Multicenter Blunt Hepatobiliary Trauma: Retrospective study

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Total number of Level 1 trauma centers = 11

Background:

Liver injury is the leading cause of death in patients with abdominal trauma, and hemorrhage is the main cause of early liver injury–related death [1]. CT is the imaging modality of choice for evaluation of patients with suspected blunt hepatic injury [2]. Radiologists play a crucial role in evaluating and triaging the patients to the next appropriate management steps. Management of hepatic injuries ranges from nonoperative management (NOM) to emergent surgery. There has been a recent shift toward recognizing the importance of hepatic vascular injury (HVI) with regard to the failure of NOM in trauma patients. The American Association for the Surgery of Trauma (AAST) released updated liver injury grading criteria in 2018 which newly incorporates active contrast extravasation and contained vascular injury (e.g., pseudoaneurysm & arteriovenous fistula) into the grading system [3].

Non-operative management of hepatic trauma with adjunctive hepatic arterial embolization is now standard of care. In a single center study by Lada *et al*. [4], 25% of liver trauma patients had HVI. In addition, patients with HVI had a 3.2-day longer length of hospital stay on average and 40.3-fold greater odds of getting angioembolization compared to those without. Patients with high-grade liver injury (AAST grades IV–V, 2018 criteria) had 3.2-fold greater odds of failing non-operative management and 14.3-fold greater odds of angioembolization compared to those without. Thus, HVI in liver trauma is common and is predictive of patient outcome and management.

A recent study by Zhao *et al*. [5] demonstrated that AAST hepatic injury grade was significantly associated with increased odds of hepatic arterial embolization in multivariate analysis. However, univariate analyses demonstrated no significant

association between CT liver injury grade, CT characteristics of liver injury, or pre-angiographic clinical data with need for hepatic arterial embolization. Thus, in patients with hepatic trauma, prediction of need for hepatic arterial embolization requires consideration of both clinical factors and imaging findings.

Biliary injuries are a well-recognized source of morbidity in the setting of acute traumatic hepatic injury managed nonoperatively, particularly if the diagnosis is delayed. Despite its clinical importance, the incidence of biliary injury in the trauma setting remains largely unknown. The role of CT in diagnosing hepatic trauma is well established. In contradistinction, there is a relative paucity of literature on the role of CT in biliary injury, likely because bile leaks are not reliably assessed at CT. The indirect CT imaging findings suggestive of bile duct injury include liver lacerations, ascites, and focal perihepatic fluid collections. Hepatobiliary scintigraphy is often required to definitively diagnose biliary injury. Thus, the optimal imaging workup of a patient with a suspected bile leak is a multimodality approach using the anatomic data provided by CT and the functional information garnered by hepatobiliary scintigraphy. There is, however, no agreed upon algorithm for the incorporation of hepatobiliary scintigraphy in the care of the traumatically injured patient. A study by LeBedis *et al.* [6] demonstrated that bile leaks are frequently encountered in trauma patients with liver lacerations (31 %). Bile leaks in the setting of hepatic trauma portend a higher morbidity, with these patients undergoing more imaging studies and therapeutic procedures while having longer lengths of hospital stay when compared to post-traumatic patients with either no biliary injury or contained bile leaks. Thus, hepatobiliary scintigraphy should be liberally applied to patients with liver trauma ideally within the first 4 days of the initial hepatic injury to diagnose and treat traumatic bile leaks. Temporary internal stenting via ERCP together with percutaneous drainage of intra-abdominal or intrahepatic bile collections is a safe and effective management strategy for biliary injury [7, 8]. An emerging tool for biliary imaging is the use of MR imaging in trauma patients with hepatobiliary agents such as gadoxetate disodium (Eovist) as it provides both anatomic and functional evaluation of the hepatobiliary system [9, 10, 11].

SPECIFIC AIMS:

NULL HYPOTHESIS 1: Identifying hepatic injuries has no effect on patient management or outcome.

AIM 1: Assess the incidence of different AAST 2018 hepatic injury grades, treatment patterns and patient outcomes.

NULL HYPOTHESIS 2: There is no difference in detection of active contrast extravasation and contained vascular injuries in the setting of hepatic trauma utilizing different CT protocols.

