Critical Review Form

Therapy

Multidisciplinary Community Hospital Program for Early & Rapid Resuscitation of Shock in Nontrauma Patients, *Chest* 2005; 127: 1729-1743

Objective: To evaluate whether staff education to enhance early recognition of shock and a protocol-directed therapy with early Intensivist involvement would reduce the time to treatment and mortality in one community hospital.

Methods: Single-center prospective pilot study at Redding (California) Medical Center (180-bed, 44 critical care bed community hospital) in two cohorts:

1) Before a multi-disciplinary educational program and organizational change of ICU attending availability and bed availability;
2) After the comprehensive program was launched.

The program included a "shock-alert" activation system, resuscitation protocols (pp. 1740-1742), and a standardized teaching package received by over 500 pre-hospital, nursing, and physician health care providers. The control group (pre-intervention) enrolled 102 patients over 2.5 years, while the protocol arm enrolled 133 patients over 1 year. Patients were screened for eligibility if they were hypotensive (systolic blood pressure < 90 mm Hg) with one of the following criteria: T ≤ 36°C, respiratory rate > 20, altered mental status, oliguria, lactic acid > 2 mmol/L, or mottled extremities. A "shock-alert" was called if there was no response to 1L intravenous fluid bolus pre-hospital or in the ED (or to a 250 mL bolus in-house). Patients were excluded if they had other reasons for hypotension (acute myocardial infarction, trauma). Primary outcome was hospital mortality. Secondary outcomes were identification of shock patients time to intervention, length of stay, and discharge location (p. 1732). *The power calculation and data analysis were conducted using a one-sided α* because "increased mortality would not modify the practice at our own institution." It is not clearly stated how data on mortality or discharge location were obtained (presumably from hospital records).

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 – this is a prospective cohort study in two groups separated by time at the same institution pre- and post-intervention.
2.	Was randomization concealed (blinded)?	No blinding. No randomization.

3.	Were patients analyzed in the groups to which they were randomized?	"In the protocol phase, all identified shock patients were included if they satisfied screening, confirmatory, and exclusion criteria, irrespective of whether they had been treated as a result of a shock alert or had received the full protocol treatment." (p. 1731)
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	The only significant difference was that all the immunosuppressed patients were in the protocol group and increased lactate levels noted in control group (Table 2, p. 1734). Also, note that only 85/189 were septic shock – our PICO question. *More concerning, however is the enrollment of 86/20, 976 shock patients over 2.5 years in the control group versus 103/9120 shock patients in the protocol group suggesting a selection bias.*
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?	Uncertain whether study discussed with patients since consent waived.
2.	Were clinicians aware of group allocation?	Yes. Not randomized.
3.	Were outcome assessors aware of group allocation?	Yes. Not randomized.
4.	Was follow-up complete?	No loss to follow-up at hospital discharge reported.
II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	a) Mortality (primary outcome) decreased in post-intervention group from 40.7 to 28.2% (ARR 12.5%, NNT = 8, p=0.035) with OR 2.4 (95% CI 1.2-5.1) on logistic regression with APACHE-II and APS.

		b) Patients who died in the control group were less ill than those who died in the protocol group (as judged by APACHE scores). c) Good outcome in 63.1% protocol versus 46.5% control (p = 0.02). d) Significant decreased time to Intensivist arrival, fluid bolus, and PA cath placement (Fig 3, p. 1736)

2.	How precise was the estimate of the treatment effect?	See Confidence Intervals noted above.
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, although at BJH we have somewhat less than 50% of our septic patients with "no past medical history" and far less readily available Intensivists or ICU beds (Table 2, p. 1734).
2.	Were all clinically important outcomes considered?	The primary outcome of mortality is the most important (patient, society, and clinician) for an initial study and "good outcome" is certainly important, but subsequent studies should also assess validated Quality of Life indicators (like SF-36), effect on other ED and/or hospitalized patients, and monetary expenses entailed in maintaining equipment and on-call physician/ancillary staff.
3.	Are the likely treatment benefits worth the potential harm and costs?	No cost-benefit analysis was performed. Non-randomized prospective design prohibits cause-effect analysis. The results, however, appear promising for improving outcomes.

Limitations

1) Single center, non-randomized prospective design prohibits evaluating cause-effect relationship (only association) or extrapolating findings to other medical centers (external validity).
2) Single-tailed Z-test leaves open the possibility of Type I error which is noting an effect in one direction when truly there was no difference between groups. The authors were willing to risk this Type I error because an erroneous conclusion in wrong direction would not have changed their practice habits, but other physicians and institutions may feel otherwise.
3) Differences in enrollment pre- and post-intervention suggest a selection bias.
4) Antibiotics for septic shock (see p. 1741) not what we are currently using at BJH as their protocols suggest very broad spectrum agents.

Bottom Line

One California community hospital multi-disciplinary program directed at educating pre-hospital providers, nurses, and physicians at the rapid recognition of shock with expeditious resuscitation and transfer to the ICU improved mortality rates and treatment times. The current prospective design and questionable selection bias suggest an immediate need for multi-institutional (academic and non-academic) randomized, controlled trials of similar organizational interventions to assess the impace of a structured educational system and protocol driven treatment guideline on other patient populations and health care systems.