Randomized, controlled trial of immediate versus delayed goal-directed ultrasound to identify the cause of nontraumatic hypotension in emergency department patients*

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Objective: We examined a physician-performed, goal-directed ultrasound protocol for the emergency department management of nontraumatic, symptomatic, undifferentiated hypotension.

Design: Randomized, controlled trial of immediate vs. delayed ultrasound.

Setting: Urban, tertiary emergency department, census >100,000.

Patients: Nontrauma emergency department patients, aged >17 yrs, and initial emergency department vital signs consistent with shock (systolic blood pressure <100 mm Hg or shock index >1.0), and agreement of two independent observers for at least one sign and symptom of inadequate tissue perfusion.

Interventions: Group 1 (immediate ultrasound) received standard care plus goal-directed ultrasound at time 0. Group 2 (delayed ultrasound) received standard care for 15 mins and goal-directed ultrasound with standard care between 15 and 30 mins after time 0.

Measurements and Main Results: Outcomes included the number of viable physician diagnoses at 15 mins and the rank of their likelihood of occurrence at both 15 and 30 mins. One hundred eighty-four patients were included. Group 1 (n = 88) had a smaller median number of viable diagnoses at 15 mins (median = 4) than did group 2 (n = 96, median = 9, Mann-Whitney U test, *p* < .0001). Physicians indicated the correct final diagnosis as most likely among their viable diagnosis list at 15 mins in 80% (95% confidence interval, 70–87%) of group 1 subjects vs. 50% (95% confidence interval, 40–60%) in group 2, difference of 30% (95% confidence interval, 16–42%).

Conclusions: Incorporation of a goal-directed ultrasound protocol in the evaluation of nontraumatic, symptomatic, undifferentiated hypotension in adult patients results in fewer viable diagnostic etiologies and a more accurate physician impression of final diagnosis. (Crit Care Med 2004; 32:1703–1708)

KEY WORDS: hypotension; shock; ultrasound; diagnosis; mortality; clinical trial

Prior research has suggested that emergency department (ED) patients with symptomatic hypotension in the absence of trauma have a high mortality rate. Jones et al. (1) found that symptomatic patients with a systolic blood pressure <100 mm Hg measured during ambulance transport had an in-hospital mortality rate of 25%. Moore et al. (2) found an 18% in-hospital mortality rate in 50 consecutive ED patients presenting with nontraumatic, symptomatic hypotension. In the latter study, emergency physicians accurately determined final

etiology of hypotension in only 24% of patients (2).

Ultrasound has emerged as a useful diagnostic tool for a variety of emergent situations, and both its availability and incorporation into emergency medicine practice are increasing (3). The diagnostic utility of ultrasound in patients with nontraumatic, undifferentiated hypotension has not been systematically evaluated. The hypothesis of the present study was that the results of an emergency physician performed, goal-directed ultrasound protocol would significantly narrow the number of potential viable diagnoses of patients with nontraumatic, symptomatic, undifferentiated hypotension and would significantly improve physician accuracy in identifying the correct diagnosis of nontraumatic, symptomatic, undifferentiated hypotension.

MATERIALS AND METHODS

Patients were enrolled from July 2002 through September 2003 in the ED at Carolinas Medical Center, an urban 800-bed teaching hos-

pital with >100,000 patient visits per year. Explicit criteria for enrollment included the following: a) age >17 yrs; b) written agreement of two independent physician observers on the presence of the first measured vital signs consistent with shock (systolic blood pressure <100 mm Hg or shock index (pulse rate/systolic blood pressure) >1.0); and c) a minimum of both one sign and one symptom listed in Table 1, recorded by each observer independently and blinded to the other observers' observations. Exclusions included a) either observer found no symptom or sign in Table 1; b) history of "low blood pressure" reported by the patient or discovered from chart review; c) cardiopulmonary resuscitation, defibrillation, or advanced cardiac life support medications before enrollment; d) history of significant trauma to the chest or abdomen in the previous 24 hrs; e) a 12-lead electrocardiogram diagnostic of acute myocardial infarction; f) presence of an obvious cause of shock that would mandate immediate specific treatment (active gastrointestinal bleeding, known drug overdose, external hemorrhage); g) referral from another hospital with a known diagnosis; h) development of signs and symptoms of shock in the ED after the results of diagnostic testing (radiographic imaging and laboratory results) were known to the treating

physician; and i) any systolic blood pressure >120 mm Hg before enrollment for patients enrolled for a shock index of >1.0.

