Form "EAST Multicenter Study Proposal"

Study Title	Reducing Routine Phlebotomy in Stable Liver and Splenic Injuries
Primary investigator / Senior researcher	Jose Prince
Email of Primary investigator / Senior researcher	jprince@nshs.edu
Co-primary investigator	Ibrahim Abd el-shafy
Use this area to briefly (1-2 paragraphs only) outline the burden of the problem to be examined	Operative intervention historically was the standard of care until in 1971 Simpson and Douglas described successful non operative treatment in select pediatric patients.[1] Non operative management of solid organ injury has become standard of care but there continues to be significant variability. In 2000 APSA published a consensus guideline for management of isolated solid organ injuries based on CT scan.[2] Decreasing resource utilization continues to be point of great interest and seen in multiple studies [3]. We have proposed, and retrospectively validated using trauma database registries, a protocol developed via a consensus at our institution. [4] This standardized protocol is the clinical care guideline at our institution for solid organ injury.
Primary aim	Reducing Routine Phlebotomy in Stable Liver and Splenic Injuries
Secondary aims	Reducing hospital stay.
Inclusion Criteria	1.Pediatric Trauma patients under 18 2.Liver and/or spleen injury grad 1-4 3.Primary presentation (not delayed presentation)
Exclusion Criteria	1.Clinical instability (age-specific tachycardia, or hypotension , tachypnea, low urine output, altered mental status, or any significant clinical deterioration that warrants increased level of care and investigation.) Patients would be removed from the pathway and undergo immediate treatment.

Therapeutic Interventions

Upon initial diagnosis of solid organ injury based on AAST injury scoring scale our patients who are hemodynamically stable with solid organ injury grade 1-4 are treated using the following protocol:

•For grade 1 and 2 injuries; Q4 hour vital signs, NPO, bathroom privileges and initial H/H upon arrival. If clinically stable the next morning diet is advanced to regular and the patient is allowed to ambulate. If patients clinically stable at 24 hours from initial evaluation patient may be discharged home.

•For grade 3 injuries: Q4 hour vital signs, NPO, bathroom privileges and initial H/H upon arrival. If the patient continues to be clinically stable by day 2 advance to a regular diet but continue bed rest with bathroom privileges. If the patient continues to be stable the next day they are allowed to ambulate and are discharged home.

•Patients with grade 4 solid organ injuries are admitted to the ICU overnight and undergo Q1 hour vitals, initial h/h upon arrival. If they continue to be clinically stable patient is transferred to the floor; the next morning advanced to a clear diet and given bathroom privileges. If patient continues to be clinically stable on the 3rd morning they are advanced to a regular diet and allowed to ambulate. If tolerated with continued clinical stability patient is discharged home. Discharge instructions include education on close follow up and activity restrictions as published in APSA guidelines.

•Patients who demonstrate any sign of clinical instability would be immediately removed from the pathway, evaluated for intervention and treated appropriately.

•Grade 5 (liver/spleen) and Grade 6 (liver) patients were excluded from the proposed pathway due to the relative complexity and rarity of those injuries.

Primary Outcome

The primary outcome variable number of blood draws.

Secondary Outcomes

hospital stay in days and number of patinets able to stay on pathway

List specific variables to be collected & analyzed

Patient Demographics

•Age

•BMI

•Sex

•Ethnicity

Clinical Data

•Date of presentation

•Grade of liver or spleen injury

•Initial H/H

•Initial HR

•Initial B/P

•Clinically stable day 1, day 2, day 3

•Discharge day

Outline the data collection plan and statistical analysis plan succinctly

We will calculate the average number of blood draws required, and hospital days in the study group using standard statistical tests. We can determine effectiveness of the study protocol from a statistical comparison to data from a similar patient population that followed historical APSA guidelines.

Outline consent procedures here, if applicable

n/a

No procedures or therapies will be provided solely for the study's purpose. The provider's clinical assessment will identify patients who fit into the defined treatment algorithm and are clinically stable.

Succinctly outline a risk/benefit analysis

Breach of patient confidentiality and privacy is an additional risk factor. We are using REDCap, a HIPPA compliant database. The study design includes steps to safeguard patient identification. No information revealing patient identification will be disseminated in publications, conference proceedings, or other public forum.

Include a brief listing of key references

1.Douglas GJ, Simpson JS. The conservative management of splenic trauma. J Pediatr Surg 1971;6:565–70.

2.Stylianos S. Evidence based guidelines for resource utilization in children with isolated spleen or liver injury. The APSA Trauma Committee. J Pediatr Surg 2000;35:164–9.

3.Stylianos S. APSA Liver/Spleen Trauma Study Group. Compliance with evidencebased guidelines in children with isolated spleen or liver injury: a prospective study. J Pediatr Surg 2002;37:453–6.

4.Rosen N, Reducing scheduled phlebotomy in stable pediatric patients with blunt liver or spleen injury. J Pediatr Surg 2014;49;759-762