Randomized Controlled Clinical Trial of Point-of-Care, Limited Ultrasonography for Trauma in the Emergency Department: The First Sonography Outcomes Assessment Program Trial

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Study objective: Annually, 38 million people are evaluated for trauma, the leading cause of death in persons younger than 45 years. The primary objective is to assess whether using a protocol inclusive of point-of-care, limited ultrasonography (PLUS), compared to usual care (control), among patients presenting to the emergency department (ED) with suspected torso trauma decreased time to operative care.

Methods: The study was a randomized controlled clinical trial conducted during a 6-month period at 2 Level I trauma centers. The intervention was PLUS conducted by verified clinician sonographers. The primary outcome measure was time from ED arrival to transfer to operative care; secondary outcomes included computed tomography (CT) use, length of stay, complications, and charges. Regression models controlled for confounders and analyzed physician-to-physician variability. All analyses were conducted on an intention-to-treat basis. Results are presented as mean, first-quartile, median, and third-quartile, with multiplicative change and 95% confidence intervals (CIs), or percentage with odds ratio and 95% CIs.

Results: Four hundred forty-four patients with suspected torso trauma were eligible; 136 patients lacked consent, and attending physicians refused enrollment of 46 patients. Two hundred sixty-two patients were enrolled: 135 PLUS patients and 127 controls. There were no important differences between groups. Time to operative care was 64% (48, 76) less for PLUS compared to control patients. PLUS patients underwent fewer CTs (odds ratio 0.16) (0.07, 0.32), spent 27% (1, 46) fewer days in hospital, and had fewer complications (odds ratio 0.16) (0.07, 0.32), and charges were 35% (19, 48) less compared to control.

Conclusion: A PLUS-inclusive protocol significantly decreased time to operative care in patients with suspected torso trauma, with improved resource use and lower charges. [Ann Emerg Med. 2006;48: 227-235.]

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INTRODUCTION

Background

Annually, more than 38 million people are evaluated in emergency departments (EDs) for trauma, the leading cause of death in persons younger than 45 years.[1] The annual incidence of torso trauma is more than 5 million, resulting in more than 500,000 operations and 50,000 deaths.[1,2] Trauma deaths result, on average, in 40 years of life lost and 18 years of productive life lost.[3] Total societal costs for trauma are estimated at more than $100 billion annually in the United States alone.[4]

The term "golden hour" is commonly used to characterize the urgent need for the care of trauma patients.[5] The golden hour paradigm states that morbidity and mortality are affected if care is delayed beyond the first hour after injury. That earlier

Editor's Capsule Summary

What is already known on this topic

The literature suggests that focused assessment with sonography for trauma (FAST) examination is sensitive for the presence of free peritoneal and pleural fluid and that nonradiologists can perform the examination quickly and accurately at the bedside. There is considerably less information about whether FAST improves patient outcomes.

What question this study addressed

This 2-center, prospective, randomized trial examined how FAST affected door-to-operative-care time in 217 patients for whom there was a concern of torso trauma. Secondary outcome measures included use of computed tomography (CT).

What this study adds to our knowledge

The authors found that patients randomized to FAST had a 64% shorter time to operative care and had fewer CT examinations of the torso (odds ratio 0.16).

How this might change clinical practice

This study provides evidence that FAST may speed operative care and reduce the use of studies dependent on ionizing radiation.

definitive care should be associated with better outcomes is intuitive and is the basis of the modern regional trauma center approach applied in many parts of the country.[6–9] Defining mechanisms to decrease time to provision of definitive care in this population must be a high priority.