This study protocol was reviewed and approved by the institutional review board for the conduct of human research before enrollment of patients. Written informed consent was obtained from all patients. The protocol allowed consent to be delayed to avoid interference with resuscitation and clinical stabilization. For incompetent patients, informed consent was obtained at a time when the patient was deemed competent. If necessary, next of kin participated in the informed consent process as soon as possible.

The study design is summarized in Figure 1. Time 0 represents the moment of enrollment. Upon recognition of a potentially eligible patient, attending physicians or 3rd-yr emergency medicine residents obtained a numbered, sealed envelope that contained the randomization assignment, study inclusion/exclusion criteria, the informed consent form, data collection sheets, and a video cassette. Patients were randomized to either the immediate goal-directed ultrasound group (group 1) or the delayed goal-directed ultrasound group (group 2).

All patients immediately received standard emergent interventions including history and physical examination, intravenous access, supplemental oxygen, continuous cardiac monitoring, electrocardiography, anteroposterior chest radiography, and a point-of care venous whole blood assay that measured serum potassium, sodium, blood urea nitrogen, glucose, lactate, hemoglobin, pH, Po_2, Pco_2, and base deficit. Figure 1 shows that patients randomized to group 1 also received the diagnostic intervention, an emergency physician performed goal-directed ultrasound protocol, initiated at time 0. All ultrasound examinations were recorded in real time on individual VHS tapes. At 15 mins after time 0, the examining physician recorded the presence or absence of ultrasound findings using an explicit list (Table 2). Then, using a written list of 21 possible causes of hypotension (Table 3), clinicians crossed through excluded diagnoses and ranked the remaining viable diagnoses in order of likelihood of occurrence. After 15 additional minutes of standard care (30 mins after time 0), clinicians completed a second, revised rank list of differential diagnoses.

Figure 1 shows that patients randomized to group 2 received identical care as group 1 during the first 15 mins after time 0 but did not receive an immediate goal-directed ultrasound protocol. At 15 mins after time 0, the examining physicians completed their first rank list of possible diagnoses drawn from the list in Table 3. At 15–30 mins after time 0, an emergency physician performed the goal-directed ultrasound protocol, thereby "crossing-over" group 2 pa-

