DEM Journal Club

Article Appraisal

Article: Does Point-of-Care Ultrasonography Improve Clinical Outcomes in Emergency Department Patients with Undifferentiated Hypotension? An International Randomized Controlled Trial from the SHoC-ED Investigators - Annals of Emergency Medicine, October 2018.

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Background and Study Objective(s):

It is appreciated that point-of-care ultrasonography (POCUS) improves clinical diagnostic accuracy in specific conditions. It assists in the rapid diagnosis of common conditions causing shock, including cardiac dysfunction, ruptured aortic aneurysm, and ruptured ectopic pregnancy. It has been assumed that it also informs and assists in initial management decisions in patients with undifferentiated shock. However, there is little evidence to date to support any patient-centered outcome benefits for the use of POCUS protocols with undifferentiated non-traumatic shock in the emergency department (ED).

The aim of this study was to assess the effect of a standardized POCUS protocol on clinical outcomes for selected patients presenting to the ED with undifferentiated hypotension.

Study Design:

The study was a randomized controlled trial of patients >19 years of age who presented to the ED with undifferentiated, nontraumatic hypotension or shock, defined as a sustained initial systolic blood pressure (sBP) < 100mmHg, or a shock index >1 with a sBP <120 mmHg. The study was conducted at three centers in North America and three centers in South Africa staffed by accredited emergency physicians with established mature POCUS programs. Exclusion criteria was extensive and included pregnancy, necessity of CPR or other advanced cardiac life support interventions, a history of trauma within 24 hours, acute MI diagnosed on ECG, patients with a clear mechanism or cause for their hypotension, transferred patients with a known diagnosis, an assumed simple vagal episode causing hypotension, and a low BP considered to be non-pathologic. Enrollment was done by convenience sampling. Patients were randomized to either the intervention group, where physicians performed their normal initial clinical assessment and then completed the required POCUS scans, or the control group, where patients received usual care without the use of POCUS.

The POCUS protocol used was clearly defined. It consisted of the four cardiac views to assess for pericardial fluid and ventricular function and size. Thoracic scans were performed on the sides of the chest to look for lung sliding and pleural effusions. FAST scan was used to examine for free fluid. The IVC was examined for size and collapsibility, and the aorta was examined for aneurysms.

Primary outcomes included survival to hospital discharge, or to 30 days if the patient remained in the hospital. Secondary outcomes included volume of IV fluid administered in the ED, rate of inotrope administration, rate of CT scanning, and hospital and ICU admission rates and lengths of stay. Results were presented in terms of differences in proportion or median between experimental and control, along with a binomial confidence interval for the observed differences.

Results:

From September 2012 to December 2016, 273 patients were enrolled, with 270 patients included in the final data analysis. Randomization was successful, with the ultrasound and control groups being adequately matched for baseline demographics and vital signs. There was no significant difference in primary outcome between ultrasonography and control groups, when the data was analyzed as a whole, or by continent. There was no significant difference between groups for any of the secondary outcomes measured.

Validity of Results:

A significant issue with this study is that 400 patients were needed to provide an 80% power to detect a reduction in mortality of 10%, assuming a mortality rate of 30% in the control group. This study only enrolled 270 patients and the mortality in the control group was less than 30%, making it impossible to determine if POCUS compared to standard care alone has no effect based on this study alone. The authors state that the slow rate of recruitment they experienced may have partly been due to concerns about randomization to the control arm from physicians (and thus limiting their access to POCUS). This acceptance of POCUS into clinical practice potentially limits the scope of this trial, and of any potential future comparative trials.

Generalizability of Results:

Exclusion criteria were extensive due to ethical concerns about randomizing certain patients to the control group, thus restricting their access to POCUS during their initial assessment. Unfortunately, this resulted in exclusion of patients from the study, such as pregnant patients and patients with suspicion of ruptured AAA, who were the most likely to show survival benefits from POCUS diagnostic assessment. The exclusion criteria also potentially skewed the distribution of diagnosis. Over 50% of patients enrolled were diagnosed with occult sepsis, a diagnosis that would not benefit much from the use of POCUS assessment, considering the myriad of non-specific findings. The results can therefore not be generalized to all patients presenting to the ED with undifferentiated hypotension or shock.

The Bottom Line:

This study was designed with good methodology, and asked an important clinical question about the use of POCUS in patients with shock, and was designed for patient oriented outcomes. However, validity of the results was limited by the study being small and underpowered, and the extensive exclusion criteria eliminated pregnant patients and patients with suspicion of ruptured AAA from the study who were the most likely to receive survival benefits from the use of POCUS. Based on this study alone, clinical practice should not be changed. There is good evidence to support the use of POCUS in the assessment of critically

ill patients in the ED, as it is known to assist in the rapid diagnosis of some specific conditions causing shock, many of which often require timely interventions. In summary, point-of-care ultrasonography, as performed in this well done randomized controlled trial to assess patient-oriented endpoints, failed to find benefit.