



Liver Biopsy Management Guideline Protocol

PURPOSE

To outline a standard of care for the management of patients undergoing liver biopsy.

PATIENT CRITERIA:

1. Liver biopsy is the standard of care for the evaluation of elevated liver enzymes
2. Liver biopsy is used to stage and grade disease in patients who have an established diagnosis and allow a prognosis to be made and complete the informed consent process for treatment so a patient can be informed of risks and benefits of treatment

SUPPORTIVE DATA:

Literature has shown the following benefits of liver biopsy:

1. Determination of the severity of liver disease (inflammation) ⁽⁷⁾⁽⁸⁾⁽¹²⁾
2. Determination of the amount of liver scar tissue (cirrhosis) ⁽⁷⁾⁽⁸⁾⁽¹²⁾
3. Diagnosis change or finalization regarding the cause of liver disease ^{(7) (9)}
4. Beneficial in determining recommendations for treatment with interferon (for patients with hepatitis, if cirrhosis is found) ^{(3) (14)}
5. Establishment of a screening process for liver cancer for patients with cirrhosis ^{(7) (9)}
6. Determination if the patient has a medication-induced liver disease. ^{(7) (13)}

OTHER CONSIDERATIONS:

1. Coagulation support with single donor platelets is recommended if the platelet count is less than 70,000 or as per the judgment of the attending MD at the time of the procedure
2. Coagulation support with FFP is recommended if INR >1.4-1.5 as per the judgment of the attending MD at the time of the procedure
3. Transjugular or laparoscopic liver biopsy is the recommended approach for high risk patients, especially in the presence of ascites, anatomical abnormalities, or an inability to correct the patient's bleeding diathesis
4. Ultrasound guided liver biopsy is per MD discretion: note that more than 70% of biopsies performed in the US are performed by Radiologists under direct imaging or by GI Hepatologists using Ultrasound guidance
5. Intervals of follow-up biopsy (s) is at the discretion of the MD managing the patient; statements by the NIH allow follow-up liver biopsies in viral hepatitis to judge disease progression. A search of the literature indicates that liver biopsies in HCV management are reasonable at 3-5 years post diagnosis. Patients with autoimmune liver disease unresponsive to therapy may require more frequent liver biopsies.

OUTCOME MEASURES:

1. Patient will be assessed by a nurse/physician/physician assistant prior to the procedure.
2. Lab work will be completed and evaluated prior to the procedure, including appropriate coagulation studies.
3. Coagulation abnormalities will be treated as per recommendations/MD's discretion

4. Patient will receive ultrasound marking or bedside ultrasound imaging prior to the procedure
5. Patient will be continuously monitored and vital signs will be stable during intra- and post-procedure period
6. Patient will receive adequate pain management.
7. Patients discharged to home immediately post-procedure will be accompanied by a responsible adult.
8. Patient/Family/SO demonstrates an understanding of post-procedure care:
 - a. understands use and administration of any prescribed medications, and possible anticoagulant properties of any herbal preparations patient may be taking
 - b. understands activity level permitted
 - c. is aware of signs and symptoms of complications such as increased pain, increased abdominal girth, weakness or dizziness, and bleeding, erythema or purulent drainage from biopsy site
 - d. understands when to seek medical attention
 - e. is aware of follow up appointment
9. Patient expresses satisfaction with care and process.

Physician's Pre-procedure Responsibilities

Pre-Op Evaluation by and Responsibilities of the Internist or Primary Care Physician (PCP):

Outpatients:

1. An Internist, PCP or the hepatologist performs a patient evaluation (History and Physical) within **one month** of the scheduled procedure
 - The H&P must include an evaluation of patient's medical problems and an assessment of the stability of these problems
 - A comprehensive H&P is required for those patients with complex medical problems
 - Appropriate lab evaluation should be done, including INR and platelet count
 - A repeat INR and platelet count may be ordered at the MD's discretion within 2 weeks of the biopsy
2. The Internist or PCP communicates with and sends a copy of the H&P to the hepatologist, gastroenterologist or interventional radiologist who will be performing the procedure. A copy is also sent to the Ambulatory Care Unit.
3. The patient is instructed regarding the following:
 - No ASA or Plavix for 5 days prior to biopsy
 - If Plavix cannot be discontinued: consider a bleeding time prior to biopsy
 - No NSAIDs for 1 day prior to biopsy
 - Other anticoagulant instructions as per the patient's hepatologist or hematologist