Table 1. Choices of symptoms and signs of shock provided to observers

| Potential Symptoms	Potential Signs
Unresponsive	Unresponsive
Syncope	Gasping respirations
Lightheadedness	Tachypnea
Fatigue	Use of accessory muscles of respiration
Thirst	Altered mental status
Dyspnea	Ashen skin color
Profound asthenia	Agitation
Unexplained severe anxiety	Delayed capillary refill > 3 secs
Sensation of impending doom	Cold distal extremities
	Incontinence of stool or urine
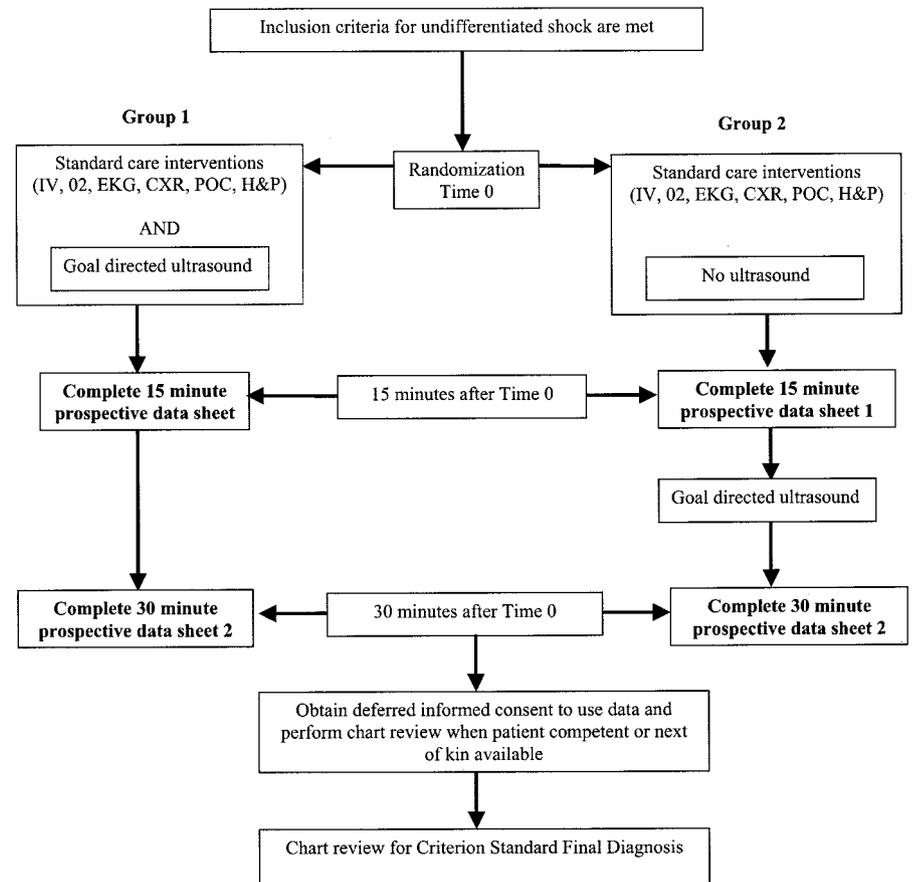
Figure 1. Flow diagram of the study design and randomization. *IV*, intravenous catheter; *EKG*, electrocardiogram; *CXR*, chest radiograph; *POC*, point of care laboratory testing; *H&P*, history and physical examination.

tients to receiving the diagnostic intervention. At 30 mins after time 0, the physician recorded the ultrasound findings and a second, revised rank list of differential diagnoses. The main purpose of this second rank list was to test the impact of the "crossing-over" on the physician's differential diagnosis list. A 90-element standardized history, physical examination, and clinical parameter data form was completed on all patients from both groups.

Technical Measurements. Arterial blood pressure was measured in all patients with an FDA-approved automated oscillometric monitoring device using stepped cuff deflation for

estimation of systolic and diastolic blood pressure (Dinamap 8100; Critikon, Tampa, FL). Initial blood pressure measurements were obtained either in the ED triage area or upon arrival into a resuscitation room in the high-acuity section of the ED.

All goal-directed ultrasound protocols were performed in B-mode gray scale using a Shimadzu SDU-400 ultrasound system with a 3.5-MHz (modal frequency range 2–4 MHz) tightly curvilinear array electronic transducer (Shimadzu Medical Systems, Torrance, CA). Goal-directed ultrasound examinations were performed by either a 3rd-yr emergency med-

Table 2. Explicit list of potential goal-directed ultrasound protocol findings

Ultrasound Finding Question	Answer Choices (Circle One)
Is intraperitoneal fluid present?	Yes or no
What is the LV function?	Hyperdynamic/normal/moderately impaired or severely impaired
What is the RV size?	Normal or dilated
Is a pericardial effusion present?	Yes or no
If yes, is tamponade physiology apparent?	Yes or no
Is an abdominal aortic aneurysm present?	Yes or no
If yes is there free intraperitoneal fluid present?	Yes or no
Is there evidence of IVC collapse?	Yes or no

LV, left ventricle; RV, right ventricle; IVC, inferior vena cava.

