic principles of fine needle aspiration and core needle biopsy can be applied to almost any site in the body, with subtle differences in technique depending on the organ being investigated and the imaging modality utilized **(3).**Use of different sized needles depends of the need to get cytological and /or histological specimens. Needles larger than 18 gauge should produce sufficient tissue for histologic examination, whereas small needles (19Gauge and smaller) should produceSufficient material for cytologicalexamination **(2)**.Even is image guided biopsy is a routine procedure elsewhere, it is recently introduced with the fellowship program in our country. Despite its recent introduction, significant number of percutaneous needle biopsies are being done yearly, the most common organs biopsied being from the chest and abdominal organs.

Currently real time image guided biopsy is being done by senior radiologists and final year residents under supervision. Even if it is the safest way to use image guidance during tissue biopsy, it is associated with certain complications ranging from simple pain up to death.

The complications are different based on the site of biopsy taken and based on the duration after the procedure.

Percutaneous needle biopsy or FNAC has been a mainstay ofoncologic diagnosis for more than two decades, since the advent of ultrasound and computed tomography (CT). The basic principles of fine needle aspiration and core needle biopsy can be applied to almost any site in the body, with subtledifferences in technique depending on the organ being investigated and the imaging modality utilized. While excisional biopsy is still appropriate in certain cases, including diagnosis of breast and brain tumors, percutaneous needle biopsy has become the standard of care in the diagnosis ofmost tumors throughout the body. Needle biopsy also is used to diagnose non-cancerous conditions, such as infection **(3).**

2. JUSTIFICATION

Even if it is universally known that image guided biopsy has associated different degrees of complications like pain, bleeding pneumothorax, organ rapture, hemoptysis and rarely death. The safety of the procedure in our setup is not yet known as to the investigators knowledge.

3. LITERATURE REVIEW

In a study done in USA for image guided Liver biopsy showed, with an overall significant complication rate of less than 1%.

Hemorrhage is most common-occurring (0.o3% to 0.1%) of patients such significant bleeding complications are more likely to occur in the biopsy of patients with malignancy and those with acute liver failure, chronic active hepatitis, or cirrhosis

Most complications occur soon after the biopsy procedure, with about 60% occurring within 2 hours and 80% within 10 hours

Several large series report mortality of percutaneous liver biopsy as (0.1%) or less

A study done by UK and European doctors on the complications of image guided liver biopsy the complications were minor pain (<30%), severe pain (<3%), vasovagal hypotension (<3%), significant hemorrhage (<0.5%), haemobilia (<0.1%), puncture of another organ (<0.1%), and death (<0.1%) **(4)**

In a study done in Iran Between October 2006 and July 2010, 1018 patients were enrolled for ultrasound guided liver biopsy, No biopsy-related death occurred in any of the patients. The most common complications were localized pain in 25 patients (80.6%) and vasovagal syncope or nausea in six patients (19.4%). The most common type was mild pain around the biopsy area that developed three hours after the biopsy. Other early complications were abdominal pain spreading to the right shoulder-arm. Interestingly, almost all vasovagal syncopes occurred during preparation, prior to biopsy (**5)**

In a study done in USA on image guided biopsy of the liver the complications were Pain: Pain is the most common complication of percutaneous liver biopsy, occurring in up to 84% of patients, including those with relatively mild discomfort. Severe bleeding is usually clinically evident within 2-4 hours, but late hemorrhage can occur even up to one week after biopsy. Mortality after liver biopsy is usually related to hemorrhage. It is very uncommon after percutaneous biopsy, but precise figures vary widely in the literature. Death due to bleeding may also be greater after biopsy of malignant lesions than in patients with diffuse parenchymal disease. The most commonly quoted mortality rate is less than or equal to 1 in 10,000 liver biopsies. A number of other complications have been reported after liver biopsy. These include pneumothorax, hemothorax, and perforationof any of several viscous organs **(6)**

