

Comparison of Automated Needle Systems for Transjugular Liver Biopsy: A Prospective Randomized Controlled Trial

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Background

- **Liver biopsy is the gold standard for the diagnosis and prognosis of both acute and chronic liver pathologies.**
 - Important for many conditions: chronic hepatitis, drug-induced liver injury, cirrhosis, etc.
 - Adequate prognostic evaluation is of growing importance as new medications to treat metabolic dysfunction-associated fatty liver disease (MAFLD) and metabolic dysfunction-associated steatohepatitis (MASH) become available.
- **Percutaneous liver biopsy is contraindicated in patients with disorders of coagulation, acute liver failure, ascites, or high adiposity. Transjugular liver biopsy (TJLB) represents a safe alternative.**
 - The TJLB approach allows for hemodynamic measurement of the hepatic and portal venous systems, providing additional insight to the presence and degree of portal hypertension.
- **To appropriately diagnose liver pathologies and help guide treatment planning, biopsy samples that are of adequate diagnostic and prognostic quality are required.**

Study Design

- **AIM: to compare the quality of biopsy samples collected from two FDA approved needle systems for TJLB.**
 - Quick-Core® (Cook Medical; Bloomington, IN)
 - Flexcore® (Argon Medical Devices; Plano, TX)
- **IRB approved. Prospective Randomized Control Trial**
 - All patients enrolled must provide informed consent
 - Randomized using a random numbers table
- **Sample Comparison:**
 - Number of attempts to obtain four samples
 - Number of fragmented samples
 - Number of complete portal tracts (CPTs- bile duct, portal vein, hepatic artery branch)
 - Sample Length
- **Additional Variables:**
 - Liver function tests, Model for End Stage Liver Disease (MELD) score, Child Pugh score, hepatic hemodynamic measurements, percent fibrosis, percent steatosis, and histologic diagnosis

Current Progress

- **14 patients have been enrolled.**
 - 9 biopsy procedures performed

Future Plans

- **Continue to enroll patients**
- **Consider expansion to multi-center trial**