Table 3. List of potential diagnoses

Potential Diagnoses	
Left ventricular failure	Tension pneumothorax
Hemoperitoneum	Anaphylaxis
Severe dehydration	Neurogenic shock
Cardiac tamponade	Valvular dysfunction
Pulmonary embolus	Occult medication error or overdose
Sepsis	Ruptured aneurysm
Aortic dissection	Myocardial ischemia/infarction
Thyrotoxicosis	Adrenal failure
Dysrhythmia	Autonomic dysfunction
Occult gastrointestinal bleed	Mesenteric ischemia
Abdominal inflammation	

icine resident or a board-certified emergency medicine attending physician. The goal-directed ultrasound protocol consists of seven views of the torso, performed in a systematic and standardized order:

1. Subcostal view: The subcostal region of the abdomen was examined for anechoic collections within the pericardium suggesting tamponade, judged to be present by visual inspection for right ventricular diastolic collapse (4–5).

2. Inferior vena cava (IVC) view: The IVC was examined for diameter and visual estimation of collapsibility to estimate intravascular volume status. A >50% collapse of IVC with inspiration was considered abnormal suggesting low intravascular volume, and <50% collapse of IVC with inspiration was considered normal suggesting normal intravascular volume (6–7).

3. Parasternal long cardiac view: The left parasternal chest was examined for visual estimation of qualitative left ventricular function and pericardial effusion. Left ventricular function was judged by visual inspection of gross wall contraction and wall thickening during systole and diastole (2, 8).

4. Apical four-chamber cardiac view: The apex of the heart was examined in the transverse plane for visual estimation of relative ventricular size and qualitative function (2, 8).

5. Hepatorenal recess view: The space between the liver and right kidney was examined for anechoic collections in a sweeping motion using both in the coronal and transverse planes to survey for free intraperitoneal fluid (9, 10).

6. The pelvis and retrovesical area were examined in both the sagittal and transverse planes for the presence of anechoic fluid collections (9, 10).

7. Abdominal aorta view: The abdomen was examined in the transverse and sagittal planes for evidence of aneurysm of the proximal and distal aorta (any diameter >3 cm) (11, 12).

Competency of emergency physician ultrasonographers was demonstrated through multiple steps. Residents undergo a 1-month rotation as part of the residency curriculum during their postgraduate year 1, and they routinely perform various noncardiac ultrasound examinations throughout residency. Attending emergency physicians have hospital credentials through Carolinas Medical Center with a minimum of 100 noncardiac and 25 cardiac ultrasounds. If residents were performing the ultrasound protocol, they were always supervised by a credentialed attending physician. Before the start of this study, all participating resident and attending physicians were given an additional course (didactic and laboratory) teaching goal-directed echocardiography, which has been previously described (8).

The criterion standard final diagnosis was established using a predefined, structured method of chart review. Explicit criteria for each potential criterion standard final diagnosis were compiled from widely accepted published definitions or were adapted from specialty textbooks (a comprehensive list of the criterion standard final diagnoses and their definitions can be obtained through correspondence with the primary author). The explicit criteria were also reviewed by and represented a consensus of three board-certified emergency physicians with >5 yrs experience and one critical care specialist. Each patient chart was initially reviewed in a structured format for explicit criteria by the principle investigator (AEJ). If all explicit criteria for a diagnosis were present, and this diagnosis matched the final charted hospital diagnosis, this was the criterion standard final diagnosis. If explicit criteria for a diagnosis were not present, or if explicit criteria for a diagnosis were present and this diagnosis were not identical to the final charted hospital diagnosis, a second independent observer was required to review the chart. If the two observers agreed independently on a diagnosis, this was the criterion standard final diagnosis. If their reviews disagreed, a third independent observer reviewed the chart. If two of the three observers' reviews agreed, this was the criterion standard final diagnosis. If all three disagreed on the diagnosis, these cases were excluded from the analysis. During review of the hospital records, all observers were blinded to the ED records (unless the patient was discharged from the ED and these were the only hospital records available), the physician differential diagnosis rank list, and the goal-directed ultrasound protocol results.