Point-of-care, limited ultrasonography (PLUS) examinations are brief and limited studies intended to rapidly answer highly focused clinical questions, ie, is there occult fluid in the peritoneal, pericardial, or pleural cavity? PLUS examinations are distinct from comprehensive ultrasonographic examinations provided by radiology departments in terms of availability, format, and indication.[10]

Published studies suggest that the accuracy of PLUS for trauma in answering highly focused clinical questions is at least 95%.[11–15] This accuracy is comparable to that obtained by radiologists.[16] In addition, the results of 2 international consensus conferences strongly recommend the use of PLUS for trauma.[17,18] Unfortunately, although the questions of accuracy, rapidity, and safety of PLUS may be discussed with great confidence, evidence-based data demonstrating improvement in therapeutic and clinical outcomes for trauma victims are lacking.[19] PLUS for trauma, used as a rapid screening tool, has the potential to reduce time to diagnosis and definitive care.[15,20]

There are approximately 4,700 EDs in the United States, with approximately 10% having PLUS capability; the number of centers with PLUS availability is increasing.[1,10] The proper introduction of PLUS (equipment and training) to an ED costs approximately $100,000 initially, followed by $20,000 per year to maintain a high-quality resource.[21] Therefore, instituting nationwide universal access to PLUS would cost approximately a billion health care dollars during 5 years.

The Sonography Outcomes Assessment Program (SOAP) is a multiphase health services research project designed to assess the effects of PLUS on patient outcomes in the emergency evaluation of common, costly, and potentially lethal clinical conditions. Toward this end, to generate hypotheses and estimate sample size for the prospective phase of this project, a pilot study was conducted using the National Trauma Data Bank of the American College of Surgeons,[2] retrospectively assessing patients with torso trauma requiring operative intervention. The analysis compared time to operation, length of stay, and hospital charges in patients evaluated with early ultrasonography and patients not so evaluated.[22]

At analysis, the National Trauma Data Bank contained 316,975 incident reports on trauma patients, including 45,365 patients with torso trauma. Thirty-five percent of these patients underwent operative care with a mean "door to operative care" time of 55 minutes (48 minutes median, 27.2 minutes SD) in patients evaluated with early ultrasonography (<2 hours from presentation) and 92 minutes (80 minutes median, 72.4 minutes SD) in patients not undergoing early ultrasonographic examination ($P<.005$), which represented a 40% reduction in median door-to-operative-care time. The analysis yielded a mean reduction in charges of $18,456, with a median difference of $10,875. These differences were maintained in linear regression models controlling for injury severity and specific diagnoses. The length-of-stay analysis revealed a 3.5-day mean, 2.2-day median reduction in hospitalization length, which was not significant in the regression models.

These data facilitated the development of the SOAP-1 study, a randomized, controlled clinical trial to assess the effects of PLUS on the time to definitive care of patients with suspected torso trauma presenting to the EDs of 2 Level I trauma centers. Secondarily, diagnostic test use, length of stay, complication rates, and hospital charges were assessed to draw inferences about clinical and societal effectiveness and lay the groundwork for hypothesis-generating of future research, including a formal cost-effectiveness analysis.

MATERIALS AND METHODS

Study Design

The study was a randomized, concealed, and controlled clinical trial. Patients enrolled were randomized to the PLUS (study) or control arms in blocks of 50 and stratified by center. Enrolled patients were randomized using a standard computer randomization program. The data sheets were coded and sealed in opaque envelopes. After screening, consenting, and enrollment, the subjects' data collection envelopes were opened, revealing group assignment. Neither the treating physicians nor the patients were blinded to the intervention.

Institutional review board approval was obtained at the coordinating center, Maricopa Hospital, and Jackson Memorial Hospital. These Level I trauma centers were chosen in part because one is supervised solely by trauma surgeons, whereas the other is supervised by emergency physicians and trauma surgeons, representative of the 2 common trauma center formats.

Selection of Participants

All adult and pediatric blunt and penetrating trauma patients, presenting to the EDs of Maricopa Hospital and Jackson Memorial Hospital throughout a 6-month period, whom the treating physician(s) suspected of having trauma to the torso were screened for eligibility for the study. Patients presenting with any one of a mechanism of injury (energy reportedly delivered to the torso), symptomatology (complaint of chest, abdominal, or pelvic pain), or physical findings (chest, abdominal, or pelvic tenderness) were suspected of having torso trauma and, therefore, eligible for enrollment and maintained in the analyses regardless of final diagnoses.

Patients or patient proxies who were unable to provide consent and those requiring immediate transfer to the operating suite were excluded.

