Form "EAST Multicenter Study Proposal"
Details #137 (submitted 10/01/2021)

Study Title	The Utility of Serial Hemoglobin Monitoring in Non-Operative Management of Blunt Splenic Injury
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Are you a current member of EAST?	Yes
If you selected "No" above please identify a Sponsor that is an active EAST member:	
My Multicenter Study proposal is...	Prospective
Use this area to briefly (1-2 paragraphs only) outline the burden of the problem to be examined	Non-operative management (NOM) has become the standard of care in trauma centers across the country for treatment of hemodynamically stable patients with low grade blunt splenic injuries (BSI). In hopes of early identifying patients who will fail NOM, institutions frequently order serial hemoglobin (S-Hgb) levels to recognize hemorrhage and anticipate a decline in hemodynamics. Patients that fail NOM are felt to do so after sudden acute blood loss from a clot that becomes disrupted or a sudden tear of a splenic artery from an expanding splenic hematoma, then patients will likely develop signs and symptoms of shock before they develop a significant drop in their hemoglobin concentration, making serial hemoglobin values less useful. We conducted a retrospective chart review of patients with BSI between 2013 in 2019 at our institution. We compared demographics, comorbidities, lab values, clinical decision-making, and outcomes for patients undergoing NOM vs operative management (OM), which also included arterial embolization (AE). The inclusion of AE in the OM group is a change from previous studies and leaves patients only being monitored without any interventions in the NOM group. 341 patients were admitted for NOM of their BSI and 37 of those failed. Although 8 of the 37 patients documented a drop in Hgb value as one of the reasons for failure of NOM, individual chart review identified that only 1 of the 8 had a drop in S-Hgb value as the main event that led to further imaging or a procedure. Furthermore, there were no differences in mortality, ICU or hospital length of stay in patients that failed NOM and had S-Hgb compared to daily Hgb (D-Hgb) values. Our pilot study supports the argument that serial Hgb values may not influence clinical decision-making in NOM of BSI and may not change clinical outcomes. Furthermore, obtaining D-Hgb values instead of S-Hgb values appears to be a safe practice with potential benefits of decreased patient venipunctures, use of resources and cost.

Primary aim

To determine if Serial compared to Daily Hemoglobin monitoring helps identify failure of non-operative management earlier

To determine whether monitoring Serial Hemoglobin values compared to Daily monitoring in the NOM group affects clinical outcomes or mortality.

Secondary aims

To determine what factors helped identify failure of NOM in patients undergoing Serial compared to Daily Hemoglobin monitoring.

To determine if there are patient subgroups that may benefit from the practice of monitoring Serial Hemoglobin values.

Inclusion Criteria

Patients 18 years or older

Patient identified to have Blunt Splenic Injury (BSI)

Patients that were admitted for non-operative management of their BSI

Admission and monitoring at a Level 1 or 2 trauma center with IR capabilities

Centers with current practice of Serial (q6 hours) or Daily Hemoglobin measurements

Exclusion Criteria

Prisoners

Patients under the age of 18

Patients that died prior to admission

Patients that died after of non-abdominal causes within 30 days of admission

Therapeutic Interventions

Operative Management to include any abdominal operation or arterial embolization

Primary Outcome

The rate of failure of NOM in patients monitored with S-Hgb and D-Hgb values

Clinical outcomes, including mortality, hospital and ICU length of stay, amount of blood transfusions or massive transfusion protocols, and interventions for patients undergoing NOM with S-Hgb and D-Hgb monitoring

Factors that helped identify F-NOM in patients undergoing S-Hgb and D-Hgb monitoring

Secondary Outcomes

Patient-dependent factors and clinical factors on presentation in patients undergoing NOM with S-Hgb and D-Hgb monitoring, and comparisons of clinical outcomes related to specific subgroups

List specific variables to be collected & analyzed

Gender

Age

BMI

Comorbidities

Physical exam, vitals, fluid and blood product requirements, ETOH and the need for mechanical ventilation on initial assessment

Findings on initial imaging

Splenic and associated injuries

Hemoglobin values and their timing

Clinical management- OM vs NOM

Success or failure of NOM and the reasons for failure

Type of intervention for those that underwent OM

Mortality

ICU and hospital LOS

Total number of blood transfusions

The data will be collected using RedCap Database. Investigators from outside institutions will be given remote access to upload de-identified data to our database.

Outline the data collection plan and statistical analysis plan succinctly

Data will be analyzed using chi-square analysis and student's t-test, with a significance set of a $p<0.05$.

Since we only had 37 patients fail NOM from 2013-2019, we will aim to enroll 20 institutions, 10 in each group for serial vs daily Hgb. We estimate the need to enroll 100-110 patients in each group for serial vs daily Hgb for patients that fail NOM. This will allow us to determine close to a 15% difference with 95% confidence interval or 10% difference with 80% confidence interval.

Include the Target Number of Centers:

20

Include the Target Number of Patients:

200

What is the anticipated time to complete this study?

18-24 months

If applicable, include a Data Power Analysis:

Outline consent procedures here, if applicable

Will ask for a waiver of consent. Institutions will be asked to adopt the hemoglobin collection frequency that most closely resembles their current practice. Surgeons will treat their patients based upon their own clinical judgement.

Will ask for waiver of consent. This is an observational study. The biggest risk of this study concerns the security of protected health information. All data uploaded to the redcap database to be analyzed will be de-identified.

Succinctly outline a risk/benefit analysis

The result of this study may answer the question of whether monitoring labs more frequently positively impacts outcomes for patients with BSI undergoing NOM. If this is not found to be of benefit, de-implementation of this practice can decrease patient venipunctures and discomfort, potentially decrease acute blood loss anemia from frequent lab draws, as well as decrease cost and use of hospital resources. Furthermore, if this practice negatively impacts outcomes, then de-implementation should improve patient care.

Include a brief listing of key references

1)Olthof DC, Joosse P, van der Vlies CH, de Haan RJ, Goslings JC. Prognostic factors for failure of nonoperative management in adults with blunt splenic injury. Journal of Trauma and Acute Care Surgery. 2013;74(2):546-557. doi:10.1097/ta.0b013e31827d5e3a

2)Peitzman AB, Heil B, Rivera L, et al. Blunt splenic injury In Adults: MULTI-INSTITUTIONAL study of the Eastern Association for the surgery of trauma. The Journal of Trauma: Injury, Infection, and Critical Care. 2000;49(2):177-189. doi:10.1097/00005373-200008000-00002

3)Poupore, NS, Boswell ND, Baginski B, Cull J, Pellizzeri K. The Utility of Serial Hemoglobin Monitoring in Non- operative Management of Blunt Splenic Injury. The American Surgeon, 2021, 0(0):1–6, doi:10.1177/00031348211048829. Accepted for publication.

4)Stassen NA, Bhullar I, Cheng JD, et al. Selective nonoperative management of blunt splenic injury. Journal of Trauma and Acute Care Surgery. 2012;73(5). doi:10.1097/ta.0b013e3182702afc