The utility of focused abdominal ultrasound in blunt abdominal trauma: a reappraisal

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Abstract

Background: Focused assessment with sonography for trauma (FAST) has become commonplace in the management of blunt abdominal trauma. However, newer computed tomography (CT) scanners have decreased imaging time for trauma patients and provide more detailed examination of abdominal contents. It was the aim of the current study to evaluate practice patterns of FAST and abdominal CT in blunt trauma victims.

Methods: This was a retrospective study of all blunt trauma patients (N = 299) who received at least 1 FAST examination in the emergency department by surgeons and were admitted. Patients were tracked for subsequent CT scanning, disposition from the emergency department, any operative findings, and survival.

Results: Twenty-one of 299 patients (7%) had a positive FAST. There were 7 deaths and 14 patients were taken directly to the operating room (OR) for control of abdominal bleeding. Thirty-one of 299 (10%) had equivocal FAST. There were 4 deaths and 8 patients were taken to the OR for control of abdominal bleeding. A total of 247 of the 299 patients had a negative FAST. CT scans were performed in 193: 15 showed a visceral injury. There were 13 deaths and 29 patients were taken to the OR (4 for bleeding). Patients with a positive FAST had a higher mortality than FAST-negative patients (P < .001) and greater likelihood for operation (P < .001). Those with equivocal FAST had a greater likelihood for operation than FAST-negative patients (P < .05).

Conclusions: FAST examinations can identify patients at risk for hemorrhage and in whom operation may be needed and, therefore, can guide mobilization of hospital resources. FAST-negative patients can be managed expectantly, using more specific imaging techniques. © 2007 Excerpta Medica Inc. All rights reserved.

Keywords: Blunt abdominal trauma; Trauma; Diagnostic ultrasound

Focused assessment with sonography for trauma (FAST) was popularized in the United States by Rozycki et al [1] in the early 1990s. Initial and follow-up experience indicated that FAST was accurate, non-invasive, and expeditious in assessing the critically injured patient in the emergency department (ED). The procedure could be performed by surgeons as well as radiologists with equal reliability [2–4] and was particularly useful in detecting blood in the abdominal cavity. As a result, FAST has largely supplanted diagnostic peritoneal lavage (DPL) in evaluating the trauma abdomen. Of late, the introduction of rapid sequence helical computed tomography (CT) has added a new dimension to the evaluation of trauma patients and has enabled surgeons to quickly assess the blunt trauma abdomen (in addition to head, spine, and chest) in more detail than can be obtained using FAST [5–7]. In fact, some investigators [8] have shown that there are no clinical parameters, including FAST, that can reliably exclude intra-abdominal injuries without performing CT, particularly in obtunded patients. Others [9] have demonstrated a low sensitivity to FAST and discordance between FAST and CT scans and have urged that FAST not be used alone to rule out intra-abdominal injuries. Importantly, in some, if not many EDs, CT scanners have been placed in close proximity so that trauma patients can be rapidly transported for CT examination and this imaging modality incorporated in the early secondary evaluation of injured patients, even to the point of near-routine “pan-scanning” [7].
How useful, then, is FAST? As CT scanners become faster and more accessible, what role does FAST play in the initial evaluation of trauma patients? Through a retrospective analysis, we sought to examine the utility of FAST performed by surgeons during the primary survey in victims of blunt trauma in an era of expanding use of CT scanning. When there is invaluable definition with contrast-enhanced abdominal CT scan, does the rather gross assessment of the abdominal cavity by ultrasound still contribute to patient care or is it a diagnostic modality whose time has come and gone?