Continuous data are presented as mean ± SD or proportions and 95% confidence intervals (CIs) computed from the Clopper-Pearson method (StatsDirect version 2.3.2). The median number of potential diagnoses in group 1 and the median number of potential diagnoses in group 2 at 15 mins were compared for significant difference with the Mann-Whitney U test. The percentage occurrence of the correct diagnosis generated from the physician viable differential diagnoses list (compared with the criterion standard final diagnosis) from group 1 vs. group 2 at both the 15- and 30-min time points was compared with 95% confidence intervals for the difference between the groups. For statistical hypothesis tests, $p < .05$ was considered significant. The sample size was estimated to detect a 20% improvement in accuracy of final diagnosis between the groups, at $\alpha = 0.05$ and $\beta = 0.20$, requiring enrollment of 90 patients per group. Anticipating an approximately 10% rate of exclusion, we planned a sample size of 200.

RESULTS

From July 2002 to September 2003, 202 patients were enrolled. Eighteen patients were subsequently excluded from analysis: Two refused informed consent, seven did not meet vital sign requirements, four did not have completed differential diagnosis data sheets, two did not have both signs and symptoms of circulatory insufficiency documented by two independent observers, one had no interpretable ultrasound images obtained, and two had no criterion standard final diagnosis. This resulted in a final study sample of 184 patients; 88 were randomized to group 1 (immediate ultrasound) and 96 were randomized to group 2 (delayed ultrasound). A total of 26 physicians enrolled subjects into the study protocol, with 11 of the physicians enrolling six or more subjects. The average time required to complete the ultrasound examination was 5.8 ± 2.1 mins. Table 4 summarizes the goal-directed ultrasound protocol findings for all patients and by final diagnostic category. Ultrasound findings do not necessarily equate to final diagnosis. For example, presence of a pericardial effusion did not necessarily mean that the final diagnosis was pericardial tamponade.

Demographics and clinical characteristics of study patients in both groups are shown in Table 5. The groups were well matched for age, race, gender, initial systolic blood pressure, pulse, and respiratory rate.

Figure 2 illustrates the difference in the median number of potential diagnoses in group 1 vs. the median number of potential diagnoses in group 2 at the 15-min time point. Group 1 had a median of four potential diagnoses vs. nine potential diagnoses in group 2 (median difference = 5; 95% CI, 4–6; Mann-Whitney U test, $p < .0001$). At the 30-min time point, group 1 still had a median of four potential diagnoses, whereas group 2 had a revised median of three potential diagnoses (Mann-Whitney U test, $p = .4463$). These data support the hypothesis that the goal-directed ultrasound protocol helps the physician shorten the list of potential causes of nontraumatic undifferentiated hypotension in ED patients.

For a shorter differential diagnosis list to improve care, it must include the true cause of hypotension. A correct diagnosis occurred when the physician's number one rank on the differential diagnosis list was the same as the criterion standard final diagnosis. At 15 mins, physicians indicated the correct diagnosis in 80% (95% CI, 70–87%) of group 1 patients vs. 50% (95% CI, 40–60%) of group 2 patients. The 30% difference of these proportions was significant (95% CI, 16–42%). These data indicate that physicians who had clinical information from both standard care plus the goal-directed ultrasound (group 1) were significantly more likely to indicate the correct final diagnosis as most likely on their differential diagnosis list compared with group 2 physicians. After group 2 patients were "crossed over" and had received the ultrasound protocol, the correct diagnosis rate increased to 78%.