Before activation of each study center, the center's PLUS director trained sonographers using a curriculum consistent with that published by the American College of Emergency Physicians[23] and credentialed or documented the proficiency of each sonographer for PLUS for trauma scanning technique. Then, the SOAP-1 Trial Steering Committee verified participating sonographers by reviewing 5 PLUS for trauma scans for technical adequacy, interpretative accuracy, and interrater reliability.

The physicians supervising the initial evaluation and resuscitation of the study population were either emergency medicine or trauma surgery attending physicians or fellows. All admitted patients were under the care of the trauma surgeons. Initial evaluating and admitting physicians, if different, were recorded.

All study subjects underwent any diagnostic intervention that the initial evaluating physician, under ordinary circumstances, would use to evaluate torso trauma patients. Study-arm patients also received PLUS, whereas the control-arm patients did not undergo PLUS.

Interventions

The PLUS-arm patients were evaluated with the focused assessment with sonography for trauma (FAST) scanning technique, a 4-view assessment of the heart (pericardial sac), right upper quadrant (Morrison's pouch and right hemithorax), left upper quadrant (splenorenal recess, left subdiaphragm, and left hemithorax), and pelvis (pouch of Douglas, or cul-de-sac) administered in the ED during the initial evaluation and resuscitation phase. FAST has been extensively described in the literature.[11–21]

The primary objective of this randomized controlled clinical trial was to determine whether PLUS among patients presenting to the ED with suspected torso trauma and not requiring immediate transfer to the operating suite would affect the time from ED arrival to direct transfer to operative care. The secondary objectives were to assess the effect of PLUS on use of computed tomography (CT) in the ED, hospital length of stay, composite complications rate, and charges for care.

Data Collection and Processing

The physician performing the initial evaluation and the admitting physician, if different, time of day, day of week, patient demographics, initial vital signs, trauma scores,[24] and time from ED arrival to direct transfer to operative care were recorded in the ED record. PLUS results were recorded on the data sheets, which were not included in the ED record. Tests done, time to disposition, and transfer from the ED were abstracted from the ED record by research assistants blinded to study group assignment.

Also recorded were all *International Classification of Diseases (ICD)* codes,[25] *Current Procedure Terminology (CPT)* codes,[26] lengths of stay, and charges based on abstraction of the medical record and the hospital billing records 1 to 2 months postevent by research assistants blinded to study group assignment. Data were secondarily uploaded to a predesigned, confidential, and secure database.[27]

Outcome Measures

Primary outcome was time from ED arrival to direct transfer to operative care in minutes. Secondary outcomes were use of CT of the torso, hospital length of stay in days, composite complications (rate of hemorrhagic shock, septic shock, multisystem organ failure, or death) based on *CPT* or *ICD* codes found in the medical record, and total charges in 2003 US dollars, derived from the hospital billing department.

Primary Data Analysis

Assuming a 35% operative care rate and using a primary outcome variable of time from ED arrival to transfer to operative care, a sample size of 246 patients (yielding 86 operative cases) was projected to detect a 40% reduction with a power of 90%, and an α set at 0.05. The rate and reduction in time were derived from the aforementioned pilot study from the National Trauma Data Bank.[22]

The data analyses were performed on an intention-to-treat basis. All patients initially suspected to have torso trauma and completing the study were included in the analyses and maintained in original group assignment, regardless of final diagnoses. All operative care cases were included in the subgroups analyses, regardless of final diagnoses. All analyses were conducted using R software (R Development, Vienna, Austria).[28]

Differences between continuous outcomes (time to operative care, length of stay, and billed charges) were