In a another study done in Japan Ottawa on the complications of image guided biopsy of the spleen, This meta-analysis showed an overall complication rate for splenic biopsy of 4.2% for all biopsies . The major complication rates were 2.2% for all biopsies, 3.2% for CNB, and 1.3% for FNAB. Nine of the 10 major complications were related to hemorrhage; the other was a pneumothorax. Splenectomy was required to treat hemorrhage in two cases; there were no deaths (**7)**

Another study done in USA study the complication rates for pleural biopsy a total of 82 patients underwent 85 image-guided pleural biopsies over a 4-year period. 80 cases were performed under CT and five under US guidance. The rate of new pneumothorax detected by chest radiography was 4.7%. No patient required a chest drain or blood transfusion to treat complications **(8)**

In a study done in US Between 2002 to 2007, 60 consecutive image-guided percutaneous biopsies were performed in patients with suspected ovarian cancer. The following variables were recorded: tissue biopsied, imaging technique, experience of operator, biopsy needle gauge, number of passes, complications, and final histology. Forty-seven patients had omental biopsies, 12 pelvic mass biopsies, and 1 para-aortic lymph node biopsy. Thirty-five biopsies were performed under ultrasound, 25 under computed tomography guidance.There were no complications **(9)**

In another study done in China, Beijing under ultrasound guidance to study the complications in a total of 88 male and 65 female patients from the peritoneum, the complications were evaluated within 12 hours after the biopsy. Fifteen patients experienced pain at the operation site, which eased off later without treatment. During ultrasonography, two cases, which showed a high-level echo flow into the abdominal cavity, were found to have bled after the biopsy; in both cases, the bleeding stopped when the transducer pressure was applied. No other serious complications occurred **(10)**

4. AIMS

To evaluate the safety of image guidedpercutaneous tissue biopsy/FNAC in BLH in a prospective study from August 20013up to August 2014

5. OBJECTIVES

5.1.General

To assess the immediate complications of image guided percutaneous biopsy/FNAC in BLH during the specified study period

5.2. Specific

-To identify the common immediate complications in image guided FNAC or biopsy

-To describe the possible causes of this complications if known

-To determine the severity of complication

6. SUBJECTS AND METHODS

6.1. Study area

The study was conducted at Black lion specialized hospital, department of Radiology, college of health science, Addis Ababauniversity. Itis the biggest teaching hospital in the country which is under the administration of the university. Currently this is the only government owned place in the country where percutaneous needle biopsyor FNAC is done under imaging guidance up to the study period for this research(up to August 2014)

6.2. Study design

A hospital based cross- sectional study was employed to address the specific objectives.

6.3. Study Population and study period

All patients who undergone this procedure from August 2013 up to August 2014 under imaging guidance from the abdomen and chest were included in the study.

6.4. Sampling and sample size

All patients whounderwent this image guided procedure in the specified period(August 2013 and August 2014) were included in the study.

6.5. Data Collection method and analysis

Well-structured and easily understandable questionnairewas prepared in English language and was asked to the patients or attendants by trained nurses and radiology residents. The questionnaire was filled at each time of the procedure and was filled by assistant nurses and radiologyresidents.

Patients were asked about any bleeding history or any family history with bleeding disorder then if there was any of these patients were asked to come with recent bleeding profile result. After that Patients were scanned by ultrasound just before procedure or requested to come with recent CXR and scanned with ultrasound if site of procedure was from the chest. After localization the site of procedure, Local anesthesia for adults and cooperative children and conscious sedation and local anesthesia if uncooperative children was given. After the procedure patients were asked for any immediate complications then werefollowed for 2 hours after the procedure and were asked again and reassessed for any immediate complications by ultrasound (if procedure was from the abdomen) andultrasound and CXR (if the procedure was from the chest) depending on the site of procedure. We chose two hours follow up because the commonest complication other than pain, hemorrhage, mostly occurs in the early two hours (around 60% hemorrhage) **(4).**

Before collecting the data, individuals were asked for willingness to be included in the study and the purpose of the study thoroughly explained to them.

Data was cleaned, edited,raw data entered to EpiData first then analyzed using SPSS(statistical package for social sciences) for window version **21** for calculating frequency distributions, cross tabulations and charts.

