Critical Review Form
Therapy

A Controlled Trial of Pre-hospital Advanced Life Support in Trauma
Annals of Emergency Medicine 1988;17:582-588

Objectives: **To test "the hypothesis that ALS had a favorable impact on mortality and morbidity by comparing the outcomes in trauma patients in a city where pre-hospital ALS is not available (Brisbane) and one where it is (Sydney)". (p. 583)**

Methods: **Consecutive mechanical and thermal trauma injury patients from Sydney (Feb – May 1984) and Brisbane (July – October 1984) who were admitted to the hospital for > 24 hours and/or died after ambulance treatment were included. Sources of data were the ambulance report forms and controller's radio logs, medical records from the 40 participating trauma centers, and autopsy records. Variables collected included response time, treatment time, and transport to hospital time. Discharge summaries were not used. Instead, "only clinically confirmed injuries noted in operation and autopsy reports or reliable diagnostic tests (radiographs, computed tomography….)" were used. Abbreviated Injury Scale and Injury Severity Scores were performed by two authors blinded to each other's score. Residual disability was assessed after head injury using the Glasgow Outcome Scale.**

Investigators analyzed cross-tabulation significance with SPSS and performed multiple regression and logistic regression analysis with GENSTAT. Regression analysis included the following variables: injury severity, ALS vs. BLS care, age, gender, and time to definitive care with mortality, ICU stay duration, hospital length-of-stay and respiratory failure the dependent variables.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?**	
1.	Were patients randomized?	No – ALS and BLS cases from two Australian cities were compared.

2.	Was randomization concealed (blinded)?	No – not randomized and all parties were aware of the care received.
3.	Were patients analyzed in the groups to which they were randomized?	Not randomized and no intention-to-treat statement.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	No. "ALS cases had a significantly higher ISS ($t = 3.0$; $p < .005$) with ALS ISS 14.5 vs. BLS ISS 12.2". However, "no significant differences in the distribution of injury severity, patient age, and time to definitive care" were demonstrated. Head and neck injuries were more common in the ALS group while major thoracic injuries were more common in the BLS group. (p. 584) Of note, doctors assisted in the pre-hospital BLS care of 23% but "they carried a minimum of equipment and performed very few ALS-type interventions such as endotracheal intubation or application of MAST".
B.	**Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?**	
1.	Were patients aware of group allocation?	Yes – not randomized or blinded.
2.	Were clinicians aware of group allocation?	Yes – not randomized or blinded.
3.	Were outcome assessors aware of group allocation?	Yes – not randomized or blinded.
4.	Was follow-up complete?	No lost to follow-up was reported.
II.	**What are the results (answer the questions posed below)?**	

1.	How large was the treatment effect?	• After exclusion of 32 cases for "legal and ethical considerations" there were 472 ALS and 589 BLS cases included in this analysis with a total of 73 deaths. Since three of these deaths had no vital signs upon EMS arrival, they were excluded from analysis. • Although not reported by the authors, the following 2x2 table and *unadjusted* RR with CIs can be computed from their data: **Died** **Lived** **ALS** 37 435 **BLS** 33 556 RR = 1.40 (95% CI 0.89 – 2.32) p=0.171 ALS 7.8% fatality vs. 5.6% for BLS. • Among critically injured no significant case fatality rate noted (ALS 35%, BLS 41%). • ALS appeared to prolong the time until death since 17/37 (46%) ALS cases died within 24 hours vs. 24/33 (73%) BLS cases. Since 43% ALS and 79% BLS cases died before arrival at the ICU, these findings suggest that the excess BLS deaths occurred between hospital arrival and ICU admission. • Respiratory failure was more common in BLS (19%) than ALS (5%) cases ($p < 0.025$). • No significant differences noted in duration of hospital and ICU stay or head-injury disability. • Logistic regression analysis found no significant relationship between ALS vs. BLS care for mortality or ICU/hospital LOS. • BLS cases spent longer time at scene than ALS cases (17 minutes vs. 13 minutes).

2.	How precise was the estimate of the treatment effect?	No CIs are reported; however, see RR CI calculated above which cross one.
III.	**How can I apply the results to patient care (answer the questions posed below)?**	
1.	Were the study patients similar to my patient?	Yes, trauma victims headed to the hospital though not Level I and level of trauma care in 1984 probably inferior to 2009.
2.	Were all clinically important outcomes considered?	Yes.
3.	Are the likely treatment benefits worth the potential harm and costs?	No, not based upon this evidence. How much time, money and personnel effort are needed to initiate and sustain pre-hospital ALS care? For what outcome?

Limitations

1) **Under-powered trial so potential Type II error. To appropriately power this study (10% mortality difference, β = 10%, power = 90%) would require 500 critically injured subjects in each group.**
2) **Insufficient reporting of patient or EMS caregiver demographics to extrapolate findings to our patients and pre-hospital system.**
3) **No analysis of level of care provided in definitive care hospital.**
4) **No report of ALS interventions. With shorter scene times than the BLS crews one wonders if any ALS interventions occurred?**
5) **Non-randomized, non-blinded design so bias from unmeasured confounding variables possible and likely. Nonetheless, in the 21-years since this was published no pre-hospital ALS vs. BLS RCT has occurred and given the more stringent IRB and medical-legal environment of the 21st century probably will not occur in the US. Therefore, this two-city non-randomized non-blinded trial currently represents a piece of the best-evidence available to guide protocol development and clinical decision making.**

Bottom Line

Among critically injured trauma patients pre-hospital ALS care does not reduce mortality, but ALS care does significantly reduce deaths within 24 hours and respiratory failure incidence.