Materials and Methods

All cases of blunt trauma admitted to the Memorial Medical Center in Johnstown, PA over a 5-year period between 2000 and 2005 and who received a FAST examination in the ED on at least 1 occasion were reviewed. Information was obtained from the trauma registry, and only those patients were included in the study whose FAST results were clearly documented. The Memorial Medical Center Level I, or Regional Resource Trauma Center, is a Pennsylvania Trauma Systems Foundation verified trauma center serving a multicounty rural area in west central Pennsylvania. All patients were brought to a trauma resuscitation area where a team of healthcare providers conducted a primary survey, necessary resuscitation, and secondary survey in a standardized, methodical fashion. The FAST examination was performed during the primary survey, after an airway and adequate oxygenation/ventilation were established. Each patient for whom the trauma team was activated received a FAST examination. The FAST examinations were performed using 4 windows: subxiphoid, right upper quadrant, left upper quadrant, and suprapubic. The critical areas for intra-abdominal bleeding were the hepatorenal space (Morrison’s pouch), the spleno-renal space, and the pelvic pouch of Douglas. The Sonosite 180Plus (Sonosite, Inc, Bothell, WA) with a 4-2 MHz transducer and Mediflat 15-color LCD monitor (Richardson Electronics, Ltd, Lafo, IL), kept in the trauma resuscitation area, was used for these examinations. The addition of a Mediflat color LCD monitor enhanced the ability to visualize intra-abdominal structures. General surgery residents performed the FAST examinations with attending surgeon supervision. There was no immediate radiology input or interpretation. The FAST examinations were classified as positive (clearly showing fluid on at least one view), equivocal (no critical views seen), or negative (good visualization in at least three windows, no fluid seen). No quantitative scoring system was used for the amount of fluid detected. The primary aim of the FAST examination was to detect intra-abdominal blood. Secondarily, the aim of FAST was to detect pericardial fluid/blood. There was no attempt to determine visceral organ injury. For purposes of analysis, the initial FAST examination was used even though, in a minority of cases, more than one FAST might have been done. ED deaths were not excluded as long as they received a FAST examination.

The FAST examinations were performed by general surgery residents with an attending trauma surgeon present. The FAST examinations were interpreted on the spot and results recorded by the trauma nurse recorder and eventually entered into the trauma registry. The FAST examinations were performed in real time. There was no “second read” nor could radiologists provide a follow-up report.

CT scans of the head, chest, abdomen, and pelvis were performed when indicated, usually if the clinical examination was equivocal or unreliable, and if the patient remained hemodynamically stable. A General Electric 4-slice Light-speed Plus scanner (General Electric Company, Piscataway, NJ) was used. Intravenous contrast only was used in chest, abdomen, and pelvis CT scans. The helical CT scanners were located adjacent to the ED on the same level. Patients were grouped into FAST-positive, FAST-equivocal, and FAST-negative. As a separate group unstable patients, defined as admitted to the ED hypotensive (systolic blood pressure <90 mm Hg), were analyzed. Disposition of the patients from the ED was then tracked. Need for emergency operation or any operation was recorded, and operative findings were noted.

Outcome measures consisted of live/die status. Where appropriate, chi-square analysis was performed with significance determined at P < .05. In this retrospective review, all patient identifiers were removed for purposes of analysis in compliance with the Health Insurance Portability and Accountability Act of 1996.

Results

Over a 5-year period between 2000 and 2005, a total of 5,294 patients were admitted to the trauma service. Initially, 324 patients were identified who had a FAST in the ED and whose results had been recorded in the trauma registry. Patients who had a FAST performed but the results had not been recorded were excluded (as all examinations were performed in real time, there was no ability to review the results). The study group, then, consisted of 299 patients who received at least 1 FAST examination in the ED with documented findings.

Of this group, 21 (7%) had a positive FAST indicating fluid (blood) in the peritoneal cavity (Fig. 1). Fourteen were taken to the operating room (OR), 10 without any further imaging studies, 4 receiving a CT scan before they were taken to the OR. Time to the OR for the 10 patients receiving only a FAST was 36 ± 13 minutes. The CT scans in the 4 patients who received them were all abnormal, showing obvious peritoneal hemorrhage. Ten of the 14 patients had more than 1 intra-abdominal or retroperitoneal injury (mean 2.6 injuries per patient). Seven of the 14 patients died, 6 in the OR, of exsanguination or irreversible shock (including 1 patient who received a CT scan at an outside hospital before going to the OR). Of the remaining 7 patients with a positive FAST, all received a CT scan. Five were admitted to the intensive care unit (ICU). In 4 of these 5 patients, the CT scan was abnormal (splenic injury in each). All were managed nonoperatively. Two were admitted to the surgical ward. All of these patients survived.