6.6. Ethical clearance

Ethical clearance had been obtained from Radiology Department Research committee and Institutional Review Board Office (**IRB**)

The questions from the questionnaire were proved not to affect the moral and personality of study subjects' .confidentiality of information of patients' identity had been ensured. Also an informed verbal consent was obtained from each individual involved in the research.

7. RESULTS

Among the 56 cases 40 (71.4%) were males and the 16 (28.9%) were females. The mean age of study subjects was 41.38 year with age range as young as 1 year old and as old as 78 years old. Of all the study subjects 22 (39.3%) were between 31 years to 45 years old range (table1)

Table 1

Age range	Frequency	Percent(%)
0-15	4	7.1
16-30	10	17.9
31-45	22	39.3
46-60	12	21.4
Above 61	8	14.3

Among the 56 cases 35 (62.5%) were taken from the abdomen and 19 (33.9%) were from the chest, 18 (32.1%) of them were taken from the liver and 8(14.3%) were taken from the lung. Among all the procedures 54 (96.4%) of the cases were FNAC and the rest were core biopsy (table2)

Table2

Variables	Frequency	Percent (%)
Site of procedure		
Chest	19	33.9
lung	8	14.3
mediastinum	6	10.3
pleura	5	8.9
Abdomen	35	62.5
renal	1	1.8
liver	18	32.1
spleen	1	1.8
peritoneum	4	7.1
retroperitoneal	2	3.6
Lymph node	3	5.3
Bowel	1	1.8
Abdominal mass of unknown origin	5	8.9
Others*	2	3.6
Tissue biopsied/FNAC taken from		
From mass	46	82.1
From Lymph node	7	12.5
From Fluid collections	3	5.4

Others* one from scrotumand one from proximalthigh mass

Among the 56 cases 32 (57.1%) were done by residents under supervision and the 24 (42.9%) were done by senior radiologists.

Among the 56 cases 56(100%) of them have under done post procedure ultrasound scanning and 11 (19.6%) bothultrasound and plain CXR exams(table3)