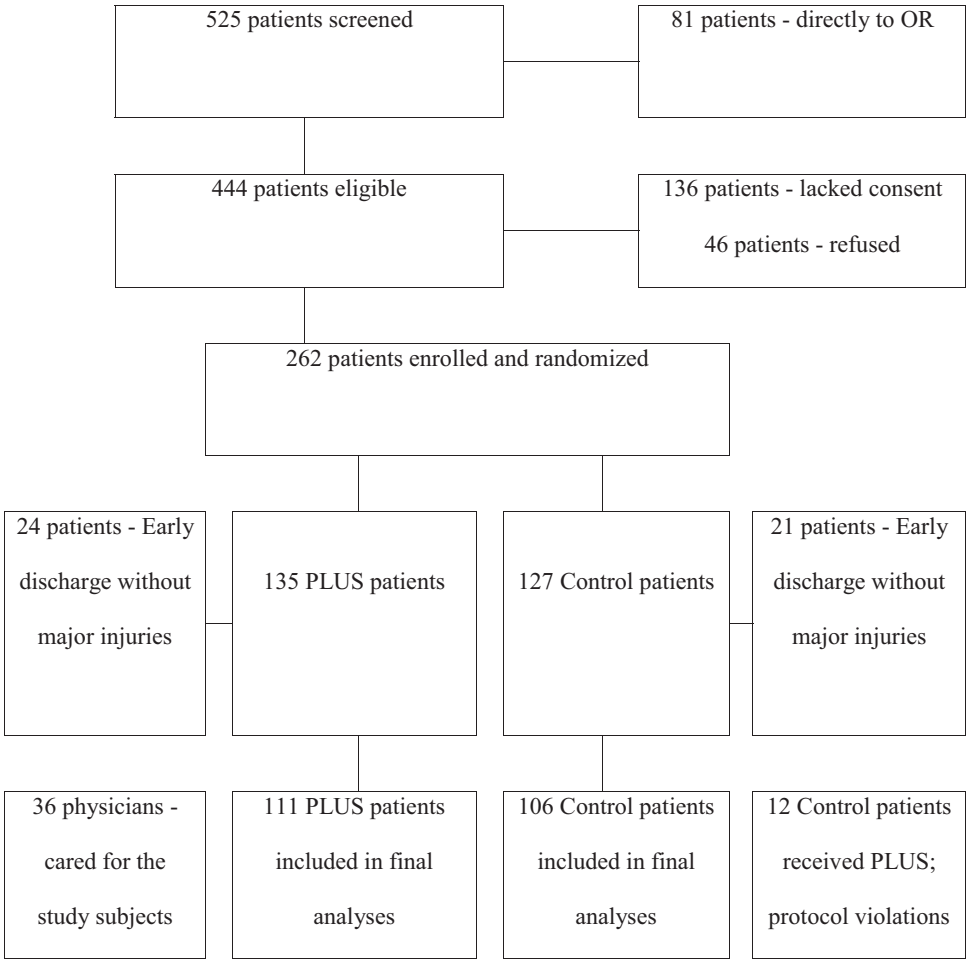

Figure 1. CONSORT participant flow diagram.

initially assessed using a *t* test after logarithmic transformation to control for significant inhomogeneity of variance and rightward skew of the data. Linear regression models were conducted on the transformed data, with assessment of multiplicative changes and their confidence intervals (CIs) associated with PLUS.

Differences in dichotomous outcomes, eg, CT use, were assessed using χ^2 analyses, followed by logistic regression models. These results are presented as percentage with odds ratio and 95% CIs.

All regression models allowed for control of the possible influence of confounders, which included age, initial vital signs, trauma scores, institution, and specific *ICD-9* and *CPT-4* coded diagnoses.

To control for the possibility of physician-to-physician practice variability and the difference in practices between the 2 sites, mixed-effects regression models were investigated; these allowed for estimation of the main effects while controlling for extra variability. Specifically, mixed-effect models were used, controlling for the aforementioned variables, with a random intercept allowed for each model to control for possible physician-to-physician variability.[29]

RESULTS

Characteristics of Study Subjects

Five hundred twenty-five patients were screened on arrival to the 2 EDs during the 6-month trial period in 2002 to 2003 (Figure 1). Four hundred forty-four (85%) patients met eligibility criteria. Eighty-one (18%) patients went directly to the operating suite, mostly (93%) because of penetrating wounds. One hundred eighty-two (41%) patients were not enrolled, because of lack of consent (136) or attending physician's refusal to randomize (46). Two hundred sixty-two patients were enrolled and randomized: 135 PLUS patients and 127 control patients.