Thirty-one patients (10%) had an equivocal FAST. Of the 4 patients in this group who received only a FAST, all were taken to the OR (45 ± 18 minutes), and 3 died in the OR (exsanguination). The remaining 27 patients received a CT scan. Five were then taken to the OR, all of whom had evidence of splenic injury. All survived. Four other patients...
were later taken to the OR for orthopedic (n = 3) or neurosurgical (n = 1) procedures. Ten patients were admitted to the ICU (1 death from cardiopulmonary arrest) and 8 were admitted to the surgical ward. All admitted to the ward survived. Of those patients receiving a CT scan, 8 were found to have fluid and/or visceral injury (liver, spleen).

The FAST was interpreted as negative in 247 patients. In this group 92 patients had only a FAST. There were 6 deaths among these patients. Three individuals suffered a cardiopulmonary arrest in the ED on or shortly after arrival, 1 patient died of progressive hypotension in the OR of pelvic bleeding despite packing of the pelvis, and 2 patients died after hospital admission of traumatic brain injury. Fifteen patients were taken to the OR: 11 for orthopedic or maxillofacial procedures, 1 for intra-abdominal bleeding, 1 for repair of the brachial artery, 1 for release of a scrotal hematoma, and 1 for craniotomy. One hundred fifty-five patients had a negative FAST and then underwent CT scanning. In 50 patients the CT scan was interpreted as abnormal. Of this group of 50 patients, there were 8 patients with evidence of bleeding on CT scan not seen on FAST and a total of 13 patients (8%) with identified visceral injuries (spleen 8, liver 3, mesentery 1, kidney 1) not detected by FAST. Ten patients were taken to the OR: 2 for control of intra-abdominal bleeding, 6 for repair of orthopedic injuries, and 2 for craniotomy. There were 6 deaths in this group, all from traumatic brain injury. The remaining 105 patients had a CT scan interpreted as negative. Of this group 18 were eventually taken to the OR for neurosurgical or orthopedic procedures. There was 1 death in this group, which occurred from rapid exsanguination from a disrupted thoracic aorta. Collectively, in the FAST-negative and CT group (N = 155), only 1 patient died of hemorrhage, and that from a torn thoracic aorta.

Thirteen patients were admitted to the ED hypotensive (systolic blood pressure <90 mm Hg) (Fig. 2). Five patients had a positive FAST, 1 had an equivocal examination, and 7 patients had a negative FAST. Eight patients went to the OR, 5 having a positive FAST, 1 with an equivocal FAST, and 2 with a negative FAST. Six also underwent CT scanning, including 1 patient with a positive FAST. All CT scans were abnormal. Of the 5 patients not going to the OR, 2 died in the ED and 3 were admitted to the ICU. There were 5 other deaths in this group of 13 patients (total 7, 54%), all from hemorrhagic shock, including 4 patients with a positive FAST.

Intergroup comparison demonstrates that patients with a positive FAST had a significantly higher mortality compared to FAST-negative patients (7/21 vs 13/247, P < .001) and a greater likelihood of the need for immediate operation (14/21 vs 4/247, P < .001). Similarly, patients with an equivocal FAST had a significantly greater likelihood for immediate operation compared to FAST-negative patients (9/31 vs 4/247, P < .05). Of patients undergoing CT the mean time from arrival in the ED to CT was 41 ± 52 minutes. Of the 186 patients who underwent CT scanning after a FAST, there were 3 deaths: 1 from cardiopulmonary arrest in the OR, 1 in the ICU (not apparently hemorrhagic), and 1 from a torn thoracic aorta.

**Comments**

The use of FAST in victims of blunt trauma in this retrospective review has identified those at risk for life-threatening hemorrhage. Patients who had a positive FAST on presentation to the ED more likely than not required emergency surgery, and 1 in 3 eventually died, from hemorrhage or its consequences. These patients were statistically more likely to die and to need immediate operation compared to FAST-negative patients. While most had only a FAST, CT scanning in the 4 patients who received one did not add anything but only confirmed intra-abdominal bleeding, and they would likely have been better served going straightaway to the OR, as an average time for CT scanning of head, chest, and abdomen at our institution, even with the helical scanner, is approximately 20 minutes. In those going straight to the OR, transport was expeditious, averaging less than 40 minutes. An additional delay for CT scanning could have resulted in irreversible bleeding. Even more ominous was the presence of hypotension on arrival to the ED. For this group of 13 patients, 5 with a positive FAST were taken to the OR, and 4 of these patients died of uncontrollable hemorrhage. Three of the remaining patients, with equivocal or negative FAST, were taken to the OR, 1 of whom died of irreversible shock.