Ninety-three percent of patients were admitted; 45% were admitted to the intensive care unit, 26% were admitted to a medical unit, 18% were admitted to a telemetry unit, and 4% died in the ED. The most common criterion standard diagnoses were septic shock (43%) followed by acute severe dehydration (28%). A complete list of the final diagnoses and their frequency of occurrence is shown in Table 6. The overall in-hospital mortality rate was 16% (29 of 184), and no significant difference in mortality rate was observed between group 1 (17%; 95% CI, 9–25%) vs. group 2 (15%; 95% CI, 9–23%). A search of both electronic hospital records and the Social Security Death Index was done for those patients who were discharged from the ED. This search identified one patient who was discharged from the ED and was dead within 30 days of enrollment. This patient had an established do-not-resuscitate order by her primary physician, and hemodialysis was being withheld due to poor prognosis.

DISCUSSION

This study tested the hypothesis that a goal-directed ultrasound protocol would help clinicians correctly identify the cause of nontraumatic symptomatic undifferentiated hypotension. The addition of the ultrasound protocol to standard care afforded physicians with the ability to compile a significantly shorter and more accurate list of possible causes of nontraumatic undifferentiated hypotension. This is the first study to demonstrate that a goal-directed ultrasound protocol can positively affect the differential diagnosis for an undifferentiated but life-threatening condition.

The ability to correctly assess the etiology of critical illness has been described as

Table 4. Ultrasound findings (percentages) recorded during the 30-min study period shown for all patients and by final diagnostic category

Goal-Directed Ultrasound Finding	All Patients (n = 184)	Infectious/Distributive (n = 141)	Cardiovascular (n = 28)	Toxicologic (n = 12)	Other (n = 3)
IVC collapse >50%	46	53	12	33	33
RV dilation	22	13	69	50	0
Pericardial effusion	17	9	54	33	0
Severe LV dysfunction	19	14	69	75	33
Free intraperitoneal fluid	15	13	27	0	0
Abdominal aortic aneurysm	4	1	2	0	33

IVC, inferior vena cava; LV, left ventricular; RV, right ventricle.

Table 5. Patient demographics and clinical characteristics

Randomization Group	Age, yrs	Race, %	Gender, %	SBP, mm Hg	Pulse, beats/min	RR, breaths/min
Group 1, n = 88 (immediate ultrasound)	55 ± 16.8	W 39, B 57	M 53, F 47	85 ± 13.0	104 ± 28.6	23 ± 7.4
Group 2, n = 96 (delayed ultrasound)	57 ± 15.9	W 49, B 47	M 57, F 43	85 ± 12.1	102 ± 29.5	24 ± 7.6

SBP, systolic blood pressure; RR, respiratory rate; W, white; B, black; M, male; F, female.

Incorporation of a goal-directed ultrasound protocol in the evaluation of nontraumatic, symptomatic, undifferentiated hypotension in adult patients results in fewer viable diagnostic etiologies and a more accurate physician impression of final diagnosis.

Table 6. Final diagnoses and their respective percentage occurrence

Infectious/distributive	77	Cardiovascular	15
Septic shock	43	Cardiomyopathy	9
Severe dehydration	28	Acute myocardial infarction	2
Occult gastrointestinal bleeding	3	Dysrhythmia	2
Hemoperitoneum	2	Pulmonary embolus	1
Adrenal insufficiency	1	Ruptured aortic aneurysm	1
Toxicologic	7	Other	1
β-blocker toxicity	3	Anaphylaxis	<1
Ca-channel blocker toxicity	2	Heat stroke	<1
Polypharmacy	2	Mesenteric ischemia	<1

Figure 2. Box-and-whisker plot of the median number of viable diagnosis. *A,* 15-min time point (median number was significantly lower in group 1 vs. group 2, Mann-Whitney U test, $p < .0001$). *B,* 30-min time point (no significant difference, $p = .4463$).