Table 3

Post procedure imaging	Frequency	Percent (%)
US	56	100
US and CXR	11	19.6

Prevalence of image guided complications

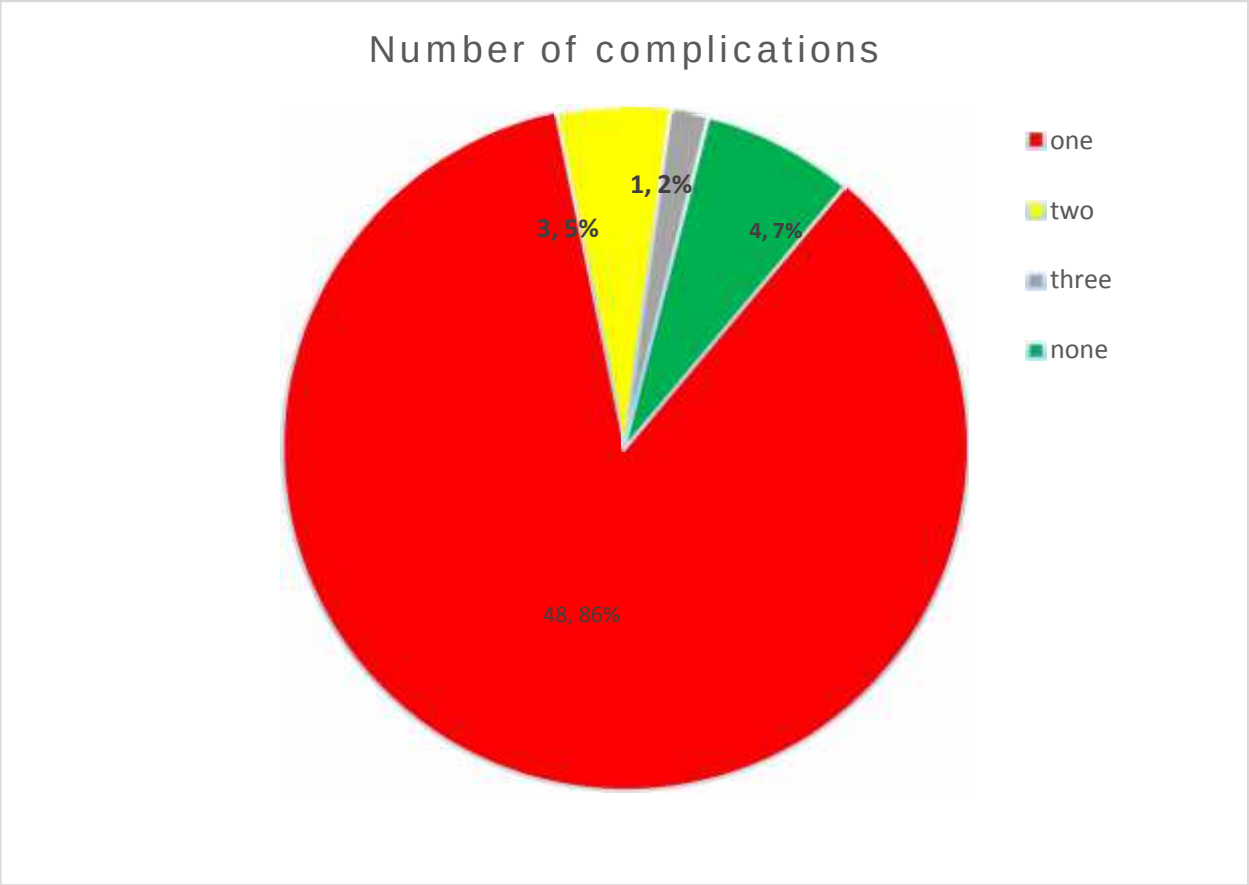
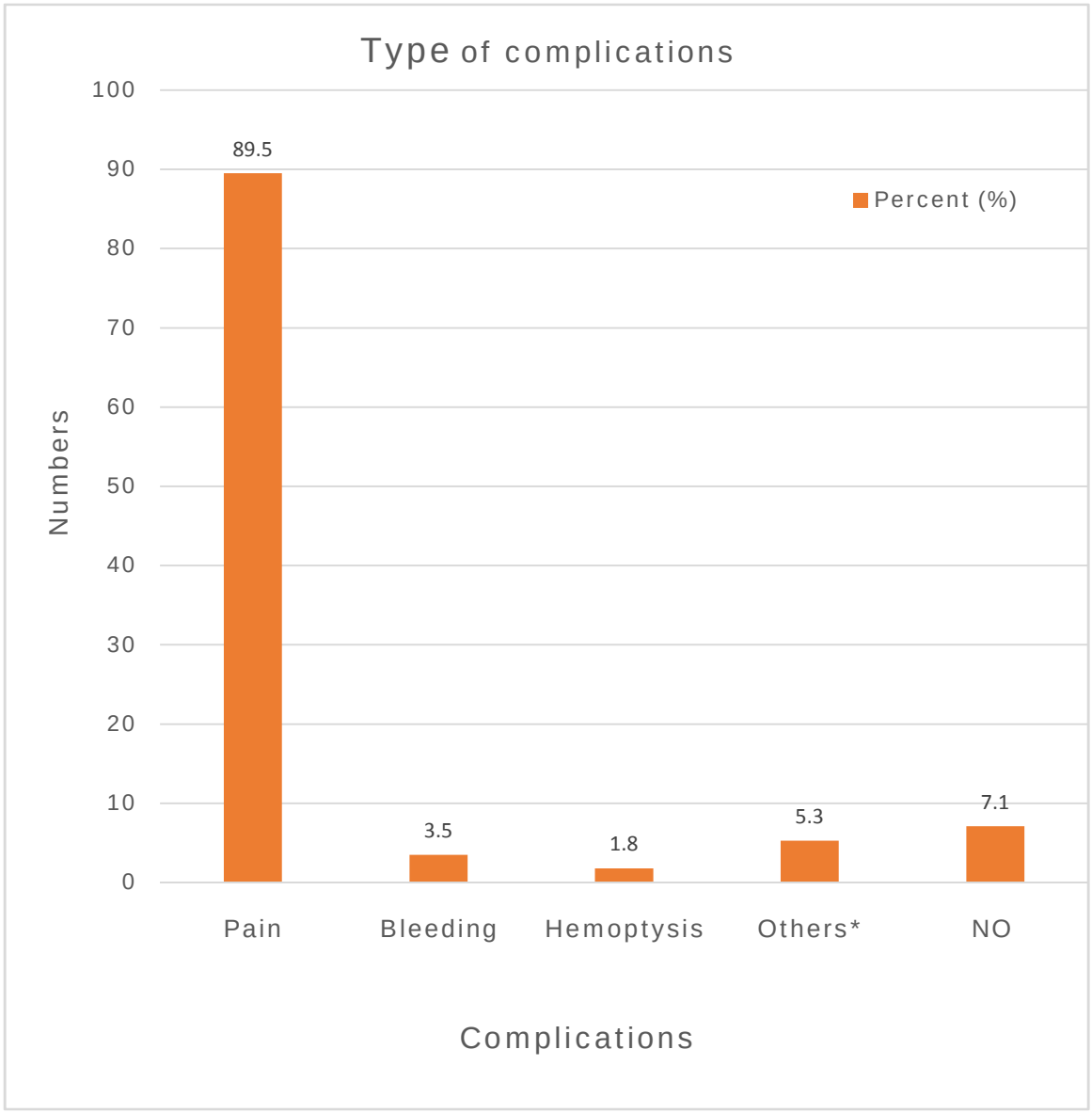