Conversely, those patients with a negative FAST in the ED fared better. Of those receiving only a FAST (n = 92),
and who were salvageable (n = 89), only 1 patient (1%) died of irreversible shock from pelvic bleeding, a situation that might not be detected by FAST. All other operative procedures in this subgroup pertained to extra-truncal injuries. Similarly, of the 155 patients receiving a CT scan after their negative FAST, there were 8 patients with bleeding not seen on FAST. Three of these patients (2%) required a celiotomy for control of hemorrhage, and 1 died as a result. The false negative rate, then, in this group of 247 patients would be 8/247, or 3%. We would submit that, while a negative FAST is a reliable indicator of the absence of significant bleeding, it is not foolproof. A negative FAST also should not be used as a qualitative assessment of intra-abdominal organ injury. CT scanning seems much better suited. Of those patients with a negative FAST, subsequent CT scanning disclosed that a number (8%) had visceral injuries.

Those patients who had an equivocal FAST—that is, the critical areas not well visualized—were a worrisome group. There were 31 such patients (10%). Nine of the 31 patients (29%) required a celiotomy for intra-abdominal bleeding, either immediately (n = 4) or within a few days. In a prospective study of FAST in blunt abdominal trauma, Boulanger et al [10] found that 6.7% of examinations were indeterminate when performed by “clinical sonographers.” A number of these patients, 21%, required celiotomy. Four of these patients eventually died, 3 from hemorrhage. There is no reassurance that an equivocal FAST means no significant bleeding. In fact, in our experience, this group was statistically more likely to need exploration than FAST-negative patients. These patients should be triaged on clinical examination and behavior in the ED, apart from FAST. The Eastern Association for the Surgery of Trauma practice management guidelines for blunt trauma[11] suggest using DPL in such cases: “DPL may also be used as a complementary examination in the hemodynamically stable patient in the presence of equivocal or negative ultrasound findings with strong clinical suspicion of visceral injury.”

The advantage of FAST in our experience was the ease and rapidity with which it could be employed. Surgeon-performed FAST, using an accessible, portable unit could be incorporated into the primary survey, in the first several minutes of the patient’s arrival, while other trauma team members are carrying out simultaneous diagnostic and therapeutic maneuvers. In our hands, surgeon-performed FAST was used only to detect free fluid (blood) in the abdominal cavity and not to assess the degree of solid organ injury, as used by Rozycki et al [12]. We would support the findings of Rose et al [13], who found that fluid seen in the right upper quadrant by FAST resulted in a high probability (73% in their experience, 67% in ours) of subsequent therapeutic celiotomy.

Our findings with clearly positive or clearly negative FAST are in agreement with results published from the University of California–San Diego [14,15], which stressed the likelihood of intra-abdominal surgical injury with a positive FAST and the unlikely presence of surgical injury with a negative FAST. While we concur that some negative FAST patients (in our series, 8%) will have visceral injuries detected by CT or later clinical course, we are not using FAST as a diagnostic tool for organ injury. Miller et al [9] emphasized the low sensitivity of FAST for hemoperito-

neum, in their experience, and the discordance between FAST and CT scans for organ injury. We fully recognize that FAST-negative patients may and should have follow-up CT if otherwise indicated. There were a small, but not insignificant, number of patients in our study who had unrecognized solid and hollow visceral injuries detected by CT. Nor are we using FAST in a selective fashion to decide on further therapeutic options, an approach advocated by Ollerton et al [16]. We now use FAST routinely for blunt abdominal trauma, as a part of the primary survey. Therapeutic decisions are then made based on all clinical information available. In this regard, FAST can be instrumental in the first decision point for trauma patients: to transport immediately to the OR or to allow for further diagnostic testing (Fig. 3).

Importantly, FAST need not be confined to the initial decision point. An advantage of FAST is that it can be used repeatedly to assess the blunt trauma abdomen and could be instrumental at any of the 3 decision points. Nevertheless, a negative FAST and a negative, reliable clinical evaluation could avoid the need for CT scanning, an approach suggested by Branney et al [2]. However, others [17] have noted the unreliability of examination alone to exclude intra-abdominal injury. In fact, routine CT scans (“pan scans”) on hemodynamically stable patients in whom a reliable examination is possible disclosed 42 of 550 patients (7.1%) with clinically significant abdominal injuries, and 6 of these individuals underwent celiotomy on the basis of CT scan alone [17]. Similarly, Pal and Victorino [5] reported that CT scanning in hemodynamically stable but obtunded blunt trauma victims identified 85 of 1,388 patients (6%) with hollow viscus injuries at an accuracy of 99.4%.