Inpatients:

1. A comprehensive history and physical exam is performed within 24 hours of admission.

	<p><u>All Patients:</u></p> <ol style="list-style-type: none"> 1. The MD/FNP/PA <u>obtains</u> informed consent from the patient and documents on the medical record that alternatives, risks and benefits have been discussed 2. <u>Provides</u> a copy of the Liver Biopsy Welcome Sheet <i>Having a Liver Biopsy</i> to the patient 3. <u>Initiates</u> the Pre-Liver Biopsy Order Set in PCIS 4. <u>Orders</u> the following as appropriate: <ul style="list-style-type: none"> ➤ Transfusion of 1 unit of single donor platelets for platelet count < 70,000 ➤ Transfusion FFP for INR >1.4 - 1.5 or as per MD's discretion
<p>Pre-procedure Labs and Tests</p>	<p><u>Recommended:</u></p> <ol style="list-style-type: none"> 1. CBC w/ diff, platelet count, PT w/ INR, clot for type and hold, other labs per MD discretion 2. Routine Chest X-Ray and EKG as per MD discretion 3. Ultrasound marking of biopsy site by Radiology or bedside ultrasound imaging by MD performing procedure
<p>Inpatient Nurse/ Nurse Facilitator's Pre-procedure responsibilities</p>	<ol style="list-style-type: none"> 1. <u>Completes</u> patient assessment by phone for all outpatients at least 2 days prior to procedure, which includes verification with patient that: <ol style="list-style-type: none"> a. Post- procedure discharge transportation is arranged b. Family structure for post-op care is available 2. <u>Instructs</u> outpatients to arrive in ASU 1 hour prior to the scheduled procedure 3. <u>Follows</u> Pre-Liver Biopsy Order Set in PCIS as per MD order 4. <u>Completes</u> a face to face interview and head to toe physical assessment on all inpatients within eight hours of admission, and q shift thereafter 5. <u>Obtains</u> pre-procedure labs and tests, per physician's order 6. <u>Notifies</u> MD of any abnormal lab/test findings 7. <u>Verifies</u> that signed informed consent and H&P are present in the patient's medical record prior to the procedure 8. <u>Verifies</u> that lab and test results are in the patient's medical record prior to the procedure

<p>ACU nurse /inpatient nurse responsibilities on the day of procedure, prior to the procedure</p>	<ol style="list-style-type: none"> 1. <u>Verifies</u> with patient NPO status: NPO for 6 hours prior to procedure if conscious sedation is planned – or – light breakfast if no sedation is anticipated 2. <u>Obtains</u> pre-procedure vital signs per physician order 3. <u>Establishes</u> EKG and oxymetry monitoring per Sedation Protocol 4. <u>Initiates</u> Sedation Protocol 5. <u>Establishes</u> IV access per pre-Liver Biopsy Order set 6. <u>Provides</u> bedside ultrasound machine (Sonosite), liver biopsy tray and biopsy needles as specified in the PCIS Pre-Liver Biopsy Order Sets: <ul style="list-style-type: none"> • 17 GA Jamshidi (soft tissue) – included in tray • 16 GA quick core needle – order separately 7. <u>Administers</u> pre-procedure FFP/platelets as appropriate/ordered by MD
<p>Physician Liver Biopsy procedure recommendations</p>	<p>The following procedure for liver biopsy is recommended:</p> <ol style="list-style-type: none"> 1. Transfuse: <ul style="list-style-type: none"> ➤ 1 unit of single donor platelets for platelet count < 70,000 ➤ Transfuse FFP for INR> 1.4 – 1.5 or as per MD discretion 2. Size of needle: <ul style="list-style-type: none"> ➤ Optimal size of liver biopsy for pathologic assessment: <ul style="list-style-type: none"> 2 cm length .5 mm diameter ➤ It is recommended that a liver biopsy needle size no larger than 16 gauge be used 3. Positioning: <ul style="list-style-type: none"> ➤ on back with hands at side – or -- ➤ Patient to lie on right side ➤ Note: literature is suggestive, but data is not conclusive re: efficacy of positioning during biopsy 4. Instruct the patient to exhale and hold his/her breath as the specimen is aspirated 5. Number of passes: <ul style="list-style-type: none"> ➤ There is no prospective study that statistically correlates the