Fig.1

Among the 56 cases 48 (87.5%) of them have at least one complication, 3 (5.4%) have two complication, 1 (1.8%) has one complication and 4 (7.1%) had no complication at all (Fig.1)



Other* (one right upper arm pain, right upper arm weakness and fatigue after the procedure, and one procedure site local air collection

Fig.2

Among the 56 cases 51 (89.5) have pain, 2(3.5%) procedure site bleeding, 1(1.8%) hemoptysis and the 3 (5.3%) have other* complications (Fig2)

Among all the cases who developed complications 16 cases needed management and among them 11 (68.7) were managed conservatively(no medication was given), 5 (31.3 %) were managed medically (given analgesics). There was no surgical interventionand death.

8. DISCUSSION

We analyzed 56 cases for whom image guided biopsy/FNAC were done during the period from August 2013 up to August 2014. Liver was the most intra-abdominal organ biopsied and pain was by far the most common complication encountered. Even if there were complications other than pain like hemorrhage, hemoptysis and others only few needed subsequent management either with observation or treated with analgesics. The rest were complications which didn't need any medical or surgical intervention. No serious complications or death were encountered associated with the procedure.

Percutaneous needle biopsy has been a mainstay of oncologic diagnosis for more than two decades in most parts of the developed world, since the advent of ultrasound and computed tomography .it hasbecome the standard of care in the diagnosis of most tumors throughout the bod **(11).**

Herein BLH, it started some three years back with the introduction of fellowship program in body imaging radiology. Before that time real time US guided biopsy were not practiced at all rather a "semi-guided" biopsy/FNAC were done where lesion is scanned, distance from the skin surface to the center of the mass measured and marked on the skin. Then most of the time pathologists were responsible to use the information to get in and take specimen. The drawbacks of these traditional way of doing biopsy/FNAC is that, structures between the lesion and the skin were ignored and movement and respiration also made us miss the target. No one knows also the rate of complication associated with the traditional method because patients were not followed at all following the procedure.