CT scanning is also becoming more expeditious. Many, if not most, CT scanners are located in close proximity to the ED and are readily accessible for trauma patients. Scan times have decreased with the introduction of the helical scanners. As a result, patients at our institution can, on average, undergo initial evaluation in the ED and have a multi-region CT scan performed in about an hour. Yet, while the patient is monitored throughout and easily reachable for interventions, the CT scanner is still far from the ideal place to resuscitate an unstable patient. Only those
who are stable and have no evidence of intra-abdominal bleeding (ie, a negative FAST) should follow this pathway.

Our study suffers from the exclusion of many of our blunt trauma patients. While the FAST examination has become part of our primary survey, done during other diagnostic and therapeutic maneuvers, results were not routinely recorded in the trauma registry. Unless we could determine the results of the initial FAST, patients were not included. All examinations had been performed in real time, so there was no opportunity to review scans retrospectively. In particular, results of FAST for unstable (hypotensive) patients might have been more meaningful if the sample size were larger. Nevertheless, it is inescapable that the use of FAST can guide initial therapy. All 5 hypotensive patients who had a positive FAST required immediate operation for critical hemorrhagic injuries.

In conclusion, we have found FAST a useful adjunct to the initial evaluation of blunt trauma patients. Those with a positive FAST are at risk for critical abdominal bleeding and are likely to need celiotomy soon. Resources can then be mobilized appropriately and patient care hopefully expedited. Therefore, FAST is helpful in the early decision point whether the patient needs immediate operation to control bleeding. Those with a negative FAST are not at substantial risk for bleeding and can be evaluated in a less urgent fashion. A distinct minority of patients cannot be assessed by FAST, and, in those situations, other clinical parameters must be followed to guide treatment. Additionally, when performed by surgeons, as in our experience, FAST should only be used as a screening tool for bleeding and should not supplant CT scans as a definitive imaging test for intra-abdominal injury.

References

Discussion
C. Clay Cothren, M.D. (Denver, CO): The results of this 5-year review are perhaps not surprising: Those with positive FAST (focused abdominal sonography for trauma) examinations, ie, evidence of intra-abdominal hemorrhage on bedside ultrasound in the trauma bay, were more likely to undergo abdominal surgery for sustained injuries. Several points in this article remind the clinician why a FAST examination is considered an excellent diagnostic adjunct. Although computed tomography (CT) scanners may be in close proximity and readily available (eg, in Dr. Wilson’s trauma center, the average time to CT scanning was 40 minutes), the scanner often is not close enough. Ultrasound can be performed within minutes of arrival and is therefore excellent for triage of the injured patient, particularly in busy trauma centers where one must prioritize the order in which some trauma patients go to the scanner, as was expertly illustrated. Moreover, several patients with equivocal ultrasound results died from hemorrhagic shock. This reminds the clinician that ultrasound is neither foolproof nor a substitute for experienced clinical judgment. Diagnostic peritoneal lavage or aspiration should remain in the surgeon’s diagnostic armamentarium.

I have several questions for the investigators:
1. First, regarding the logistics of the ultrasound itself, could you more precisely define what constitutes an equivocal FAST examination finding? Do you repeat the ultrasound examination, particularly in those patients with an equivocal initial examination? We often find that hypotensive patients do not manifest a positive examination until they are resuscitated enough to actually bleed from their internal injuries.
2. Second, according to the article, <5% of all patients evaluated at your level I trauma center were included in your study population. Do all patients undergo FAST examination in your emergency department? Do you believe that there was a selection bias with inclusion of only a small percentage of your overall trauma population? Perhaps a larger inclusion sample would alter your somewhat alarming 30% mortality rate.
3. Finally, I would be curious to know if patient hemodynamics were included in your overall prediction model and how this would affect your conclusions. I think we all recognize that a positive FAST examination heightens the urgency of clinical evaluation, but it is a positive FAST examination, in addition to hemodynamic instability, that determines the need for immediate decision making in the trauma bay. Also, did you stratify your patients with positive, equivocal, and negative FAST examinations by hemodynamics? Did all patients with a positive FAST examination undergo therapeutic laparotomy?

