Critical Review Form
Therapy

PGY-4

HYPERLINK "http://pmid.us/27344928" Ross EM, Redman TT, Harper SA, Mapp JG, Wampler DA, Miramontes DA. Dual defibrillation in out-of-hospital cardiac arrest: A retrospective cohort analysis. Resuscitation. 2016 Sep;106:14-7.

Objectives: **"to determine if prehospital DD [dual defibrillation] is associated with better neurologically intact survival in out-of-hospital cardiac arrest." (p. 15)**

Methods: **This retrospective cohort analysis was conducted using data collected prospectively in the San Antonio Fire Department (SAFD) Out-of-Hospital Cardiac Arrest (OHCA) Quality Assurance/Quality Improvement (QA/QI) database between January 2013 and December 2015. During this period, SAFD EMS protocol included consideration of DD after three attempts at standard defibrillation (200 J) during OHCA for refractory or recurrent ventricular fibrillation (VF). The final decision over the use of DD was at the discretion of the lead paramedic. When DD was used, one set of pads was placed in the anterior-posterior position, and a second set was placed to the right of the sternum and over the apex. Shock delivery was simultaneous, for a total energy of 400 J.**

Patients with refractory or recurrent VF who received either DD or at least four conventional defibrillation attempts at 200 J between January 2013, and December 2015 were eligible. Patients with incomplete data were excluded. Data was abstracted from the OHCA QA/QI database by two authors who were blinded to patient outcome (but not study hypothesis). Outcomes were collected from the database as well as hospital records, obituary reviews, and the Social Security Death Index. The primary outcome was neurologically intact survival to hospital discharge, defined by a Cerebral Performance Category (CPC) score of 1 or 2. Secondary outcomes were prehospital ROSC, survival to hospital admission, and survival to hospital discharge.

Out of 3470 cases of OHCA treated during the specified period, there were 302 cases recurrent or refractory VF. Twenty-three cases were excluded due to incomplete data. Of the 279 remaining, 50 were treated with DD and 229 with standard defibrillation. The mean ages of the two groups were 59.4 and 61.4 years, respectively.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis?**	
1.	Were patients randomized?	No. This was a retrospective study conducted using prospectively collected data. The decision to use

		DD or not was made at the discretion of the lead paramedic, which could lead to selection bias.
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?	N/A. The study was not randomized.
3.	Were patients analyzed in the groups to which they were randomized?	N/A. The study was not randomized, and patients were analyzed according to whether or not they received DD.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	No. Patients were similar with respect to age and gender, but significantly more patients in the control group suffered a witness arrest compared to the DD group (54.6% vs. 38.0%, p = 0.04), and more patients in the control group had bystander CPR (45.4% vs. 30%, p = 0.06). Witnessed arrest and bystander CPR have both been shown to be predictors of survival from OHCA (Sasson 2010).
B.	**Did experimental and control groups retain a similar prognosis after the study started?**	
1.	Were patients aware of group allocation?	No. While this was not a blinded study, patients were in cardiac arrest and hence would not have been aware of what treatments were being administered.
2.	Were clinicians aware of group allocation?	Yes. This was not a blinded study and hence paramedics (and later physicians) would have been aware of what treatments were provided. Given that the study was conducted retrospectively, and that "the protocol of SAFD EMS was to consider DD after administering three 200J conventional defibrillations during an OHCA resuscitation," it seems unlikely that performance bias on the part of clinicians would have had any impact on outcomes.
3.	Were outcome assessors aware of group allocation?	Uncertain. While the authors noted that the two authors who extracted the cases were "blinded to the outcomes of the patients," there is no mention as to who assessed the outcomes, and whether they were blinded to treatment group or not.
4.	Was follow-up complete?	Purportedly yes. Since the outcomes of interest did not extend past hospital discharge, it seems likely that outcome data was available for all eligible

		patients. The authors do not specifically mention loss to follow-up.
II.	**What are the results ?**	
1.	How large was the treatment effect?	• For the primary outcome, neurologically intact survival to discharge, there was no statistically significant difference between the groups: 6% in the DD group and 11.4% in the control group (OR 0.50, 95% CI 0.15-1.72). • ROSC by EMS occurred in 28% of patients receiving DD and 37.6% of patients in the control group (OR 0.85, 95% CI 0.33-1.27). • Survival to hospital admission occurred in 32% of the DD group and 35.4% of the control group (OR 0.86, 95% CI 0.45-1.65). • Survival to hospital discharge occurred in 8% of the DD group and 14.4% of the control group (OR 0.52, 95% CI 0.17-1.53).
2.	How precise was the estimate of the treatment effect?	See above. This was very small study and the resulting confidence intervals are quite wide.
III.	**How can I apply the results to patient care?**	
1.	Were the study patients similar to my patient?	Yes. These were patients in an urban population suffering out of hospital cardiac arrest with likely similar comorbidities (though these were not detailed) and similar EMS run times to those seen in our institution.
2.	Were all clinically important outcomes considered?	No. The study only addressed outcomes to hospital discharge. The Research Working Group of the American Heart Association Emergency Cardiovascular Care Committee has recommended that large trials designed to have a major impact should use longer-term endpoints at least 90 days out coupled with some neurological and quality-of-life assessment. They also did not address cost or quality-of-life.
3.	Are the likely treatment benefits worth the potential harm and costs?	Uncertain. Based on this study alone, dual defibrillation did not improve outcomes and actually showed a trend toward worse outcomes. Having said that, patients in the DD group were less likely to have a witnessed arrest and less likely to receive bystander CPR, two factors that have been shown to improve survival in OHCA. Additionally, selection bias may have led paramedics to attempt DD in patients who were already at risk of worse outcomes.

Limitations:

1. **This was not a randomized trial. The decision to use DD or not was made at the discretion of the lead paramedic, which could lead to selection bias.**

2. **This was a very small study and clearly lacked the power to determine if a potentially clinically significant effect size was achieved with statistical significance.**

3. **The two groups were not well balanced with regards to known predictive factors. Specifically, significantly more patients in the control group suffered a witness arrest compared to the DD group and more patients in the control group had bystander CPR. Witnessed arrest and bystander CPR have both been shown to be predictors of survival from OHCA (Sasson 2010).**

4. **It is not clear who determined outcomes and whether or not they were blinded to group allocation (observer bias).**

5. **The study measured only short-term outcomes, including survival to hospital discharge. The Research Working Group of the American Heart Association Emergency Cardiovascular Care Committee has recommended that large trials designed to have a major impact should use longer-term endpoints at least 90 days out coupled with some neurological and quality-of-life assessment.**

Bottom Line:

This small, retrospective study comparing patients in OHCA due to refractory v-fib or v-tach who received dual defibrillation to those receiving standard defibrillation found no statistically significant difference in any of the measured outcomes between the two groups. The size of the study, as well as issues regarding the observational nature of the study, including a significant imbalance in the percent of patients with witnessed arrest and the percent receiving bystander CPR, make it difficult to interpret these results and apply them to patient care.