Critical Review Form
Therapy

Ferrada P, Evans D, Wolfe L, et al. Findings of a randomized controlled trial using limited transthoracic echocardiogram (LTTE) as a hemodynamic monitoring tool in the trauma bay. J Trauma Acute Care Surg. 2014 Jan;76(1):31-7; discussion 37-8.

Objectives: "To evaluate the impact of LTTE (limited transthoracic echocardiogram) image-guided resuscitation on patient outcome... during the initial phase of trauma resuscitation" (p. 32)

Methods: This prospective, open-label, randomized controlled trial was conducted at Virginia Commonwealth University Hospital from July 1 to December 31, 2012. Patients arriving in the trauma bay (TB) with a systolic blood pressure ≤ 100 mm Hg, a mean arterial pressure ≤ 60 mm Hg, or a pulse ≥ 120 bpm during the initial resuscitation or en route to the hospital were eligible for enrollment. Prisoners and pregnant women were excluded. Patients were randomized by calendar day to either have an LTTE performed (even days) or to not have LTTE performed (odd days).

All LTTEs were performed by trauma attending surgeons, emergency department attending surgeons, emergency medicine residents, or surgical residents, and results included contractility (good or poor), fluid status, and pericardial effusion (present or absent). Fluid status was assessed by assessing IVC size and collapsibility or, in cases where the IVC could not be visualized, by visualizing ventricular filling. LTTE images were reviewed by an attending in real time and were used to alter therapy. Images were also reviewed retrospectively to assess quality.

Outcome measures included volume of IV fluids administered, percent of patients requiring blood or blood products, need for ICU admission, time to operating room, and mortality.

There were 215 patients enrolled in the study, 92 of whom had an LTTE performed, 123 of whom did not. The mean age was 38.7 years and the average injury severity score (ISS) was 19.1.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis?**	
1.	Were patients randomized?	Sort of. Patients were pseudo-randomized by day of the month, with patients presenting on even days "randomized" to have LTTE performed, while those presenting on odd days were "randomized" to not have LTTE performed.
2.	Was randomization concealed (blinded)? In other words, was it possible to subvert the randomization process to ensure that a patient would be "randomized" to a particular group?	No. While randomization was not concealed (i.e. everybody knew which group patients would be allocated to based on the day of the month), it would not have been possible to subvert this process, since it was already decided.
3.	Were patients analyzed in the groups to which they were randomized?	Purportedly yes. The authors make no mention of failure to adhere to the allocation process and hence make no mention of how such patients were handled.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Yes. Patients were similar with respect to age, the presence of medical comorbidities (COPD, CAD, obesity, prior CVA, hypertension, chronic renal failure), mechanism of injury, baseline injury severity (ISS, revised trauma score), and baseline lactate.
B.	**Did experimental and control groups retain a similar prognosis after the study started?**	
1.	Were patients aware of group allocation?	Yes. Patients were not blinded, and those who were conscious would be aware that LTTE was being performed. Despite this fact, it is unlikely that performance bias on the part of the patients would have affected outcomes.
2.	Were clinicians aware of group allocation?	Yes. Clinicians would have been fully aware of whether or not patients had LTTE performed, and resuscitation was based in part on the results of this. It is quite possible that performance bias on the part of the clinicians would have affected outcomes.
3.	Were outcome assessors aware of group allocation?	Yes. While it would have been possible to blind outcomes assessors to group allocation, the authors do not mention doing so. The outcomes assessed were mostly objective, but it is still possible that some degree of observer bias could have affected outcomes.

4.	Was follow-up complete?	Yes. All of the outcomes were limited to the initial hospital stay, therefore outcome data was available for all patients.
II.	**What are the results ?**	
1.	How large was the treatment effect?	• Patients in the LTTE group received significantly less fluid on average than those in the non-LTTE group: 1.5 L vs. 2.5 L ($p < 0.0001$). • Mean time to OR was significantly shorted in patients in the LTTE group compared to the non-LTTE group: 35.6 vs. 79.1 minutes ($p = 0.0006$). • Patients in the LTTE group were more likely to be admitted to the ICU than those in the non-LTTE group: 80.4% vs. 67.2%, RR 1.2 (95% CI 1.0 to 1.4). • There was a trend toward lower mortality in patients in the LTTE group, but this did not reach statistical significance: 11% vs. 19.5%, RR 0.56 (95% CI 0.28 to 1.11).
2.	How precise was the estimate of the treatment effect?	See above.
III.	**How can I apply the results to patient care?**	
1.	Were the study patients similar to my patient?	Likely yes. This study was conducted at a large, urban trauma center and enrolled patients with the "highest level of alert" (which should correspond to a Level 1 trauma in our institution). These patients were either hypotensive or significantly tachycardic. A third of the patients suffered penetrating injuries, which would likely be similar to the proportion of patients we see.
2.	Were all clinically important outcomes considered?	Mostly yes. The authors assessed mortality, time to OR, proportion of patients requiring ICU admission, and volume of fluids administered. They did not address cost, total time spent in the trauma bay, renal failure, or volume overload.
3.	Are the likely treatment benefits worth the potential harm and costs?	Yes. The use of LTTE to direct volume resuscitation is a low-risk, low-cost intervention that seems to decrease the volume of fluids administered and reduce the time until transport to the OR. It did seem to result in an increase to ICU admission, which likely would increase the cost of care, but this was accompanied by a statistically nonsignificant reduction in mortality.

Limitations:

1. **Patients were pseudo-randomized by day of the month (even vs. odd). True randomization with proper allocation concealment would have been feasible in such a study.**

2. **No primary outcome was specified. This should be done *a priori*.**

3. **No sample size calculation was performed, and it is unclear how the authors determined the appropriate sample size for the study. The study was underpowered to detect a potentially important reduction in mortality with statistical significance.**

4. **The authors did not address the potential effect of training level or specialty on outcomes or quality of LTTE performed. A secondary analysis could have easily made such an assessment.**

Bottom Line:

This pseudorandomized trial of the use of LTTE to direct resuscitation of hypotensive trauma patients demonstrated less fluid administration, less time to OR, and higher ICU admission rates among those patients undergoing LTTE. Given the lack of risk associated with this bedside ultrasound technique, it makes sense to use LTTE to guide resuscitation in such patients. Some methodological flaws may limit the internal validity of the study (pseudorandomization, lack of outcome assessor blinding).