Advances in imaging techniques have led to greater precision in targeting tumors and allowing for minimally invasive percutaneous biopsy of tissue inaccessible to minor surgery, such as lung lesions. Percutaneous biopsy also is beneficial in the staging of patients with cancer, particularly when another treatment method may be more appropriate than surgical resection. Advantages of percutaneous biopsy over surgical excisional biopsy include time and cost savings and reduction in morbidity. Complication rates of percutaneous**(3).**

Rate of complication is very low and most occur within hours of the procedure**(3).** We followed our subjects for only two hours, so we might missed cases who developedcomplications later after the procedure which might have occurred even after 24hrs of the procedure **(10)** hemorrhage and pain being the most common complications encountered **(1).**Our study also demonstrate these. Those who developed hemorrhage were having no known risk or deranged coagulation profile for those who were tested. Concerning intrathoracic FNAC/ biopsy, hemothorax and pneumothorax are the common complications listed in the literatures **(8).** these complications were not encountered in our series, the reason behind might be that only we did few intrathoracicFNAC, more over all intrathoracic specimens were taken with FNAC rather than biopsy even if needle size is not associated with increased risk of hemorrhage **(2).**

Major complications like massive life threatening hemorrhages and death are reported associated with image guided biopsy, no serious complications or death occurred in our study probably with the same justification.

9. CONCLUSION

Image guided (ultrasound guided) FNAC is a safe procedure that can be done by both senior radiologists and senior radiology residents without major complications but giving adequate local anesthesia should be strictly followed as the commonest complication is local pain.

10. LIMITATIONS OF THE STUDY

This is a single center study to generalize

The other limitation is all of the cases were done under ultrasound guidance hence we can't tell the complication that will occur CT guided procedures

More than 95% of the procedures are FNAC

Because patients were only followed for two hours post procedure (except one patient who was followed for 18 hours), this also may affect our study results.

11. RECOMMENDATIONS

Strict and adequate analgesia/anesthesia should be given to control the procedure associated pain

The rate of success of the procedure should be studied

Patients should be followed for long hours possible

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13. ANNEXE

Questionnaire

1. Socio-demographic data
    1.1. Card no:----------
    1.2. Full Name:----------
    1.3. Age:----------
    1.4. Sex: Male ☐ Female ☐
    1.5. Referred from:----------
        1.5.1. Regular outpatient clinic
        1.5.2. Emergency department
        1.5.3. Referral Clinic
        1.5.4. Wards
            1.5.4.1. Medical ☐
            1.5.4.2. Surgical ☐
            1.5.4.3. Pediatric ☐
            1.5.4.4. Gynecology ☐
            1.5.4.5. Other (specify) ----------
2. Clinical profile
    2.1. Clinical DX: (one dx the reason for biopsy)----------
    2.2. Radiological DX:----------
    2.3. Radiological dx made based on
        2.3.1. Plain film ☐
        2.3.2. Ultrasound ☐
        2.3.3. CT ☐
        2.3.4. MRI ☐
    2.4. Clinical bleeding diathesis (history including family history)

        Yes ☐ No ☐
    2.5. Bleeding profile Checked ☐ normal ☐ abnormal ☐

Not checked ☐

3. Procedure
   3.1. Site of procedure-
      3.1.1. Lung ☐
      3.1.2. Mediastinum ☐
      3.1.3. Liver ☐
      3.1.4. Spleen ☐
      3.1.5 Other(specify) ----------

   3.2. Tissue biopsied
      3.2.1. Mass ☐
      3.2.2. Lymph node ☐
      3.2.3. Fluid collections ☐
   3.3. Type of specimen taken
      3.3.1. Core biopsy ☐
      3.3.2. FNAC ☐
   3.4. Procedure done by:
      3.4.1. senior radiologist ☐
      3.4.2. Resident under supervision ☐
   3.5. post procedure imaging----------
      3.5.1. US ☐
      3.5.2. CXR ☐
      3.5.3. CT ☐
4. Procedural complications
   4.1. Pain ☐
   4.2. Bleeding ☐
   4.3. organ rupture(GB) ☐
   4.4. pneumothorax ☐
   4.5. pneumomediastinum☐
   4.6. hemoptysis ☐
   4.7. pulmonary hemorrhage ☐
   4.8. others specify ----------

5. complication managed ☐
    5.1. conservatively ☐
    5.2. Medical intervention ☐
    5.3. Surgical intervention ☐