Does the Use of Point of Care Ultrasonography Improve Survival in Emergency Department Patients with Undifferentiated Hypotension? The first Sonography in Hypotension and Cardiac Arrest in the Emergency Department (SHOC-ED1) Study; 
An International Randomized Controlled Trial


Introduction
Point of care ultrasound (PoCUS) is an established tool in the initial management of patients with undifferentiated hypotension in the emergency department (ED). While PoCUS protocols have been shown to improve early diagnostic accuracy, there is little published evidence for any mortality benefit. We report the findings from our international multicenter randomized controlled trial, assessing the impact of a PoCUS protocol on survival and key clinical outcomes.

Methods
Recruitment occurred at 7 centres in North America (4) and South Africa (3). Scans were performed by PoCUS-trained physicians. Screening at triage identified patients (SBP<100 or shock index>1), randomized to PoCUS or control (standard care with no PoCUS) groups. Demographics, clinical details and study findings were collected prospectively. Initial and secondary diagnoses were recorded at 0 and 60 minutes, with ultrasound performed in the PoCUS group prior to secondary assessment. The primary outcome measure was 30-day/discharge survival. Secondary outcome measures included diagnostic accuracy, changes in vital signs, acid-base status, and length of stay. Categorical data was analyzed using Fishers test, and continuous data by Student T test and multi-level log-regression testing. (GraphPad/SPSS) Final chart review was blinded to initial impressions and PoCUS findings.

Results
265 patients were enrolled with follow-up fully completed. Baseline comparisons confirmed effective randomization. There was no difference between groups for the primary outcome of survival; PoCUS 101/134 (75.4%; 95% CI 67.4 to 81.9%) vs. Control 99/131 (75.6%; 95% CI 0.67.5 to 82.2%); RR 1.00 (95% CI 0.87 to 1.14; p=1.00). There were no differences in the secondary outcomes; ICU and total length of stay. Our sample size has a power of 0.80 (α:0.05) for a moderate effect size. Other secondary outcomes are reported separately.

Conclusion
This is the first RCT to compare PoCUS to standard care for undifferentiated hypotensive ED patients. We did not find any survival or length of stay benefits with the use of a PoCUS protocol, though a larger study is required to confirm these findings. While PoCUS may have diagnostic benefits, these may not translate into a survival benefit effect.