**Steve Smith, M.D.** (Wichita, KS): I have questions regarding the education and training of the surgeons who performed the FAST examinations. How many of the surgeons in your study went through the American College of Surgeons-sponsored ultrasound courses, either the basic module, the advanced module, or the new resident course that has become available? Second, I was also concerned by the small volume of FAST examinations performed during a 5-year period: only 299. That is, on average, only 60 exams/y, which I assume were performed by several different surgeons. Was this volume adequate to train or maintain expertise in performance of the FAST examination? Ultrasound is notoriously user dependent. Third, some of our European or Asian colleagues have followed a protocol in which they tried to quantify the amount of blood present based on FAST examination findings. Did you make any effort to do that?

**Fred Moore, M.D.** (Houston, TX): I want to comment on one of your indications on FAST examination. Most people would not argue with the fact that FAST examination is valuable in the unstable patient. However, you showed us a very small percentage of patients who were actually hypotensive. Could you provide us with a definition of instability? Four patients had a positive FAST examination, then underwent CT scan, and finally ended up going to the operating room. What happened to those patients?

**Ronald Stewart, M.D.** (San Antonio, TX): Most people do not quibble with the fact that if the FAST examination is positive, it is helpful; however, they might quibble with your conclusions. I think you said that if the FAST examination is negative, the patient is not at risk for bleeding. However, looking at your data, I would say 30% of those with negative FAST had positive CT scan findings. It looked to me like 43 of those patients went to the operating room, and 2 had definite hemorrhage. It seems to me that if the FAST examination was negative per your interpretation, it did not mean the patient was not at risk for bleeding. My second question is this: What were your sensitivity and specificity as well as your positive and negative predictive values?

**Tom Helling, M.D.** (Johnstown, PA): Dr. Cothren, the equivocal FAST was a FAST examination during which critical angles could not be seen. Therefore, there was no positive identification of blood or fluid in the abdomen. Usually, this could be the result of a number of things; for example, the presence of air often will obscure adequate visualization. All patients who underwent FAST examination were trauma-team activations. The reason there were relatively few patients in our study is because, until recently, the results of FAST examination were not routinely recorded in the trauma database and therefore could not be accurately identified in our retrospective review. Therefore, this is a subset of a much larger group of patients who underwent FAST examination and may reflect some selection bias, but it was not through intention. With regard to the hemodynamic status of our patients, FAST examination was only one diagnostic modality used in trauma patients. Clearly, other clinical parameters were taken into account, and overall patient management was a reflection of our clinical assessment. Not all patients who had a positive FAST examination underwent laparotomy, at least not in this series, but it is a worrisome finding, and most patients will need surgery. It is certainly something that is useful in mobilizing hospital resources for the treatment of these critically injured patients.

Dr. Smith, our residents do not have any formal training in ultrasound. Each resident performs ultrasound with an attending surgeon. All surgeons covering the trauma service are Critical Care Board certified and have some experience in performing ultrasound examinations. The attending surgeon is always in attendance when FAST examination is performed. However, I think that formal education is something we certainly should consider on an ongoing basis for our new residents. We did not quantify the volume of blood; it was simply a matter of blood being present or absent.

Dr. Moore, a FAST examination is routinely performed in all trauma-team activations in the first few minutes after the patient’s arrival by surgical residents while other members of the team are performing other treatment or diagnostic maneuvers. Four patients underwent CT scan and then were taken to the operating room. However, one of those patients had undergone CT scan at an outside hospital before coming to us. This was the only patient who died in that group of four. It is hard to tell whether not having done that CT scan would have brought the patient to us more quickly and whether that patient’s life could have been saved. The other three patients who underwent scan after positive FAST examination survived.

Dr. Stewart, the statement that patients with negative FAST findings are not at risk for bleeding is inaccurate. It is more correct to say that they do not seem to be at risk for immediate hemorrhage that would produce life-threatening issues. Certainly many of these patients were at risk for bleeding with solid-organ injury. Many were managed nonoperatively; some, as you might recall, were taken to the operating room after their CAT scan. We do not have any information, I am sorry, on the sensitivity and specificity of patients in our study; I apologize for that.