	<p>number of passes with increased risk of complications</p> <ul style="list-style-type: none"> ➤ Community standard is to perform 1-2 passes to obtain tissue for pathology and additional studies as needed ➤ Trends in the literature state that more than 1-2 passes may be associated with an increased risk of complications although this data is derived from studies where large 14 gauge needles may have been used and liver imaging for liver biopsy was infrequent or not used <p>6. Tissue is commonly needed for quantitative iron and or copper as well as special stains and molecular testing, therefore 2 biopsies may be required to obtain adequate tissue to decrease sampling error, and prevent need for patient to return for a second procedure</p> <p>7. Studies:</p> <ul style="list-style-type: none"> ➤ Specimen to Pathology ➤ tissue for HCV RNA assay ➤ tissue for quantitative iron ➤ tissue for quantitative copper ➤ 2 red barrier tubes for Dr.Gish (special study). Spin and place serum in Lab Fridge ASAP.
<p>Post-procedure monitoring: ACU/ Nursing Unit</p>	<p><u>Initiate</u> post liver biopsy order set:</p> <ol style="list-style-type: none"> 1. <u>Resume</u> pre-liver biopsy diet as soon as patient is awake and alert 2. <u>Monitor</u> vital signs q 15 minutes x 4, and q 30 minutes x 4, with additional VS as indicated/ordered 3. <u>Maintain</u> bedrest for a minimum of one hour post procedure, or until stable 4. <u>Positioning</u> post-procedure: <ul style="list-style-type: none"> ➤ Recommended in literature: apply pressure to the biopsy site, and then roll the pt to the right side and instruct him/her to remain on the side for 1 hour to help prevent bleeding or bile leakage ➤ Note: literature is suggestive, but not conclusive with regard to efficacy. 5. <u>Obtain</u> Hemogram post-procedure as per order set or as ordered by MD 6. <u>Order</u> <ul style="list-style-type: none"> ➤ Chest X-ray, standard (PA & Lat- routine), ASAP. Indication: post liver biopsy, Rule out pneumothorax. House staff to review films. ➤ US of liver: R/O hematoma: call results to MD

Reportable Conditions	<p>7. <u>Observe</u> patient for:</p> <ul style="list-style-type: none"> ➤ increased pain ➤ increased abdominal girth ➤ weakness or dizziness ➤ bleeding, erythema or purulent drainage from biopsy site
	<p>1. <u>Notify MD</u> for</p> <ul style="list-style-type: none"> a. SBP <100, HR> 120 b. Respiratory distress c. change in LOC d. signs of bleeding (increased abdominal girth, drop in Hct and Hgb) e. patient report of severe persistent abdominal pain
Discharge Criteria (Outpatients)	<p>1. Patients can be discharged within 2 hours post-procedure and with 1 hour or more optional observation based on MD and RN judgment of patients clinical status and symptoms when:</p> <ul style="list-style-type: none"> ▪ discharge criteria are met <ul style="list-style-type: none"> ➤ vital signs are stable ➤ Hct and Hgb are within normal limits ➤ Pain is minimal ➤ Patient is awake and back to baseline mental status and mobility ▪ Transport to home is available (for outpatients) ▪ Patient/Family demonstrates an understanding of post -procedure care
Follow up Instructions	<p>1. <u>Instruct patient</u> that he/she will receive information about their biopsy results via:</p> <ul style="list-style-type: none"> a. Clinic appointment b. Telephone call <p>2. <u>Instruct patient</u> regarding:</p> <ul style="list-style-type: none"> a. Use and administration of any prescribed medications b. Activity level permitted (no heavy lifting for 48 hours) c. Diet d. Significance of pain, increased abdominal girth, weakness dizziness or lightheadedness, and increased bleeding/drainage from biopsy site e. When and where to seek medical attention (Recommended: patient to return to Emergency Department and /or notify MD) f. Any follow up appointments
Documentation	<p>1. <u>Document</u> pre- and post- procedure patient assessment findings on Ambulatory Care Flow Sheet</p> <p>2. <u>Document</u> discharge assessment criteria and score on Ambulatory</p>

Care Flow Sheet

3. Document education provided to the patient on the nursing flow sheet
4. Document initiation of, use of, and modifications to this protocol on the nursing flow sheet.

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