Two hundred seventeen (83%) patients—111 PLUS and 106 control patients—completed the trial and were included in the final analyses. Forty-five patients, all without major injuries, who left the ED within a few hours were excluded. One hundred seventy-four of the 217 (80%) patients were admitted,

Table 1. Patient characteristics: comparing PLUS and control groups (mean with [first quartile, median, third quartile] or percentage with 95% CIs).

Characteristic	PLUS (N=111)	Control (N=106)
Age, y	27 [19, 22, 31]	27 [19, 22, 29]
Sex, %, female	35	31
Ethnicity, % (determined by investigators)		
Black	13	22
White	32	26
Hispanic	43	38
Time since injury, min	76 [30, 46, 60]	59 [34, 45, 70]
Revised trauma score (0–7.8)	7.4 [6.7, 7.5, 7.8]	7.2 [6.8, 7.5, 7.8]
Injury Severity Score (0–75)	15 [8, 12, 22]	15 [9, 13, 20]
Torso trauma, %*	55±8	56±8
Abdominal trauma, %*	33±4	33±7
Cardiac trauma, %*	1±4	2±4
Thoracic trauma, %*	21±9	21±8
Operation-requiring patients (%)	26±8	32±9
Admitted patients (%)	83±7	78±8

*Specific *ICD-9* and *CPT-4* codes used in all regression models.

63 of 217 (29%) patients underwent operative care, and 9 patients died, suggesting a moderate- to high-acuity population. Of the excluded patients, 154 (85%) were admitted, and 63 (35%) patients went to operative care. Twelve control patients received PLUS in violation of protocol, but were maintained in the control group in the intention-to-treat analysis.

Thirty-six physicians provided care to the study subjects either as initial evaluators or admitting physicians: 24 at Maricopa Hospital (15 emergency physicians and 9 trauma surgeons) and 12 physicians (all trauma surgeons) at Jackson Memorial Hospital.

The baseline demographics, time since injury, trauma scores, rates and types of torso injuries, and operative and admission requirements of the study groups are presented in Table 1. No group-to-group variability was appreciated in analyses of comparing demographics, baseline clinical characteristics, trauma scores, time of day, day of the week, and specific *ICD-9* or *CPT-4* coded diagnoses.

Study-arm patients received PLUS evaluation, on average, 18 minutes after arrival. Ninety-seven of 111 (87%) patients had adequate scans (29 positive and 68 negative), whereas 13% were indeterminate scans.

Sixty-three of 217 (29%) patients went to operative care. Fifty-seven patients had blunt trauma, and 6 patients had penetrating injuries. There were no nontherapeutic operations in the study population. No bluntly traumatized patient with a negative PLUS result went to operative care. The time from ED arrival to transfer to operative care was on average 57 minutes (median 60, IQR [interquartile range] 41, 70) for PLUS patients and 166 minutes (median 157, IQR 90, 78) for control patients. Patients requiring operative care and undergoing PLUS were transferred to operative care in 64% less time than control patients needing operative care. These data and baseline characteristics of operative care patients are shown in Table 2.

This result was derived from initially examining a mixed-effect linear regression model to control for possible physician-to-physician variability. This variability was slight, but the original model was maintained for all analyses. For each outcome, we controlled for institution, age, vital signs, trauma scores, and specific *ICD-9* and *CPT-4* coded diagnoses.

Twelve control patients received a PLUS scan in violation of the study protocol; they were maintained in the control group in all analyses. Only 1 of these patients had a positive PLUS result and went to operative care in 22 minutes. The other 11 patients had negative PLUS results, all had negative CT results, and none required operative care.

A total of 145 of 217 (67%) patients had a CT done in an average time of 75 minutes. PLUS patients had an odds ratio of 0.16 (95% CI 0.07 to 0.32) compared to control patients to undergo CT (Table 3), assessed with a logistic regression model controlling for the variables listed above. Whether the patient eventually went to operative care was also considered in this and in all subsequent models. PLUS operative care patients compared with control operative care patients in terms of CT use yielded an odds ratio of 0.07 (0.01, 0.29).

This difference in CT use was especially striking among the patients with a positive PLUS result, in which only a quarter underwent subsequent CT. In the patients with negative PLUS scan results, two thirds went to CT.