AIM 2a: Compare the incidence of hepatic vascular injuries (active extravasation and contained vascular injuries) on arterial, portal venous and delayed MDCT phases through the liver.

AIM 2b: Patient outcomes with respect to vascular injuries will be compared, specifically failure of nonoperative management (need for readmission within 30 days, continuing resuscitation, etc.) and interval need for surgery after arterial embolization.

NULL HYPOTHESIS 3: There is no difference in patient management or outcome between blunt hepatic trauma patients who have and do not have associated biliary injuries.

AIM 3a: Assess the rate of biliary imaging (nuclear medicine hepatobiliary scintigraphy, ERCP or MRCP with hepatobiliary agent) with respect to AAST 2018 hepatic injury grade.

AIM 3b: Assess the incidence of biliary injury on biliary imaging with respect to both AAST 2018 grade and the central versus peripheral (<3cm or >3cm from intrahepatic IVC) location of the hepatic injury.

AIM 3c: In those patients with concomitant biliary injury, compare the rates of nonoperative management, biliary intervention (ERCP, interventional radiology, etc), surgical management and patient outcome.

Study Design: Multicenter, retrospective with double-blinded trauma CT reading by two expert emergency radiologists with adjudication by a third expert emergency radiologist.

Study Population:

Inclusion criteria: Adults (≥18 years old) who sustained blunt hepatic trauma over a 10-year timeframe (1/1/13-12/31/23) and underwent an admission CT of the abdomen and pelvis (≥16 MDCT) within 12 hours of admission.

Exclusion criteria: Penetrating trauma, CT obtained > 12 hours after initial presentation and/or patient left AMA or deceased before CT obtained.

Sample size: Estimated study size is 2,000-3,000 patients; or approximately 250 patients/site.

Workflow:

1. **Cohort identification:** After local IRB approval, trauma registry lists at each institution will be requested for adults (≥18 years old) who have sustained blunt liver trauma 1/1/13-12/31/23. Each subject will be given a study identification (e.g. BU001, BU002) which will be used to link to the subject MRN. This master key will be housed in a secure HIPAA compliant manner at each institution and never shared.
2. **Data collection**: For all study sites, clinical data from chart review and blind reading imaging data will be directly entered into two separate data sheets (Clinical Data and Imaging Data) on Boston Medical Center's REDCap, a web-

based tool that will serve as the data repository for our study. Admission CT scans and any follow-up MRCPs/nuclear medicine HIDA scans will be anonymized and labeled with the appropriate study identification numbers by each site. These imaging studies will then be uploaded to a secure web based PACS (ideally ACR PACS if funding is obtained). The expert emergency radiologists will only have access to the imaging data sheet at the time of imaging blindreading (controlled via the Data Access Group function in REDCap). After reader training, each imaging study will be blind read by two expert emergency radiologists on this trial (randomized reading lists created by a statistician will be provided to each site PI) and the blind reading imaging data entered into the imaging data sheet housed on BMC's REDCap. Discrepant results will be adjudicated by a third expert emergency radiologist.

3. **Analysis** - After data cleaning and adjudication of discrepant imaging blind readings, the clinical and imaging data will be exported from BMC's REDCap for statistical analysis.

Timeline:

Site PI's will be considered co-authors for publications derived from this project. All other collaborators at each site will be considered non-author contributors as outlined by ICMJE. The non-author contributors will be acknowledged as "Participating Investigators" if they give written permission via email.

- Initial invitation to sites: December 2023
- IRB submission/DUA execution: Spring/Summer 2024 - rolling
- Prepare slide deck for instructions on blind reading and data recording: Summer/Fall 2024
- Cohort identification through trauma registry at each site after IRB approval: estimating ~300 patients per site (assuming 2,000-4,000 trauma admission per year/site)
- De-identified cases prepared for blind reading: January-March 2025
- Collect medical record and radiology report data recording (Institution PIs): starting Summer 2024
- Abstract draft submission of analysis of clinical data to ASER and RSNA
- Manuscript submission of clinical data to Emergency Radiology
- CT blind reading with adjudication and analysis– Year 2
- Abstract draft submission of analysis of imaging data to ASER and RSNA
- Second manuscript submission of clinical and imaging data to Emergency Radiology

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