**Form** "EAST Multicenter Study Proposal"

<table>
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<tr>
<th><strong>Study Title</strong></th>
<th>Can we be FASTeR? A multicenter study utilizing Right sided roll to improve sensitivity of the FAST</th>
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<tr>
<td><strong>Primary investigator / Senior researcher</strong></td>
<td>P Jason Granet</td>
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<td><strong>Email of Primary investigator / Senior researcher</strong></td>
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<td><strong>Co-primary investigator</strong></td>
<td>Danielle Pigneri</td>
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<td><strong>Are you a current member of EAST?</strong></td>
<td>No</td>
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<td><strong>If you selected &quot;No&quot; above please identify a Sponsor that is an active EAST member:</strong></td>
<td>P Jason Granet</td>
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<td><strong>My Multicenter Study proposal is...</strong></td>
<td>Prospective</td>
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Despite advances in imaging studies and the widespread acceptance of the Acute Trauma Life Support (ATLS) algorithm, the assessment and management of the hypotensive trauma patient remains challenging. Rapid diagnosis and treatment of intraabdominal hemorrhage is often lifesaving. The Focused Assessment with Sonography in Trauma (FAST) examination is now part of ATLS and has become increasingly utilized over the last several years. The FAST examination provides a fast, bedside, non-ionizing, non-invasive form of evaluation for hemoperitoneum with excellent specificity (94.7-99.6% in most series). The sensitivity of this examination, however, is far from perfect (20-60%). Improving the sensitivity of the FAST examination would allow for the faster identification and treatment of innumerable trauma patients with life-threatening intraabdominal hemorrhage.

Our study aims to explore the potential improvement in detection of intraabdominal fluid after turning patients onto their right side. Patients are routinely turned for examination of their back and removal of the rigid spine board during the secondary survey. Changing practice towards routine turning to the patient’s right side can potentially improve outcomes without delaying care. It has already been shown that a standard FAST examination is most likely to detect hemoperitoneum in Morison’s pouch (hepatorenal recess), the most dependent portion of the abdomen. We hypothesize that this change in position will concentrate any intraabdominal fluid into Morison’s pouch, thus making detection of smaller volumes of fluid more likely. A recent pilot study performed within our institution demonstrated earlier identification of intraabdominal fluid with FAST examination after Right sided roll (FASTeR) when compared to standard FAST examination. Our aim is to perform a large, multicenter study aimed at evaluating this phenomenon in trauma patients. We plan to prospectively collect data for creation of a multicenter database. Patients would undergo both standard FAST examination and, when appropriate (see Methods), a FASTeR examination. Our aim is to compare the sensitivity of standard FAST examination with the sensitivity of FASTeR examination in detecting hemoperitoneum. Positive FASTeR examinations will be compared to computed tomography (CT) imaging or operative findings to differentiate true positives from false positives.

**Primary aim**

Our aim is to compare the sensitivity of standard FAST examination with the sensitivity of FASTeR examination in detecting hemoperitoneum.

**Secondary aims**

Positive FASTeR examinations will be compared to computed tomography (CT) imaging or operative findings to differentiate true positives from false positives.

**Inclusion Criteria**

All trauma patients who present as a Trauma Activation with clinical history or physical signs of blunt abdominal trauma and hemodynamic instability.
Exclusion Criteria

- Patients under 18 years of age
- Pregnant females
- Prisoners
- Patients with prohibitive right sided chest trauma
- Patients in extremis undergoing salvage maneuvers (chest compressions or emergent surgical intervention) which prevents performance of an ultrasound examination
- Patients who leave against medical advice or are otherwise removed from the medical system before their work up has been completed

Therapeutic Interventions

This is a prospective observational study only. Patients will be managed according to the acting surgeon's discretion.

Primary Outcome

The primary endpoint will be the number of patients who had a positive FASTeR examination after a negative standard FAST examination.

Secondary Outcomes

The secondary endpoint will be significant injuries identified via CT imaging or intraoperative findings after positive FASTeR.

List specific variables to be collected & analyzed

Data that will be collected include age, gender, initial Trauma Bay vital signs, medical record number, mechanism of injury, results of FAST examination, results of FASTeR examination, and injury complex as confirmed by CT imaging or intraoperative findings. Both the CT scan and any surgical intervention that the participant undergoes as a study subject will be performed through routine standard of care procedures. All data will be de-identified prior to publication.

Hemodynamically unstable patients with clinical history or physical signs suspicious for blunt abdominal trauma will undergo standard FAST examination in the emergency department as per ATLS protocol. During the secondary survey, all patients are rolled for examination of their back and removal of the rigid spine board, per ATLS. In our study, we will standardize this practice so that all patients are rolled onto their right side for this portion of the examination. Patients with extensive right sided chest trauma will be excluded at the discretion of the Trauma physician. After right-sided roll, a repeat ultrasound examination of the right upper quadrant will be performed.

We anticipate a rolling accrualment of patients over a two year period. A sample size calculation was performed to estimate the needed total participant accrualment to provide a power of 90% and an alpha of <0.05. Standard FAST examination should identify up to 60% of patients with significant intraabdominal injury. If we assume that FASTeR will identify hemoperitoneum in 1 of 4 patients with intraabdominal injury and previous negative FAST examination, then our needed sample size is 209 participants. To account for patients meeting exclusion criteria, we will plan to accrue 250 patients. Given that this sample size calculation was based on estimation regarding the sensitivity of FASTeR in this patient population, interim analyses regarding primary endpoint will be conducted after 100 participants have been accrued and again after 200 participants have been accrued. Patient charts will be reviewed in increments of 10 patients as they are enrolled.
This a prospective observational study, which will prospectively record data without altering the manner in which the patients is managed by the surgeon and institution. Accordingly, an informed consent waiver is requested. All data will be recorded on a data sheet and transferred to a secured database without patient identifiers.

There are no expected medical risks to the study participants in excess of the normal risks of FAST examination, which is minimal. Early identification of hemoperitoneum has been shown to be strongly correlated with increased survival rates. If this study allows small volumes of hemoperitoneum to be identified at an earlier time than was previously possible, patients may benefit from earlier diagnosis and treatment.

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6. Pigneri DA, Granet PJ. Can we be FASTeR? FAST examination after rolling to the Right dramatically increases sensitivity.