Among patients admitted, PLUS patients spent on average 6.2 days (median 4.0, IQR 1.0, 8.0 days) in the hospital, and control patients, on average, spent 10.2 days (median 5.0, IQR 2.0, 12.0 days). The regression model after logarithmic transformation indicated a 27% reduction in length of stay (Table 3).

PLUS operative care patients did spend 10.7 days, on average, in the hospital (median 8.0, IQR 4.0, 22.0 days), and control operative care patients spent 15.1 days (median 12.0, IQR 5.0, 23.6 days), though this difference was not important after controlling for these other variables. Further, for the patients who went to operative care, there was no difference in length of stay between PLUS and control patients in this small subgroup analysis.

Composite complications rate was lower in the PLUS group: PLUS patients had an odds ratio of 0.27 (95% CI 0.11 to 0.67) compared to control patients. Sex was a particularly important factor in differences in the rate of complications. Male patients had an odds ratio of 0.38 (0.16, 0.93) compared to female patients, and operative intervention increased the composite complications rate, odds ratio 3.1 (1.2, 8.1), compared to patients not going to operative care.

Further, for just patients who went to operative care, complications were less for PLUS patients, who had a complication rate odds ratio of 0.17 (0.02, 0.86) compared to controls. This model also found sex to be important in

Table 2. Baseline characteristics and time from ED arrival to operative care comparing PLUS and control groups.*

OR Patients Only	PLUS (N=29)†	Control (N=34)
Age, y	23 [20, 21, 22]	22 [18, 22, 24]
Sex, female, %	26	29
Revised trauma score (0–7.8)	6.8 [6.7, 7.5, 7.8]	6.7 [6.6, 7.5, 7.8]
Injury Severity Score (0–75)	22 [17, 22, 29]	21 [15, 18, 26]
Glasgow Coma Scale score (0–15)	12 [10, 14, 15]	12 [10, 13, 15]
Torso trauma (%)	86±9	84±9
Time from ED arrival to OR transfer, min	57 [41, 60, 70]	166 [90, 157, 178]

OR, Operative care.
*Mean with [first quartile, median, third quartile] or percentage with 95% CIs.
†Multiplicative changes with 95% CI of time from ED arrival to OR transfer associated with PLUS, 0.36 (0.24, 0.52).

Table 3. Secondary outcome variables: comparing PLUS and control groups (mean [first quartile, median, third quartile] with multiplicative change and [95% CI]) or (percentage with odds ratio and [95% CI]).

Subgroups	PLUS	Control	Multiplicative Changes or Odds Ratios With 95% CIs Associated With PLUS
All patients	(N=111)	(N=106)	
CT done (%)	53 [44, 62]	85 [76, 92]	Odds ratio=0.16 [0.07, 0.31]
Total charges, $	16,100 [5,700, 10,600, 19,000]	31,500 [6,700, 16,400, 43,600]	Multiplicative change=0.65 [0.52, 0.81]
Admitted patients only	(N=92)	(N=83)	
Hosp-LOS, days	6.2 [1.0, 4.0, 8.0]	10.2 [2.0, 5.0, 12.0]	Multiplicative change=0.73 [0.54, 0.99]
OR patients only	(N=29)	(N=34)	
CT done (%)	25 [10,47]	78 [56, 93]	Odds ratio=0.07 [0.01, 0.29]
Hosp-LOS, days	10.7 [4.0, 8.0, 22]	15.1 [5.0, 12.0, 23.6]	Multiplicative change=0.40 [0.16, 1.00]
Composite complications, %*	21 [11, 27]	38 [28, 46]	Odds ratio=0.17 [0.02, 0.86]
Total charges, $	28,400 [15,100, 22,600, 37,100]	47,600 [29,500, 43,800, 55,700]	Multiplicative change=0.90 [0.54, 1.48]

Hosp-LOS, Hospital length-of-stay.
*Composite complications rate is rate of hemorrhagic shock, septic shock, multisystem organ failure, or death.

controlling for complication rate: men had an odds ratio of 0.06 (0.01, 0.28) relative to women for having a complication.