the essence of the discipline of emergency medicine (13, 14). We have observed in current clinical practice that the process of reducing the differential diagnosis in a patient with undifferentiated, nontraumatic hypotension is often disorganized, inefficient, and laborious. Our outcome data prove the need for a systematic and organized approach to diagnosing the cause of symptomatic, nontraumatic, undifferentiated hypotension. This is the third successive report in which we have found the in-hospital mortality rate of patients with nontraumatic, undifferentiated hypotension to equal or exceed the mortality rate of other high-profile disease presentations including acute myocardial infarction, pulmonary embolism, or penetrating chest trauma (1, 2, 15–17). Furthermore, the data in Table 6 show that majority of patients were found to have a criterion standard diagnosis that warranted specific, unique treatments. These observations reinforce the importance of developing a specific diagnostic algorithm to elucidate etiology in patients with undifferentiated hypotension. Stated another way, these data show a window of opportunity for physicians to provide more specific treatment for nontraumatic, undifferentiated hypotension than just infusion of crystalloid and monitoring of hemodynamic indexes.

We designed the goal-directed ultrasound protocol to rapidly include or exclude potentially reversible or treatable causes of nontraumatic, symptomatic, undifferentiated hypotension based on seven views of the torso. Each view was intended to provide an answer to a binary question: to include or exclude pericardial tamponade, left ventricular dysfunction, right ventricular dilation, intravascular volume depletion, intraperitoneal fluid, and aortic aneurysm. On average, this information was obtained within 6 mins. Access to this information allowed physicians to produce a rank list one half the length and 30% more accurate than clinicians who had access to only standard history and physical examination, laboratory, radiographic, and electrocardiographic information. The finding that the median number of diagnoses equalized between the groups at the 30-min time point when both standard care information and ultrasound results were known in both groups reinforces the assertion that the initial difference in median number of diagnoses seen between the groups at 15 mins was a direct result of the goal-directed ultrasound protocol.

As with any imaging study, the findings of the goal-directed ultrasound protocol were interpreted in the context of the clinical setting. This helps explain why abnormal findings on the goal-directed ultrasound examination sometimes did not equate to the final diagnosis. The data indicate that abnormal findings on the ultrasound examination often required further interpretation to determine whether the findings were significant. For example, 19% of patients had severe cardiac dysfunction, but the clinicians had to draw from other data to decide if this finding indicated a significant pathological process (e.g., myocardial ischemia or hypodynamic sepsis) or a process that was probably not a cause of hypotension (e.g., chronic heart failure in a dehydrated patient). Indeed, the data suggest that normal findings on ultrasound examination were often used by clinicians to objectively exclude potential causes of undifferentiated hypotension that are difficult to eliminate at the bedside (e.g., abdominal aortic aneurysm).

An important point that must be considered when incorporating technology such as ultrasonography into new applications (such as the evaluation of patients with nontraumatic, symptomatic, undifferentiated hypotension) is whether the information gained and used had any deleterious effects or result in any erroneous diagnoses. In this study of 184 patients, at the time point that the ultrasound results were first known to the treating physician (15-min time point for group 1 and 30-min time point for group 2), only two patients were deemed to have a final diagnosis that was not included on the initial physician differential diagnosis list. Both of the patients were in group 2. One of these patients was initially thought by the treating physician to most likely have septic shock yet had a final diagnosis of heat stroke. The ultrasound protocol in this patient had no positive findings, and the patient had a good clinical outcome. The second patient was initially thought to have suffered a pulmonary embolism with findings on the ul-
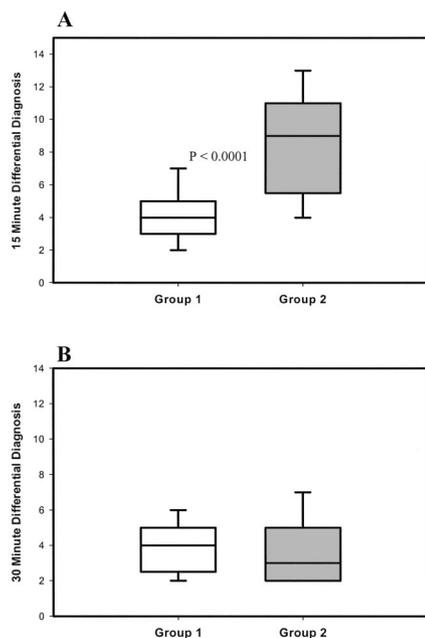
trasound protocol of right ventricular dilation and hypokinesis. Unfortunately, the patient had active metastatic cancer and was allowed to die without confirmatory diagnostic testing. She was deemed by independent observers to have a final diagnosis of septic shock, and no postmortem examination was performed. No other patients had a criterion standard final diagnosis excluded from the differential diagnosis list using the information gained from the goal-directed ultrasound protocol. No patient had an ultrasound finding that led to an unnecessary, invasive procedure such as pericardial aspiration, angiography, or surgical exploration.