Among all study patients, total charges were lower for PLUS patients: PLUS patients were charged, on average, $16,100 (median $10,600, IQR $5,700, $19,000) compared to control patients, who averaged $31,500 (median $16,400, IQR $6,700, $49,600). Those with higher Revised Trauma Scores were charged on average less ($5,400 less for every increase in Revised Trauma Scores score by 1); those with higher Injury Severity Scores were charged on average more ($1,200 more for every increase in Injury Severity Scores by 1); men were charged on average $8,000 less, and patients who had longer time since injury had charges that were more on average ($36/minute since injury). The multiplicative change in billed charges associated with PLUS indicated a 35% (19, 48) reduction (Table 3).

PLUS operative care patients had charges that were, on average, $28,400 (median $22,600, IQR $15,100, $37,100), and control operative care patients averaged $47,600 (median $43,800, IQR $29,500, $55,700). After controlling for these other variables, whether the patient went to operative care was not important in explaining total cost in this small subgroup analysis (Table 3).

LIMITATIONS

There were numerous limitations to our trial. First, the physicians treating the study subjects were not blinded to group assignment; they were required to integrate PLUS findings into the clinical decisionmaking process, which may have introduced a bias toward more rapid provision of care in the intervention group.

Second, 41% of eligible patients were not enrolled in the trial, because of lack of consent or attending refusal. The limited data available from the respective institutional trauma registries showed an 85% admission rate and 35% operative requirement rate in the excluded patients, both slightly higher than the study population's, suggesting a slightly more acute population.

Third, there was a 17% dropout rate after enrollment, but all these patients left from the ED without major injuries, suggesting imprecise screening for suspected torso trauma. This

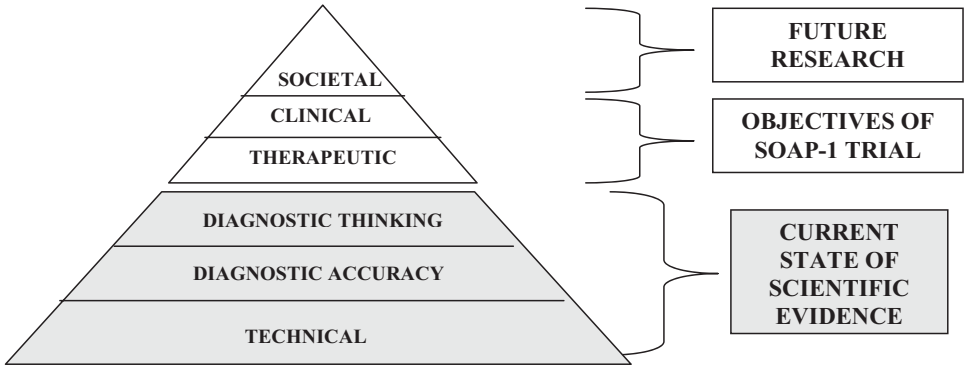

Figure 2. Fryback-Pearl hierarchic model of test effectiveness assessment applied to PLUS for trauma.

is further evidenced by the fact that only 55% of our study population had torso trauma among their final diagnoses despite our initial suspicions based on the history, symptomatology, and physical examination findings.

Fourth, other than time of day and day of week, we did not control for institutional issues, such as operative care availability, in our analysis of time from ED arrival to transfer to operative care. Additionally, unmeasured confounders may influence lengths of stay, complications, and charges. These other factors may or may not have been balanced in the study groups.

Furthermore, our basic premise that earlier definitive care should be associated with better outcomes is intuitive and not yet proven. Our investigation did not include serial observations of markers for hypoperfusion or the accumulation of oxygen debt, such as lactate levels or base deficit calculations, without which a causal linkage between early definitive care and improved outcomes remains unproven. The golden hour paradigm and understanding the recursive relationship between early provision of definitive care and better clinical outcomes requires further study.

Finally, despite the growing reliance on interventional radiology around the country, few patients in our study received definitive care from these less invasive interventions. Therefore, we are unable to draw any inferences about the ability of PLUS to facilitate the "conversion" from operative to interventional radiologic care.

DISCUSSION

The purpose of this randomized controlled clinical trial was to assess the effect of PLUS for trauma on time from ED arrival to transfer to definitive care for patients suspected of having torso trauma. We found that PLUS resulted in a clinically relevant reduction in time to definitive care for patients with torso trauma.

Additionally, PLUS-evaluated patients underwent less CT, spent fewer days in the hospital, had fewer complications, and had substantially lower total charges for care. These data, derived from a moderate- to high-acuity population at 2 Level I trauma centers with varied personnel and clientele, support the expansion of PLUS capabilities to all Level I trauma centers. The data analyses controlled for interinstitutional and physician-to-physician practice variability using mixed-effect regression models.

The theoretical basis of this trial was the "golden hour" paradigm of trauma care, the foundation for the nation's system of designated regionalized trauma centers.[6–9] However intuitive this concept, evidence-based data supporting it are sparse. Lerner and Moscati[30] conducted an extensive literature search in 2001 for the scientific basis for the golden hour concept and found no objective data from prospective trials to support it.

It has been posited that early definitive care results in earlier correction of hypoperfusion and decreased oxygen debt.[31–33] The cumulative effects, a potential cascade of benefits, are more efficient resource use, better outcomes, and, consequently, shorter lengths of stay and lower charges.

Of interest, the reductions in length of stay, complication, and charges in the PLUS-evaluated patients occurred in all patients, both operatively treated and nonoperatively treated groups, which was not anticipated, and its explanation is unclear. There may have been a benefit of "clearance" of operative care-requiring torso trauma, which facilitated other types of care, ie, neurosurgery, in a subset of patients, leading to shorter lengths of stay, fewer complications, and reduced charges.

Pearl[34] used an emergency medicine perspective to elaborate on a logical hierarchic model of effectiveness assessment for diagnostic tests, first described by Fryback[35] and Fryback and Thornbury.[36] The SOAP was designed to assess the effect of PLUS, using the Fryback-Pearl hierarchic model for assessment of diagnostic test effectiveness (Figure 2).

The first 3 echelons of assessment are technical, diagnostic accuracy, and diagnostic thinking effectiveness. These levels of effectiveness assessment about PLUS for trauma are well represented in the literature.[11–21] The highest strata of Pearl's assessment hierarchy are therapeutic, clinical, and societal effectiveness. Therapeutic effectiveness, the thrust of the current trial, involves assessing whether the test leads to improved

treatment, ie, better therapy or more rapid provision of an established therapy. The use of time to delivery of definitive therapy as an adjunct marker is consistent with other time-sensitive treatments such as thrombolytics for acute myocardial infarction. Clinical effectiveness concerns whether the test improves patient outcomes, ie, reduces morbidity. Finally, societal effectiveness pertains to whether the test can positively influence outcomes at the population level, ie, enhancement of quality of life and overall societal cost-effectiveness.

The secondary outcomes analyses presented here will be used to generate strategies for future research to assess the outcomes at the apex of the hierarchic pyramid. For example, these trial data demonstrated a reduction in charges and morbidity, as measured by the composite complications rate. If the per-patient cost of the introduction and use of PLUS is less than the charge reduction found in the pilot study and this prospective trial and if patients derive clinical benefit from PLUS, as suggested by the morbidity reduction, the resulting cost-effectiveness analysis should be positive. A formal economic analysis using items charges and department-specific ratios of cost to charge will be conducted.

In summary, PLUS for trauma reduced time to operative care and was associated with decreased diagnostic test use, hospital length of stay, composite complications rate, and total charges. With universal PLUS availability, trauma patients in Level I trauma centers should receive definitive care more rapidly. Therefore, the benefits of PLUS may be multidimensional and include better ED and hospital resource utilization, decreased morbidity, and cost-effectiveness.

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Author contributions: LAM, WMB, and CAM conceived the study and designed the trial. LAM and CAM supervised the conduct of the trial and data collection. EL, MGM, and PL undertook recruitment of participating centers and patients and managed the data, including quality control. WMB provided statistical advice on study design and analyzed the data. LAM drafted the manuscript, and all authors contributed substantially to its revision. LAM takes responsibility for the paper as a whole.

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