The goal-directed ultrasound protocol used in this study requires knowledge of both cardiac and noncardiac emergency ultrasonography. Although some may argue that this requires specialty training, it is important to note that 26 physicians from our institution enrolled patients into this study and 11 of those physicians enrolled six or more patients. These results represent the potential for the generalizability of this goal-directed ultrasound protocol to settings outside of our institution.

The study design did not include a classic control group (i.e., a group that received no ultrasound protocol). From the standpoint of strength of study design, a control group would have been preferred with a hard end point such as mortality. Indeed, in the planning phase, we recognized the absence of published evidence to suggest the direction or magnitude of effect of an ultrasound protocol on the outcome of hypotensive patients. However, we had a duty to protect the study subjects from potential risk that could have resulted from randomization to a group where ultrasound was not employed. This concern was compounded by our anticipation that informed consent would usually be obtained after randomization occurred. Of relevance, our research group was previously criticized for obtaining informed consent before resuscitation in a noninterventional study of cardiac ultrasound performed on hypotensive ED patients (18). We believe that the present study design was the best option to test our hypothesis and maintain ethical and safe treatment of our patients.

Several aspects of this report warrant critical evaluation. First, this study did not measure the effect of incorporation of the goal-directed ultrasound protocol on any patient-oriented outcomes such as time to definitive treatment or in-hospital mortality. In our data collection, however, we did observe that only 60% of the patients enrolled in this study received therapies (other than intravenous fluids) that are generally accepted as treatments for serious diseases such as sepsis, myocardial infarction, pulmonary embolism, and cardiomyopathy. Second, both the number of median diagnoses and percentage of indication of the correct final diagnosis equalized at 30 mins in both groups (the time point that both groups had both ultrasound results and standard care). It remains possible that this equality was a result of time and not the information gained from the ultrasound. Third, it is possible that the difference in median number of viable diagnoses seen at 15 mins was biased by the enrolling physician to include more potential diagnoses in group 2 (the delayed ultrasound group). This is unlikely, however, given the fact that 26 physicians enrolled patients into the study and only the study investigators were familiar with the exact study hypotheses and planned data analysis. Last, resident physicians enrolled patients into this protocol. It remains possible that if the only physicians enrolling patients were more clinically experienced (i.e., board-certified attending physicians), this would have resulted in both fewer differential diagnoses and a more accurate final diagnosis.

CONCLUSIONS

This study presents data from a randomized, controlled trial of the use of an immediate vs. delayed goal-directed ultrasound protocol in the management of nontraumatic, symptomatic, hypotensive ED patients with uncertain etiology. Physicians caring for the patients who received immediate goal-directed ultrasound in addition to standard care vs. standard care alone reported significantly fewer viable diagnostic etiologies of illness and more accurately reported the correct final diagnosis as most likely among the potential diagnostic etiologies. Incorporating this goal-directed ultrasound protocol into the routine evaluation of patients with symptomatic, nontraumatic, undifferentiated hypotension has the potential to lead to more timely and more accurate diagnosis of these critically ill patients.

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